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8 BEFORE THE	
9 BOARD OF PHARMACY 9 DEPARTMENT OF CONSUMER AFFAIRS	
10 STATE OF CALIFORNIA	
11 In the Matter of the Accusation Against: Case No. 5010	
12 ADVANCE MEDICAL PHARMACY 112 La Cara Via Swite 100	
13112 La Casa Via, Suite 100 Walnut Creek, CA 94598FIRST AMENDED ACCUSATION	
14 Original Permit Number No. PHY 46345	
15 and	
16 JAMES PO KWONG YUEN 112 La Casa Via, Suite 100	
17 Walnut Creek, CA 94598	
18 Pharmacist License No. RPH 43557,	
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20 Respondents.	
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23 Complainant alleges:	
24 PARTIES	
25 1. Virginia Herold (Complainant) brings this First Amended Accusation solely in h	er
26 official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of	
27 Consumer Affairs.	
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1 FIRST AMENDED ACCUSA	TION

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.

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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.

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STATUTORY PROVISIONS

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

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

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"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) 1 2 of Section 11153 of the Health and Safety Code. 3 . . . "(j) The violation of any of the statutes of this state, of any other state, or of the United 4 States regulating controlled substances and dangerous drugs. 5 6 . . . "(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the 7 violation of or conspiring to violate any provision or term of this chapter or of the applicable 8 federal and state laws and regulations governing pharmacy, including regulations established by 9 the board or by any other state or federal regulatory agency. 10 . . ." 11 9. Section 4021 of the Code provides that a "controlled substance" means any substance 12 listed in Schedules I through V contained in Health and Safety Code section 11053 et seq. 13 Section 4105, subdivision (a) of the Code states: "All records or other documentation 10. 14 of the acquisition and disposition of dangerous drugs and dangerous devices by any entity 15 licensed by the board shall be retained on the licensed premises in a readily retrievable form." 16 Section 4113, subdivision (c) of the Code states: 17 11. "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state 18 and federal laws and regulations pertaining to the practice of pharmacy." 19 Section 4306.5 of the Code provides, in pertinent part: 12. 20 "Unprofessional conduct for a pharmacist may include any of the following: 21 "(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or 22 her education, training, or experience as a pharmacist, whether or not the act or omission arises in 23 the course of the practice of pharmacy or the ownership, management, administration, or 24 operation of a pharmacy or other entity licensed by the board. 25 "(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement 26 his or her best professional judgment or corresponding responsibility with regard to the 27 111 28 3

FIRST AMENDED ACCUSATION

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

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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."

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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)."

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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 17 purpose by an individual practitioner acting in the usual course of his or her professional practice. 18 The responsibility for the proper prescribing and dispensing of controlled substances is upon the 19 prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the 2.0prescription. Except as authorized by this division, the following are not legal prescriptions: (1) 21 an order purporting to be a prescription which is issued not in the usual course of professional 22 treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of 23 controlled substances, which is issued not in the course of professional treatment or as part of an 24 authorized narcotic treatment program, for the purpose of providing the user with controlled 25 substances, sufficient to keep him or her comfortable by maintaining customary use." 26

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1	16. Section 11162.1 of the Health and Safety Code states, in pertinent part:
2	"(a) The prescription forms for controlled substances shall be printed with the following
3	features:
4	"(1) A latent, repetitive 'void' pattern shall be printed across the entire front of the
5	prescription blank; if a prescription is scanned or photocopied, the word 'void' shall appear in a
6	pattern across the entire front of the prescription.
.7	"(2) A watermark shall be printed on the backside of the prescription blank; the watermark
8	shall consist of the words 'California Security Prescription.'
9	····
10	"(7)(A) Six quantity check off boxes shall be printed on the form so that the prescriber may
11	indicate the quantity by checking the applicable box where the following quantities shall appear:
12	1-24; 25-49; 50-74; 75-100; 101-150; 151 and over.
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14	(8) Prescription blanks shall contain a statement printed on the bottom of the prescription
15	blank that the 'Prescription is void if the number of drugs prescribed is not noted.'
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17	(13) An identifying number assigned to the approved security printer by the Department of
18	Justice.
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20	"(b) Each batch of controlled substance prescription forms shall have the lot number printed
21	on the form and each form within that batch shall be numbered sequentially beginning with the
22	numeral one.
23	" · · ·
24	17. Section 11164 of the Health and Safety Code states, in pertinent part:
25	"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor
26	shall any person fill, compound, or dispense a prescription for a controlled substance, unless it
27	complies with the requirements of this section.
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	5 FIRST AMENDED ACCUSATION
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"(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, 1 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 4 prescriber's address and telephone number; the name of the ultimate user or research subject, or 5 contact information as determined by the Secretary of the United States Department of Health and 6 Human Services; refill information, such as the number of refills ordered and whether the 7 prescription is a first-time request or a refill; and the name, quantity, strength, and directions for 8 use of the controlled substance prescribed. 9

