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

In the Matter of the Accusation Against: **ADVANCE MEDICAL PHARMACY** **112 La Casa Via, Suite 100** **Walnut Creek, CA 94598** **Original Permit No. PHY 46345** **JAMES PO KWONG YUEN** **112 La Casa Via, Suite 100** **Walnut Creek, CA 94598** **Pharmacist License No. RPH 43557** Respondents.	Case No. 5010 OAH No. 2015040997 **STIPULATED SURRENDER OF LICENSE AND ORDER**

DECISION AND ORDER

The attached Stipulated Surrender of License 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 April 20, 2016.

It is so ORDERED March 21, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation Against: **ADVANCE MEDICAL PHARMACY** **112 La Casa Via, Suite 100** **Walnut Creek, CA 94598** **Original Permit Number No. PHY 46345** **and** **JAMES PO KWONG YUEN** **112 La Casa Via, Suite 100** **Walnut Creek, CA 94598** **Pharmacist License No. RPH 43557,** Respondents.	Case No. 5010 OAH No. 2015040997 **STIPULATED SURRENDER OF LICENSE AND ORDER**

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

PARTIES

1. Virginia Herold (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 Kamala D. Harris, Attorney General of the State of California, by Nicholas Tsukamaki, Deputy Attorney General.

2. Advance Medical Pharmacy and James Po Kwong Yuen (Respondents) are represented in this proceeding by attorney Ivan Petrzelka, whose address is: 2855 Michelle Drive, Suite 180, Irvine, CA 92606.

3. On or about April 17, 2003, the Board issued Original Permit Number PHY 46345 to Advance Medical Pharmacy (Respondent AMP). The Original Permit Number was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2016, unless renewed.

4. On or about July 27, 1990, the Board issued Pharmacist License Number RPH 43557 to James Po Kwong Yuen (Respondent Yuen). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 29, 2016, unless renewed.

JURISDICTION

5. First Amended Accusation No. 5010 was filed before the Board and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on April 13, 2015. Respondents timely filed their Notice of Defense contesting the Accusation. A First Amended Accusation was properly served on Respondents on January 12, 2016. A copy of First Amended Accusation No. 5010 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 5010. Respondents also have carefully read, fully discussed with counsel, and understand the effects of this Stipulated Surrender of License and Order.

7. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel at their own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their 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.

8. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

9. Respondent AMP understands and agrees that the charges and allegations in First Amended Accusation No. 5010, if proven at a hearing, constitute cause for imposing discipline upon its Pharmacy Permit. For the purpose of resolving this matter without the expense and uncertainty of further proceedings, Respondent AMP agrees that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation; Respondent AMP hereby gives up its right to contest those charges. Respondent AMP hereby surrenders its Pharmacy Permit No. PHY 46345 for the Board's formal acceptance.

10. Respondent AMP understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of its Pharmacy Permit without further process.

11. Respondent Yuen understands and agrees that the charges and allegations in First Amended Accusation No. 5010, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License. For the purpose of resolving this matter without the expense and uncertainty of further proceedings, Respondent Yuen agrees that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation; Respondent Yuen hereby gives up his right to contest those charges. Respondent Yuen hereby surrenders his Pharmacist License Number RPH 43557 for the Board's formal acceptance.

12. Respondent Yuen understands that by signing this stipulation he enables the Board to issue an order accepting the surrender of his Pharmacist License without further process.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that

they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender 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 Surrender of License and Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

15. This Stipulated Surrender of License and 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 Surrender of License and 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, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 46345, issued to Advance Medical Pharmacy (Respondent AMP), and Pharmacist License No. RPH 43557, issued to James Po Kwong Yuen (Respondent Yuen) are surrendered and accepted by the Board of Pharmacy. The effective date of the Decision as to Respondent AMP only shall be stayed until May 1, 2016, at which time the pharmacy shall be sold or closed.

1. The surrender of Respondent AMP's Pharmacy Permit and Respondent Yuen's Pharmacist License and the acceptance of these surrendered licenses by the Board shall constitute the imposition of discipline against Respondents. This stipulation constitutes a record of the discipline and shall become a part of Respondents' license history with the Board of Pharmacy.

