

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

In the Matter of the Accusation Against:

**SETON MEDICAL CENTER CORP. dba
SETON MEDICAL CENTER,
Original Permit No. HSP 45703 and
Sterile Compounding Permit No. LSC 100405; and**

**MARTHA ELISABETH YASAVOLIAN,
Original Pharmacist License No. RPH 41591,**

Respondents

Agency Case No. 6774

OAH No. 2020020649

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary and 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 January 20, 2021.

It is so ORDERED on December 21, 2020.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Greg M. Lippe", is written over a horizontal line.

By

Greg Lippe
Board President

1 XAVIER BECERRA
Attorney General of California
2 CHAR SACHSON
Supervising Deputy Attorney General
3 GREGORY TUSS
Deputy Attorney General
4 State Bar No. 200659
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Attorneys for Complainant
7

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

12 In the Matter of the Accusation Against:

13 **SETON MEDICAL CENTER CORP.**
14 **DBA Seton Medical Center**
15 **1900 Sullivan Avenue**
Daly City, CA 94015

16 **Original Permit No. HSP 45703**
17 **Sterile Compounding Permit No. LSC**
100405,

18 **MARTHA ELISABETH YASAVOLIAN**
19 **1004 W. Rose Circle**
Los Altos, CA 94024-5035

20 **Original Pharmacist License No. RPH**
21 **41591,**

22 Respondents.

Case No. 6774
OAH No. 2020020649

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER AS TO
RESPONDENT MARTHA ELISABETH
YASAVOLIAN ONLY

23
24 IT IS STIPULATED AND AGREED by and between the parties to these proceedings that
25 the following matters are true:

26 **PARTIES**

27 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
28 (Board), Department of Consumer Affairs. She brought this action solely in her official capacity

1 and is represented in this matter by Xavier Becerra, Attorney General of the State of California,
2 and Gregory Tuss, deputy attorney general.

3 2. Martha Elisabeth Yasavolian (Respondent) is represented in this proceeding by
4 attorney Robert Hahn, whose address is Law Office of Gould & Hahn, 2550 Ninth Street, Suite
5 101, Berkeley, CA 94710.

6 3. On April 23, 1988, the Board issued Original Pharmacist License No. RPH 41591
7 to Respondent. This pharmacist license was in full force and effect at all times relevant to the
8 charges brought in this accusation and will expire on September 30, 2021, unless renewed.

9 **JURISDICTION**

10 4. Accusation No. 6774 was filed before the Board and is currently pending against
11 Respondent. The accusation and all other statutorily required documents were properly served on
12 Respondent on October 28, 2019. Respondent timely filed her notice of defense contesting the
13 accusation.

14 5. A copy of Accusation No. 6774 is attached as exhibit 1 and incorporated by
15 reference.

16 **ADVISEMENT AND WAIVERS**

17 6. Respondent has carefully read, fully discussed with counsel, and understands the
18 charges and allegations in Accusation No. 6774. Respondent has also carefully read, fully
19 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
20 Order.

21 7. Respondent is fully aware of her legal rights in this matter, including the right to a
22 hearing on the charges and allegations in the accusation; the right to confront and cross-examine
23 the witnesses against her; the right to present evidence and to testify on her own behalf; the right
24 to the issuance of subpoenas to compel the attendance of witnesses and the production of
25 documents; the right to reconsideration and court review of an adverse decision; and all other
26 rights accorded by the California Administrative Procedure Act and other applicable laws.

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

1 **CULPABILITY**

2 9. Respondent understands and agrees that the charges and allegations in Accusation
3 No. 6774, if proven at a hearing, constitute cause for imposing discipline upon her pharmacist
4 license.

5 10. For the purpose of resolving the accusation without the expense and uncertainty of
6 further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual
7 basis for the charges in the accusation and that Respondent gives up her right to contest those
8 charges.

9 11. Respondent agrees that her pharmacist license is subject to discipline and she
10 agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

11 **CONTINGENCY**

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

21 13. The parties understand and agree that portable document format (PDF) and
22 facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and
23 facsimile signatures, shall have the same force and effect as the originals.

24 14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be
25 an integrated writing representing the complete, final, and exclusive embodiment of their
26 agreement. It supersedes any and all prior or contemporaneous agreements, understandings,
27 discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and
28 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.