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REGULATORY PROVISIONS

California Code of Regulations, title 16, section 1707, subdivision (a) states: 18. 12 "Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and 13 subdivision (c) of Section 4333 of the Business and Professions Code, a waiver shall be granted 14 to any entity licensed by the board for off-site storage of the records described in subdivisions (a), 15 (b) and (c) of Section 4105 of the Business and Professions Code unless the applicant has, within 16 the preceding five years, failed to produce records pursuant to Section 4081 of the Business and 17 Professions Code or has falsified records covered by Section 4081 of the Business and 18 Professions Code." 19

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

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"(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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1	20. California Code of Regulations, title 16, section 1714, subdivision (b) states: "Each
2	pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that
3	drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall
4	be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy."
5	21. California Code of Regulations, title 16, section 1715, subdivision (a) states: "The
6	pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the
7	Business and Professions Code shall complete a self-assessment of the pharmacy's compliance
8	with federal and state pharmacy law. The assessment shall be performed before July 1 of every
9	odd-numbered year. The primary purpose of the self-assessment is to promote compliance
10	through self-examination and education."
11	22. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:
12	"(d) A drug product shall not be compounded until the pharmacy has first prepared a
13	written master formula record that includes at least the following elements:
14	••••
15	"(3) Expiration dating requirements.
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17	"(5) Process and/or procedure used to prepare the drug.
18	"(6) Quality reviews required at each step in preparation of the drug.
19	"(7) Post-compounding process or procedures required, if any.
20	•••
21	"(h) Every compounded drug product shall be given an expiration date representing the date
22	beyond which, in the professional judgment of the pharmacist performing or supervising the
23	compounding, it should not be used. This 'beyond use date' of the compounded drug product
24	shall not exceed 180 days from preparation or the shortest expiration date of any component in
25	the compounded drug product, unless a longer date is supported by stability studies of finished
26	drugs or compounded drug products using the same components and packaging. Shorter dating
27	than set forth in this subsection may be used if it is deemed appropriate in the professional
28	judgment of the responsible pharmacist.
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2	(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-
3	charge shall complete a self-assessment for compounding pharmacies developed by the board.
4	(Incorporated by reference is 'Community Pharmacy & Hospital Outpatient Pharmacy
5	Compounding Self-Assessment' Form 17M-39 Rev. 02/12.) That form contains a first section
6	applicable to all compounding, and a second section applicable to sterile injectable compounding.
7	The first section must be completed by the pharmacist-in-charge before any compounding is
8	performed in the pharmacy. The second section must be completed by the pharmacist-in-charge
9	before any sterile injectable compounding is performed in the pharmacy. The applicable sections
10	of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year,
11	within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a
12	new pharmacy license. The primary purpose of the self-assessment is to promote compliance
13	through self-examination and education."
14	23. California Code of Regulations, title 16, section 1735.3 provides, in relevant part:
15	"(a) For each compounded drug product, the pharmacy records shall include:
16	"(1) The master formula record.
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18	"(8) The expiration date of the final compounded drug product.
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20	24. California Code of Regulations, title 16, section 1735.5 provides, in relevant part:
21	"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure
22	manual for compounding that establishes procurement procedures, methodologies for the
23	formulation and compounding of drugs, facilities and equipment cleaning, maintenance,
24	operation, and other standard operating procedures related to compounding.
25	"(b) The policy and procedure manual shall be reviewed on an annual basis by the
26	pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
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	8 FIRST AMENDED ACCUSATION

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.

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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."

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COSTS

19 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.

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FACTUAL BACKGROUND

26 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.

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31. While at the facility, the inspectors reviewed Respondent AMP's compounding 6 process for compounded drug products. During this review, the inspectors determined that 7 Respondent AMP's pharmacy records did not contain master formulas for compounded drug 8 products that included certain required elements, including expiration dating requirements, the 9 process and/or procedure used to prepare the drug, quality reviews required at each step in 10 preparation of the drug, and any required post-compounding process or procedures. In addition, 11 Respondent AMP's pharmacy records did not contain the expiration date of final compounded 12 drug products. 13

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

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

34. While at the facility, one of the inspectors requested a current pharmacy selfassessment 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.