2. Respondent AMP shall lose all rights and privileges as a pharmacy in California as of May 1, 2016.

3. The Board shall expedite the processing of an application for transfer of ownership of Respondent AMP if an application for a temporary permit is received by a new prospective owner of Respondent AMP.

4. In the event Respondent AMP is not sold by May 1, 2016, Respondent AMP shall, within ten (10) days of the effective date of the Board's Decision and Order, arrange for destruction or transfer of dangerous drugs and controlled substances to a facility licensed by the Board, provide proof of such to the Board, and submit a completed Discontinuance of Business form. Respondent AMP shall further arrange for the transfer of records of acquisition and disposition of dangerous drugs to a premises licensed and approved by the Board. Also, ten (10) days prior to the effective date of the Board's Decision and Order, Respondent AMP shall arrange for the continuation of care for ongoing patients of the pharmacy by, at a minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients.

5. Respondent Yuen shall lose all rights and privileges as a pharmacist in California as of the effective date of the Board's Decision and Order.

6. Respondent AMP shall cause to be delivered to the Board its original permit and, if one was issued, its wall certificate, on or before May 1, 2016. Respondent Yuen shall cause to be delivered to the Board his pocket license and, if one was issued, his wall certificate, on or before the effective date of the Decision and Order.

7. Respondents may not apply for any license, permit, or registration from the Board for three (3) years from the effective date of this Decision. If Respondents ever apply for licensure in the State of California the Board shall treat it as a new application for licensure. Respondents must comply with all the laws, regulations, and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in First Amended Accusation No. 5010 shall be deemed to be true, correct, and admitted by Respondents when the Board determines whether to grant or deny the application or petition. Respondents are required to report this surrender as disciplinary action.

8. Respondents shall pay the Board its costs of investigation and enforcement in the amount of $68,889.00 prior to the issuance of a new or reinstated license.

9. If Respondents should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in First Amended Accusation No. 5010 shall be deemed to be true, correct, and admitted by Respondents for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.\

ACCEPTANCE

I am authorized to act on behalf of Respondent Advance Medical Pharmacy. I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with Advance Medical Pharmacy's attorney, Ivan Petrzelka. I understand the stipulation and the effect it will have on Advance Medical Pharmacy's Pharmacy Permit. Advance Medical Pharmacy enters into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agrees to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 2-12-16

JAMES PO KWONG YUEN for
Respondent ADVANCE MEDICAL PHARMACY

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

DATED: 2-12-16

JAMES PO KWONG YUEN
Respondent

I have read and fully discussed with Respondents Advance Medical Pharmacy and James Po Kwong Yuen the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: February 12, 2016

IVAN PETRZELKA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: February 12, 2016

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

NICHOLAS TSUKAMAKI
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 5010

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JOSHUA A. ROOM
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Attorneys for Complainant

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

In the Matter of the Accusation Against: **ADVANCE MEDICAL PHARMACY** **112 La Casa Via, Suite 100** **Walnut Creek, CA 94598** **Original Permit Number No. PHY 46345** **and** **JAMES PO KWONG YUEN** **112 La Casa Via, Suite 100** **Walnut Creek, CA 94598** **Pharmacist License No. RPH 43557,** Respondents.	Case No. 5010 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

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

/ / /

2. On or about April 17, 2003, the Board issued Original Permit Number PHY 46345 to Advance Medical Pharmacy (Respondent AMP). The Original Permit Number was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2016, unless renewed.

3. On or about July 27, 1990, the Board issued Pharmacist License Number RPH 43557 to James Po Kwong Yuen (Respondent Yuen). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 29, 2016, unless renewed.

JURISDICTION

4. This First Amended 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.

5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 et seq.) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 et seq.).

6. Section 4300, subdivision (a) of the Code provides that every license issued by the Board may be suspended or revoked.

7. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, 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

8. Section 4301 of the Code provides in relevant part:

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

. . .

"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

. . .

"(j) The violation of any of the statutes of this state, 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.

. . ."

9. Section 4021 of the Code provides that a "controlled substance" means any substance listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

10. Section 4105, subdivision (a) of the Code states: "All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form."

11. 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."