15. In consideration of these 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 ORDERED that Original Pharmacist License No. RPH 41591 issued to Respondent Martha Elisabeth Yasavolian is revoked. However, the revocation is stayed and Respondent is placed on probation for two 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 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

1 probation. Any period(s) of delinquency in submission of reports as directed may be added to the
2 total period of probation. Moreover, if the final probation report is not made as directed,
3 probation shall be automatically extended until such time as the final report is made and accepted
4 by the Board.

5 3. **Interview with the Board.** Upon receipt of reasonable prior notice, Respondent
6 shall appear in person for interviews with the Board or its designee, at such intervals and
7 locations as are determined by the Board or its designee. Failure to appear for any scheduled
8 interview without prior notification to Board staff, or failure to appear for two or more scheduled
9 interviews with the Board or its designee during the period of probation, shall be considered a
10 violation of probation.

11 4. **Cooperate with Board Staff.** Respondent shall timely cooperate with the Board's
12 inspection program and with the Board's monitoring and investigation of Respondent's
13 compliance with the terms and conditions of her probation, including but not limited to: timely
14 responses to requests for information by Board staff; timely compliance with directives from
15 Board staff regarding requirements of any term or condition of probation; and timely completion
16 of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall
17 be considered a violation of probation.

18 5. **Continuing Education.** Respondent shall provide evidence of efforts to maintain
19 skill and knowledge as a pharmacist as directed by the Board or its designee.

20 6. **Reporting of Employment and Notice to Employers.** During the period of
21 probation, Respondent shall notify all present and prospective employers of the decision in Case
22 No. 6774 and the terms, conditions and restrictions imposed on Respondent by the decision, as
23 follows:

24 Within 30 days of the effective date of this decision, and within 10 days of undertaking
25 any new employment, Respondent shall report to the Board in writing the name, physical address,
26 and mailing address of each of her employer(s), and the name(s) and telephone number(s) of all
27 of her direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-
28 in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if

1 known. Respondent shall also include the reason(s) for leaving the prior employment.

2 Respondent shall sign and return to the Board a written consent authorizing the Board or its
3 designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing
4 those employer(s) or supervisor(s) to communicate with the Board or its designee, concerning
5 Respondent's work status, performance, and monitoring. Failure to comply with the requirements
6 or deadlines of this condition shall be considered a violation of probation.

7 Within 30 days of the effective date of this decision, and within 15 days of Respondent
8 undertaking any new employment, Respondent shall cause (a) her direct supervisor, (b) her
9 pharmacist-in-charge, designated representative-in-charge, responsible manager, or other
10 compliance supervisor, and (c) the owner or owner representative of her employer, to report to the
11 Board in writing acknowledging that the listed individual(s) has/have read the decision in Case
12 No. 6774, and terms and conditions imposed by it. If one person serves in more than one role
13 described in (a), (b), or (c), the acknowledgment shall so state. It shall be Respondent's
14 responsibility to ensure that these acknowledgment(s) are timely submitted to the Board. In the
15 event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term
16 of probation, Respondent shall cause the person(s) taking over the role(s) to report to the Board in
17 writing within 15 days of the change acknowledging that he or she has read the decision in Case
18 No. 6774, and the terms and conditions imposed by it.

19 If Respondent works for or is employed by or through an employment service,
20 Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed
21 by the Board of the decision in Case No. 6774 and the terms and conditions imposed by it in
22 advance of Respondent commencing work at such licensed entity. A record of this notification
23 must be provided to the Board upon request.

24 Furthermore, within 30 days of the effective date of this decision, and within 15 days of
25 Respondent undertaking any new employment by or through an employment service, Respondent
26 shall cause the person(s) described in (a), (b), and (c) above at the employment service to report
27 to the Board in writing acknowledging that he or she has read the decision in Case No. 6774 and
28 the terms and conditions imposed by it. 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 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 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 \$3,000.00. Respondent shall make said payments as directed by the Board. 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 year prior to the end date of probation.

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1 10. **Probation Monitoring Costs.** Respondent shall pay any costs associated with
2 probation monitoring as determined by the Board each and every year of probation. Such costs
3 shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to
4 pay such costs by the deadline(s) as directed shall be considered a violation of probation.

5 11. **Status of License.** Respondent shall, at all times while on probation, maintain an
6 active, current pharmacist license with the Board, including any period during which suspension
7 or probation is tolled. Failure to maintain an active, current pharmacist license shall be
8 considered a violation of probation.