12. Section 4306.5 of the Code provides, in pertinent part:

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

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

"(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the

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dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

. . ."

13. Section 4333, subdivision (a) of the Code states: "All prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years."

14. Section 4342, subdivision (a) of the Code states:

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

15. Section 11153, subdivision (a) of the Health and Safety Code states:

"A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

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16. Section 11162.1 of the Health and Safety Code states, in pertinent part:

"(a) The prescription forms for controlled substances shall be printed with the following features:

"(1) A latent, repetitive 'void' pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word 'void' shall appear in a pattern across the entire front of the prescription.

"(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words 'California Security Prescription.'

. . .

"(7)(A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear: 1-24; 25-49; 50-74; 75-100; 101-150; 151 and over.

. . .

"(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the 'Prescription is void if the number of drugs prescribed is not noted.'

. . .

"(13) An identifying number assigned to the approved security printer by the Department of Justice.

. . .

"(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

. . ."

17. Section 11164 of the Health and Safety Code states, in pertinent part:

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

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

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

. . ."

REGULATORY PROVISIONS

18. California Code of Regulations, title 16, section 1707, subdivision (a) states:

"Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver shall be granted to any entity licensed by the board for off-site storage of the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code."

19. California Code of Regulations, title 16, section 1707.2 provides, in pertinent part:

"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

. . .

"(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

. . ."

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20. California Code of Regulations, title 16, section 1714, subdivision (b) states: "Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy."

21. California Code of Regulations, title 16, section 1715, subdivision (a) states: "The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

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

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

. . .

"(3) Expiration dating requirements.

. . .

"(5) Process and/or procedure used to prepare the drug.

"(6) Quality reviews required at each step in preparation of the drug.

"(7) Post-compounding process or procedures required, if any.

. . .

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This 'beyond use date' of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

. . .

"(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is 'Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment' Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

23. California Code of Regulations, title 16, section 1735.3 provides, in relevant part:

"(a) For each compounded drug product, the pharmacy records shall include:

"(1) The master formula record.

. . .

"(8) The expiration date of the final compounded drug product.

. . ."

24. California Code of Regulations, title 16, section 1735.5 provides, in relevant part:

"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

. . ."

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25. California Code of Regulations, title 16, section 1735.7 provides, in relevant part:

"(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

"(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

. . ."

26. California Code of Regulations, title 16, section 1735.8, subdivision (a) states: "Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products."

27. California Code of Regulations, title 16, section 1761, subdivision (a) states: "No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription."

COSTS

28. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL BACKGROUND

February 28, 2012 Inspection

29. On or about February 28, 2012, two Board inspectors performed an inspection of Advance Medical Pharmacy located at 112 La Casa Via, Suite 100, Walnut Creek, CA 94598.

30. During the course of their inspection, the inspectors found numerous outdated products in the pharmacy's active inventory, including numerous large bulk compounding items that did not contain expiration dates. The inspectors also determined that Respondent AMP's compounding records did not contain documentation of the pharmacist(s) who checked certain compounded products.

31. While at the facility, the inspectors reviewed Respondent AMP's compounding process for compounded drug products. During this review, the inspectors determined that Respondent AMP's pharmacy records did not contain master formulas for compounded drug products that included certain required elements, including expiration dating requirements, the process and/or procedure used to prepare the drug, quality reviews required at each step in preparation of the drug, and any required post-compounding process or procedures. In addition, Respondent AMP's pharmacy records did not contain the expiration date of final compounded drug products.

32. The inspectors further determined that Respondent AMP did not have records to show that pharmacy staff had been trained to perform compounding. The inspectors also determined that Respondent AMP stored prescription documents and invoices in a locked area shared with other businesses at a storage unit, but that Respondent AMP had not obtained a waiver to do so.

September 5, 2013 Inspection

33. On or about September 5, 2013, two Board inspectors performed a second inspection of Advance Medical Pharmacy.

34. While at the facility, one of the inspectors requested a current pharmacy self-assessment and a current compounding self-assessment. Respondent Yuen, Respondent AMP's pharmacist-in-charge (PIC), was unable to provide the inspector with either of these documents.

35. During the inspection, one of the inspectors determined that numerous bulk compounding products did not contain expiration dates and that Respondent AMP's current inventory contained outdated products.

36. The inspectors also reviewed Respondent AMP's compounding policies and procedures. The inspectors determined that those policies and procedures did not contain certain

information, such as a written quality assurance plan, the frequency of cleanings, and the evaluation of compounded products for qualitative and quantitative integrity.

37. While at the facility, one of the inspectors reviewed Respondent AMP's records for a compounded drug product and determined that those records did not contain a master formula.

38. The inspectors also determined that Respondent AMP did not have current training records for compounding staff.

39. At one point during the inspection, the inspectors asked Respondent Yuen for certain prescription records. Respondent Yuen informed the inspectors that the requested records were in storage. When one of the inspectors asked Respondent Yuen if he had obtained an off-site storage waiver for those records, Respondent Yuen replied that he had forgotten to get it done.

40. During the inspection one of the inspectors observed a patient picking up a prescription at Advance Medical Pharmacy. The prescription contained a change in directions. One of Respondent AMP's pharmacy technicians asked the patient if the patient "wanted consultation" for the prescription, which the patient declined. At no point did the pharmacy technician request a consultation for the patient from a pharmacist.

April 15, 2015 Inspection

41. On or about April 15, 2015, two Board inspectors performed another inspection of Advance Medical Pharmacy. During the course of their inspection, the inspectors found numerous outdated products in the pharmacy's active inventory.

42. After the April 15, 2015 inspection, Respondent Yuen provided the inspectors with Respondent AMP's prescription dispensing records for the period from October 1, 2013 to April 15, 2015. A review of those records revealed the following:

a. On or about June 2, 2014, Respondent AMP dispensed a prescription for oxycodone that was missing the following security features: (1) a latent "void" across the entire front; (2) a watermark on the back indicating "California Security Prescription"; (3) quantity check boxes; (4) a statement that the prescription is void if the number of drugs is not noted; (5) an identifying number assigned to the approved security printer; and (6) the sequential batch number.

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b. For certain patients, Respondent AMP dispensed excessive, and in some cases potentially lethal, doses and/or amounts of controlled substances, including oxycodone, acetaminophen containing controlled substances, methadone, fentanyl, zolpidem, and zaleplon.

c. Respondent AMP dispensed over 200 early refills.

43. Fentanyl is an opioid controlled substance that is more potent than morphine, oxycodone, and heroin. Fentanyl comes in several forms, one of which is an oral product designed to be absorbed as it dissolves in the lining of the mouth. That form of fentanyl is known as transmucosal fentanyl. The Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy program is an FDA-required program that defines appropriate patients for TIRF medications as only those patients with cancer who are opioid-tolerant and on around-the-clock opioid therapy. The purpose of the TIRF program is to mitigate the risk of misuse, abuse, addiction, overdose, and serious complications due to the use of TIRF medications.

44. Respondent AMP is enrolled in the TIRF program. A review of Respondent AMP's prescription dispensing records indicates that Respondent AMP dispensed TIRF medications to certain patients who did not meet the requirements of the TIRF program, and therefore should not have received TIRF medications. Respondent AMP dispensed TIRF medications without verifying the required cancer diagnosis, without questioning a high starting dose, and without verifying out-of-area patients with the same last name and address. In addition, Respondent AMP dispensed TIRF medications to a patient where the prescription was invalid, in that it did not contain a date written by the prescriber.

Corresponding Responsibility

45. Between January 1, 2009 and April 15, 2015, Respondent AMP filled approximately 16,177 controlled substances prescriptions for numerous patients of different prescribers. There were warning signs or "red flags" indicating that those prescriptions may not have been issued for a legitimate medical purpose. Those red flags include, but are not limited to, the following:

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a. Both the patients and the prescribers were from outside Respondent AMP's service area;

b. A high percentage of the prescriptions were paid for with cash;

c. Requests by patients for early refills;

d. Prescriptions for unusually large quantities and doses of controlled substances;

e. Overlapping prescriptions from two (2) different prescribers;

f. Prescriptions that were pre-printed or rubber-stamped with the drug name; and

g. A prescription that did not contain certain security features or a date written by the prescriber.