9 If Respondent's pharmacist license expires or is cancelled by operation of law or
10 otherwise at any time during the period of probation, including any extensions due to tolling or
11 otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and
12 conditions of this probation not previously satisfied.

13 12. **License Surrender While on Probation/Suspension.** Following the effective
14 date of this decision, should Respondent cease practice due to retirement or health, or be
15 otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish her
16 license, including any indicia of licensure issued by the Board, along with a request to surrender
17 the license. The Board or its designee shall have the discretion whether to accept the surrender or
18 take any other action it deems appropriate and reasonable. Upon formal acceptance of the
19 surrender of the license, Respondent will no longer be subject to the terms and conditions of
20 probation. This surrender constitutes a record of discipline and shall become a part of the
21 Respondent's license history with the Board.

22 Upon acceptance of the surrender, Respondent shall relinquish her pocket and/or wall
23 license, including any indicia of licensure not previously provided to the Board within 10 days of
24 notification by the Board that the surrender is accepted if not already provided. Respondent may
25 not reapply for any license from the Board for three years from the effective date of the surrender.
26 Respondent shall meet all requirements applicable to the license sought as of the date the
27 application for that license is submitted to the Board, including any outstanding costs.

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1 13. **Practice Requirement – Extension of Probation.** Except during periods of
2 suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in
3 California for a minimum of 80 hours per calendar month. Any month during which this
4 minimum is not met shall extend the period of probation by one month. During any such period
5 of insufficient employment, Respondent must nonetheless comply with all terms and conditions
6 of probation, unless Respondent receives a waiver in writing from the Board or its designee.

7 If Respondent does not practice as a pharmacist in California for the minimum number of
8 hours in any calendar month, for any reason (including vacation), Respondent shall notify the
9 Board in writing within 10 days of the conclusion of that calendar month. This notification shall
10 include at least: the date(s), location(s), and hours of last practice; the reason(s) for the
11 interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume
12 practice at the required level. Respondent shall further notify the Board in writing within ten (10)
13 days following the next calendar month during which Respondent practices as a pharmacist in
14 California for the minimum of hours. Any failure to timely provide such notification(s) shall be
15 considered a violation of probation.

16 It is a violation of probation for Respondent's probation to be extended pursuant to the
17 provisions of this condition for a total period, counting consecutive and non-consecutive months,
18 exceeding 36 months. The Board or its designee may post a notice of the extended probation
19 period on its website.

20 14. **Violation of Probation.** If Respondent has not complied with any term or
21 condition of probation, the Board shall have continuing jurisdiction over Respondent, and the
22 Board shall provide notice to Respondent that probation shall automatically be extended, until all
23 terms and conditions have been satisfied or the Board has taken other action as deemed
24 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
25 to impose the penalty that was stayed. The Board or its designee may post a notice of the
26 extended probation period on its website.

27 If Respondent violates probation in any respect, the Board, after giving Respondent notice
28 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that

1 was stayed. If a petition to revoke probation or an accusation is filed against Respondent during
2 probation, or the preparation of an accusation or petition to revoke probation is requested from
3 the Office of the Attorney General, the Board shall have continuing jurisdiction and the period of
4 probation shall be automatically extended until the petition to revoke probation or accusation is
5 heard and decided, and the charges and allegations in Accusation No. 6744 shall be deemed true
6 and correct.

7 **15. Completion of Probation.** Upon written notice by the Board or its designee
8 indicating successful completion of probation, Respondent's license will be fully restored.

9 **16. Remedial Education.** Within 90 days of the effective date of this decision,
10 Respondent shall submit to the Board or its designee, for prior approval, an appropriate program
11 of remedial education related to sterile compounding and recordkeeping. The program of
12 remedial education shall consist of at least 10 hours per year, 50 percent of which must be live
13 webinar or in-person education, at Respondent's own expense. All remedial education shall be in
14 addition to, and shall not be credited toward, continuing education (CE) courses used for license
15 renewal purposes for pharmacists.

16 Failure to timely submit for approval or complete the approved remedial education shall
17 be considered a violation of probation. The period of probation will be automatically extended
18 until such remedial education is successfully completed and written proof, in a form acceptable to
19 the Board, is provided to the Board or its designee.

20 Following the completion of each course, the Board or its designee may require
21 Respondent, at her own expense, to take an approved examination to test Respondent's
22 knowledge of the course. If Respondent does not achieve a passing score on the examination that
23 course shall not count towards satisfaction of this term. Respondent shall take another course
24 approved by the Board in the same subject area.

25 **17. No Ownership or Management of Licensed Premises.** Respondent shall not
26 own, have any legal or beneficial interest in, nor serve as a manager, administrator, member,
27 officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation
28 currently or hereinafter licensed by the Board. Respondent shall sell or transfer any legal or

1 beneficial interest in any entity licensed by the Board within 90 days following the effective date
2 of this decision and shall immediately afterword provide written proof to the Board. Failure to
3 timely divest any legal or beneficial interest(s) or provide documentation of it shall be considered
4 a violation of probation.

5 **ACCEPTANCE**

6 I have carefully read this Stipulated Settlement and Disciplinary Order and have fully
7 discussed it with my attorney, Robert Hahn. I understand the stipulation and the effect it will
8 have on my pharmacist license. I enter into this Stipulated Settlement and Disciplinary Order
9 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
10 Board of Pharmacy.

11 DATED: _____

MARTHA ELISABETH YASAVOLIAN
Respondent

13 I have read and fully discussed with Respondent Martha Elisabeth Yasavolian the terms
14 and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I
15 approve its form and content.

16 DATED: _____

ROBERT HAHN
Attorney for Respondent

18 ///

1 beneficial interest in any entity licensed by the Board within 90 days following the effective date
2 of this decision and shall immediately afterword provide written proof to the Board. Failure to
3 timely divest any legal or beneficial interest(s) or provide documentation of it shall be considered
4 a violation of probation.

5 ACCEPTANCE

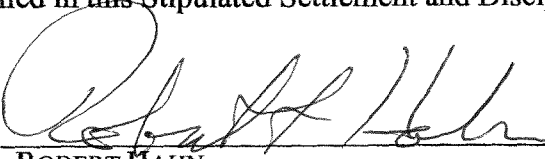
6 I have carefully read this Stipulated Settlement and Disciplinary Order and have fully
7 discussed it with my attorney, Robert Hahn. I understand the stipulation and the effect it will
8 have on my pharmacist license. I enter into this Stipulated Settlement and Disciplinary Order
9 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
10 Board of Pharmacy.

11 DATED: 9/11/20


12 MARTHA ELISABETH YASAVOLIAN
Respondent

13 I have read and fully discussed with Respondent Martha Elisabeth Yasavolian the terms
14 and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I
15 approve its form and content.

16 DATED: 9/11/20


17 ROBERT HAHN
Attorney for Respondent

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ENDORSEMENT

This Stipulated Settlement and Disciplinary Order is submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
CHAR SACHSON
Supervising Deputy Attorney General

GREGORY TUSS
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

This Stipulated Settlement and Disciplinary Order is submitted for consideration by the Board of Pharmacy.

DATED: September 23, 2020

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
CHAR SACHSON
Supervising Deputy Attorney General



GREGORY TUSS
Deputy Attorney General
Attorneys for Complainant

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Exhibit 1

Accusation No. 6774

1 XAVIER BECERRA
Attorney General of California
2 CHAR SACHSON
Supervising Deputy Attorney General
3 GREGORY TUSS
Deputy Attorney General
4 State Bar No. 200659
455 Golden Gate Avenue, Suite 11000
5 San Francisco, CA 94102-7004
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Attorneys for Complainant
7

8 **BEFORE THE**
9 **BOARD OF PHARMACY**
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11 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 6774

12 **SETON MEDICAL CENTER CORP.**
13 **DBA Seton Medical Center**
14 **1900 Sullivan Avenue**
Daly City, CA 94015

ACCUSATION

15 **Original Permit No. HSP 45703**
16 **Sterile Compounding Permit No. LSC**
100405,

17 **MARTHA ELISABETH YASAVOLIAN**
18 **1004 W. Rose Circle**
Los Altos, CA 94024-5035

19 **Original Pharmacist License No. RPH**
20 **41591,**

21 Respondents.
22

23 **PARTIES**

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

27 2. On February 19, 2002, the Board issued Original Permit No. HSP 45703 to Seton
28 Medical Center Corp. to do business as Seton Medical Center (Respondent Seton). This original

1 permit was in full force and effect at all times relevant to the charges brought in this accusation
2 and will expire on February 1, 2020, unless renewed.