46. Despite the presence of those red flags, Respondent Yuen failed to exercise his corresponding responsibility to determine whether the suspicious prescriptions were issued for a legitimate medical purpose by, for example, accessing the Controlled Substance Utilization Review and Evaluation System (CURES), verifying the validity of the prescription with the prescriber, verifying that the individual presenting the prescription was the patient, evaluating whether the prescribed drug therapy was appropriate, and inquiring into the nature of the prescriber's medical practice.

FIRST CAUSE FOR DISCIPLINE

(Clearly Excessive Furnishing of Controlled Substances)

47. Respondents are subject to disciplinary action under section 4301, subdivision (d) of the Code in that they furnished excessive amounts of controlled substances to various patients. The circumstances of this conduct are set forth above in paragraph 42.b.

SECOND CAUSE FOR DISCIPLINE

(Failure to Complete a Compounding Self-Assessment)

48. Respondent Yuen is subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1735.2, subdivision (j), in that Respondent Yuen did not complete the required self-assessment for compounding pharmacies prior to allowing drug products to be compounded. The circumstances of this conduct are set forth above in paragraph 34.

THIRD CAUSE FOR DISCIPLINE

(Failure to Complete a Pharmacy Self-Assessment)

49. Respondent Yuen is subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1715, subdivision (a), in that Respondent Yuen did not complete the required self-assessment of the pharmacy's compliance with federal and state pharmacy law. The circumstances of this conduct are set forth above in paragraph 34.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Pharmacy Records on Premises)

50. Respondents are subject to disciplinary action under sections 4301, subdivision (o), 4105, subdivision (a), 4113, subdivision (c), and/or 4333, subdivision (a) of the Code in that Respondents did not maintain pharmacy records and documentation on the premises and did not obtain a waiver for off-site storage of records as provided for by California Code of Regulations, title 16, section 1707, subdivision (a). The circumstances of this conduct are set forth above in paragraphs 32 and 39.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Provide Oral Consultation)

51. Respondent Yuen is subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1707.2, subdivision (b)(1)(B), in that Respondent Yuen failed to provide an oral consultation to a patient who purchased from Respondent AMP a prescription with a change in directions. The circumstances of this conduct are set forth above in paragraph 40.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain a Complete Written Policy and Procedure Manual for Compounding)

52. Respondents are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1735.5, subdivisions (a) and/or (b), in that Respondents failed to maintain a complete and/or

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updated written policy and procedure manual for compounding. The circumstances of this conduct are set forth above in paragraph 36.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Written Compounding Training Records for Pharmacy Personnel)

53. Respondents are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1735.7, subdivisions (a) and/or (b), in that Respondents failed to maintain written compounding training records for pharmacy personnel. The circumstances of this conduct are set forth above in paragraphs 32 and 38.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain a Written Quality Assurance Plan)

54. Respondents are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1735.8, subdivision (a), in that Respondents failed to maintain a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products. The circumstances of this conduct are set forth above in paragraph 36.

NINTH CAUSE FOR DISCIPLINE

(Maintaining Outdated Products in Current Inventory)

55. Respondents are subject to disciplinary action under sections 4301, subdivision (o), 4113, subdivision (c), 4306.5, subdivision (a), and 4342 of the Code, and California Code of Regulations, title 16, section 1714, subdivision (b) in that Respondent AMP maintained outdated products in its current inventory. The circumstances of this conduct are set forth above in paragraphs 30, 35, and 41.

TENTH CAUSE FOR DISCIPLINE

(Failure to Provide Expiration Dates for Compounded Drug Products)

56. Respondents are subject to disciplinary action under sections 4301, subdivision (o), 4113, subdivision (c), and 4306.5, subdivision (a) of the Code, and California Code of

Regulations, title 16, section 1735.2, subdivision (h) in that Respondents failed to provide expiration dates for compounded drug products. The circumstances of this conduct are set forth above in paragraphs 31 and 35.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Complete Records for Compounded Drug Products)

57. Respondents are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, sections 1735.2, subdivisions (d)(3) and (d)(5)-(d)(7), and 1735.3, subdivisions (a)(1), (a)(4), and (a)(8), in that Respondent AMP's records for compounded drug products did not include the master formula record, the identity of the pharmacist reviewing the final drug product, or the expiration date of the final compounded drug product. The circumstances of this conduct are set forth above in paragraphs 30, 31, and 37.