3 3. On June 9, 2014, the Board issued Sterile Compounding Permit No. LSC 100405
4 to Respondent Seton. This sterile compounding permit was in full force and effect at all times
5 relevant to the charges brought in this accusation and will expire on February 1, 2020, unless
6 renewed.

7 4. On April 23, 1988, the Board issued Original Pharmacist License No. RPH 41591
8 to Martha Elisabeth Yasavolian (Respondent Yasavolian). This original pharmacist license was
9 in full force and effect at all times relevant to the charges brought in this accusation and will
10 expire on September 30, 2019, unless renewed.

11 **JURISDICTION**

12 5. This accusation is brought before the board under the authority of the following
13 laws. All section references are to the Business and Professions Code unless otherwise indicated.

14 6. Section 4300 states in part:

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

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

19 “(1) Suspending judgment.

20 “(2) Placing him or her upon probation.

21 “(3) Suspending his or her right to practice for a period not exceeding one year.

22 “(4) Revoking his or her license.

23 “(5) Taking any other action in relation to disciplining him or her as the board in its
24 discretion may deem proper.”

25 7. Section 4300.1 states:

26 “The expiration, cancellation, forfeiture, or suspension of a board-issued license by
27 operation of law or by order or decision of the board or a court of law, the placement of a license
28 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board

1 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
2 proceeding against, the licensee or to render a decision suspending or revoking the license.”

3 8. Section 4304 states:

4 “The board may deny, revoke, or suspend any license issued pursuant to Section 4161 for
5 any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of
6 Division 104 of the Health and Safety Code.”

7 **STATUTORY PROVISIONS**

8 9. Section 4301 states in part:

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

13 . . .

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

18 **REGULATORY PROVISIONS**

19 10. California Code of Regulations, title 16, section 1735.3, states in part:

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

21 . . .

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

23 . . .

24 “(B) The date the drug preparation was compounded.

25 . . .

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

28 . . .

1 “(J) Documentation of quality reviews and required post-compounding process and
2 procedures.”

3 11. California Code of Regulations, title 16, section 1751.8, states in part:

4 “In conformity with and in addition to the requirements and limitations of section 1735.2,
5 subdivision (h), every sterile compounded drug preparation shall be given and labeled with a
6 beyond use date that does not exceed the shortest expiration date or beyond use date of any
7 ingredient in sterile compounded drug preparation, nor the chemical stability of any one
8 ingredient in the sterile compounded drug preparation, nor the chemical stability of the
9 combination of all ingredients in the sterile compounded drug preparation, and that, in the
10 absence of passing a sterility test in accordance with standards for sterility testing found in
11 Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through
12 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference,
13 that would justify an extended beyond use date, conforms to the following limitations:

14 . . .

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

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

22 . . .

23 “(e) Where any sterile compounded drug preparation was compounded either outside of
24 an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of
25 subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled ‘for
26 immediate use only’ and administration shall begin no later than one hour following the start of
27 the compounding process. Unless the ‘immediate use’ preparation is immediately and completely
28 administered by the person who prepared it or immediate and complete administration is

1 witnessed by the preparer, the preparation shall bear a label listing patient identification
2 information, the names and amounts of all ingredients, the name or initials of the person who
3 prepared the compounded sterile preparation, and the exact one-hour beyond use date and time.
4 If administration has not begun within one hour following the start of the compounding process,
5 the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded.
6 This provision does not preclude the use of a PEC to compound an ‘immediate use’ preparation.
7 A PEC used solely to compound ‘immediate use’ preparations need not be placed within an ISO
8 Class 7 cleanroom, with an ante-area. Such ‘immediate use’ preparations shall be compounded
9 only in those limited situations where there is a need for immediate administration of a sterile
10 preparation compounded outside of an ISO class 5 environment and where failure to administer
11 could result in loss of life or intense suffering. Any such compounding shall be only in such
12 quantity as is necessary to meet the immediate need and the circumstance causing the immediate
13 need shall be documented in accordance with policies and procedures.”

14 **COST RECOVERY**

15 12. Section 125.3, subdivision (a), states:

16 “Except as otherwise provided by law, in any order issued in resolution of a disciplinary
17 proceeding before any board within the department or before the Osteopathic Medical Board,
18 upon request of the entity bringing the proceedings, the administrative law judge may direct a
19 licensee found to have committed a violation or violations of the licensing act to pay a sum not
20 to exceed the reasonable costs of the investigation and enforcement of the case.”

21 **FACTUAL BACKGROUND**

22 13. On January 3, 2019, the Board conducted a sterile compounding inspection at
23 Respondent Seton, an inpatient pharmacy. Respondent Yasavolian had been the pharmacist-in-
24 charge since November 16, 2015.

25 14. The inspection revealed that Respondent Seton had compounded sterile drug

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1 preparations outside an ISO Class 5¹ PEC² as immediate use, including 771 sterile drug
2 preparations compounded between November 21, 2018, to January 3, 2019. None of these
3 preparations had documentation of the circumstance showing that failure to immediately
4 administer could result in loss of life or intense suffering. Some of these preparations were
5 medium risk compounds, had more than one dose compounded, and were assigned beyond use
6 dates that were longer than one hour.

7 15. Respondent Seton assigned beyond use dates that were longer than 12 hours to
8 sterile preparations compounded in a segregated compounding area, including 81 sterile
9 preparations compounded between December 4, 2018, to January 3, 2019.

10 16. Respondent Seton's compounding logs, including those from December 4, 2018,
11 to January 3, 2019, did not document quality reviews, post-compounding process and procedures,
12 compounding date, or beyond use date and time of the final compounded drug preparation.

13 **FIRST CAUSE FOR DISCIPLINE**

14 **Unprofessional Conduct – Failure to Meet Criteria for Immediate Use Compounding**

15 17. Respondents have subjected their permits and license to discipline for the
16 unprofessional conduct of failing to meet the criteria to compound immediate use sterile drug
17 preparations (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1751.8, subd. (e)).
18 The circumstances are set forth above in paragraphs 13-14 above.

19 **SECOND CAUSE FOR DISCIPLINE**

20 **Unprofessional Conduct – Incorrect Assignment of Beyond Use Dates**

21 18. Respondents have subjected their permits and license to discipline for the
22 unprofessional conduct of assigning beyond use dates greater than 12 hours to preparations
23 compounded in a segregated area (Bus. & Prof. Code, §§ 4301, subd. (o); Cal. Code Regs., tit. 16,
24 § 1751.8, subd. (d)(1)). The circumstances are set forth above in paragraphs 13 and 15 above.

25
26 ¹ A clean environment standard developed by the International Organization for
Standardization (ISO) that has at most 105 particles per cubic meter of air.

27 ² Primary engineering controls (PEC) is device or room that provides an ISO Class 5
28 environment. While a PEC can be a room, it is commonly a hooded area certified to ISO Class 5
standards.

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THIRD CAUSE FOR DISCIPLINE

Unprofessional Conduct – Failure to Document Quality Reviews, and Post-compounding Processes and Procedures

19. Respondents have subjected their permits and license to discipline for the unprofessional conduct of failing to document quality reviews, and post-compounding process and procedures in compounding logs (Bus. & Prof. Code, §§ 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(J)). The circumstances are set forth above in paragraphs 13 and 16 above.

FOURTH CAUSE FOR DISCIPLINE

Unprofessional Conduct – Failure to Document Compounding Date

20. Respondents have subjected their permits and license to discipline for the unprofessional conduct of failing to document the compounding date in compounding logs (Bus. & Prof. Code, §§ 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(B)). The circumstances are set forth above in paragraphs 13 and 16 above.

FIFTH CAUSE FOR DISCIPLINE

Unprofessional Conduct – Failure to Document Beyond Use Date and Time

21. Respondents have subjected their permits and license to discipline for the unprofessional conduct of failing to document beyond use date and time of the final compounded drug preparation in compounding logs (Bus. & Prof. Code, §§ 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(H)). The circumstances are set forth above in paragraphs 13 and 16 above.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this accusation, and that following the hearing, the Board of Pharmacy issues a decision:

1. Revoking or suspending Original Permit No. HSP 45703 issued to Respondent Seton;
2. Revoking or suspending Sterile Compounding Permit No. LSC 100405 issued to Respondent Seton;

1 3. Revoking or suspending Original Pharmacist License No. RPH 41591 issued to
2 Respondent Yasavolian;

3 4. Ordering respondents to pay the board the reasonable costs of the investigation and
4 enforcement of this case under Business and Professions Code section 125.3; and

5 5. Taking such other and further action as deemed necessary and proper.
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8 DATED: October 24, 2019



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

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