TWELFTH CAUSE FOR DISCIPLINE

(Filling, Compounding, and/or Dispensing Prescriptions for Controlled Substances Where Prescription Form Is Missing Required Information and Features)

58. Respondents are subject to disciplinary action under sections 4301, subdivision (o), 4113, subdivision (c), and 4306.5, subdivision (a) of the Code, and Health and Safety Code sections 11162.1, subdivisions (a)(1), (a)(2), (a)(7)(A), (a)(8), (a)(13), and (b), and 11164, subdivision (a)(1) in that Respondents filled, compounded, and/or dispensed prescriptions for controlled substances where the prescription form was missing certain required information and features. The circumstances of this conduct are set forth above in paragraphs 42.a. and 44.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Exercise Corresponding Responsibility When Dispensing Controlled Substances)

59. Respondents are subject to disciplinary action under sections 4301, subdivisions (j) and/or (o), 4113, subdivision (c), and/or 4306.5, subdivision (b) of the Code, and Health and Safety Code section 11153, subdivision (a), in that Respondent Yuen failed to exercise corresponding responsibility when dispensing controlled substances and dangerous drugs. The circumstances of this conduct are set forth above in paragraphs 42.c. and 43 through 46.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Contact Prescriber)

60. Respondents are subject to disciplinary action under sections 4301, subdivisions (j) and/or (o), and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1761, subdivision (a), in that Respondent Yuen failed to contact certain prescribers to obtain information needed to validate prescriptions containing significant errors, omissions, irregularities, uncertainties, ambiguities and/or alterations. The circumstances of this conduct are set forth above in paragraphs 43 through 46.

DISCIPLINE CONSIDERATIONS

61. To determine the degree of discipline, if any, to be imposed on Respondent AMP, Complainant alleges that on or about August 16, 2012, the Board issued Citation Number CI 2011 51390 to Respondent AMP for violating section 4126.5, subdivision (a)(4) of the Code (improper furnishing of dangerous drugs). The Board ordered Respondent AMP to pay a fine in the amount of $31,500. That Citation is now final and is incorporated by reference as if fully set forth.

62. To determine the degree of discipline, if any, to be imposed on Respondent AMP, Complainant alleges that on or about February 8, 2013, the Board issued Citation Number CI 2011 51511 to Respondent AMP for violating section 4342, subdivision (a) of the Code (action by Board to prevent sale of drugs lacking quality or strength). The Board ordered Respondent AMP to pay a fine in the amount of $500. That Citation is now final and is incorporated by reference as if fully set forth.

63. To determine the degree of discipline, if any, to be imposed on Respondent Yuen, Complainant alleges that on or about August 16, 2012, the Board issued Citation Number CI 2012 53586 to Respondent Yuen for violating section 4126.5, subdivision (a)(4) of the Code (improper furnishing of dangerous drugs). The Board ordered Respondent Yuen to pay a fine in the amount of $5,000. That Citation is now final and is incorporated by reference as if fully set forth.

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64. To determine the degree of discipline, if any, to be imposed on Respondent Yuen, Complainant alleges that on or about February 8, 2013, the Board issued Citation Number CI 2012 55562 to Respondent Yuen for violating section 4342, subdivision (a) of the Code (action by Board to prevent sale of drugs lacking quality or strength). The Board ordered Respondent Yuen to pay a fine in the amount of $750. That Citation is now final and is incorporated by reference as if fully set forth.

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 Pharmacy Permit Number PHY 46345 issued to Advance Medical Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 43557 issued to James Po Kwong Yuen;

3. Ordering James Po Kwong Yuen and Advance Medical Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case pursuant to Business and Professions Code section 125.3;

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

DATED: 1/8/16

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

SF2013406710