27 36. The inspectors also reviewed Respondent AMP's compounding policies and
28 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.

- 3 37. While at the facility, one of the inspectors reviewed Respondent AMP's records for a
 4 compounded drug product and determined that those records did not contain a master formula.
- 5 38. The inspectors also determined that Respondent AMP did not have current training
 6 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.

16 April 15, 2015 Inspection

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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.

Fentanyl is an opioid controlled substance that is more potent than morphine, 43. 5 oxycodone, and heroin. Fentanyl comes in several forms, one of which is an oral product 6 designed to be absorbed as it dissolves in the lining of the mouth. That form of fentanyl is known 7 as transmucosal fentanyl. The Transmucosal Immediate Release Fentanyl (TIRF) Risk 8 Evaluation and Mitigation Strategy program is an FDA-required program that defines appropriate 9 patients for TIRF medications as only those patients with cancer who are opioid-tolerant and on 10 around-the-clock opioid therapy. The purpose of the TIRF program is to mitigate the risk of 11 misuse, abuse, addiction, overdose, and serious complications due to the use of TIRF 12 medications. 13

44. Respondent AMP is enrolled in the TIRF program. A review of Respondent AMP's 14 prescription dispensing records indicates that Respondent AMP dispensed TIRF medications to 15 certain patients who did not meet the requirements of the TIRF program, and therefore should not 16 have received TIRF medications. Respondent AMP dispensed TIRF medications without 17 verifying the required cancer diagnosis, without questioning a high starting dose, and without 18 verifying out-of-area patients with the same last name and address. In addition, Respondent AMP 19 dispensed TIRF medications to a patient where the prescription was invalid, in that it did not 20contain a date written by the prescriber. 21

22 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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1	a. Both the patients and the prescribers were from outside Respondent AMP's service
2	area;
3	b. A high percentage of the prescriptions were paid for with cash;
4	c. Requests by patients for early refills;
5	d. Prescriptions for unusually large quantities and doses of controlled substances;
6	e. Overlapping prescriptions from two (2) different prescribers;
7	f. Prescriptions that were pre-printed or rubber-stamped with the drug name; and
8	g. A prescription that did not contain certain security features or a date written by the
9	prescriber.
10	46. Despite the presence of those red flags, Respondent Yuen failed to exercise his
11	corresponding responsibility to determine whether the suspicious prescriptions were issued for a
12	legitimate medical purpose by, for example, accessing the Controlled Substance Utilization
13	Review and Evaluation System (CURES), verifying the validity of the prescription with the
14	prescriber, verifying that the individual presenting the prescription was the patient, evaluating
15	whether the prescribed drug therapy was appropriate, and inquiring into the nature of the
16	prescriber's medical practice.
17	FIRST CAUSE FOR DISCIPLINE
18	(Clearly Excessive Furnishing of Controlled Substances)
19	47. Respondents are subject to disciplinary action under section 4301, subdivision (d) of
20	the Code in that they furnished excessive amounts of controlled substances to various patients.
21	The circumstances of this conduct are set forth above in paragraph 42.b.
22	SECOND CAUSE FOR DISCIPLINE
23	(Failure to Complete a Compounding Self-Assessment)
24	48. Respondent Yuen is subject to disciplinary action under sections 4301, subdivision
25	(o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section
26	1735.2, subdivision (j), in that Respondent Yuen did not complete the required self-assessment
27	for compounding pharmacies prior to allowing drug products to be compounded. The
28	circumstances of this conduct are set forth above in paragraph 34.
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ļ	FIRST AMENDED ACCUSATION

1	THIRD CAUSE FOR DISCIPLINE
2	(Failure to Complete a Pharmacy Self-Assessment)
3	49. Respondent Yuen is subject to disciplinary action under sections 4301, subdivision
4	(o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section
5	1715, subdivision (a), in that Respondent Yuen did not complete the required self-assessment of
6	the pharmacy's compliance with federal and state pharmacy law. The circumstances of this
7	conduct are set forth above in paragraph 34.
8	FOURTH CAUSE FOR DISCIPLINE
9	(Failure to Maintain Pharmacy Records on Premises)
10	50. Respondents are subject to disciplinary action under sections 4301, subdivision (o),
11	4105, subdivision (a), 4113, subdivision (c), and/or 4333, subdivision (a) of the Code in that
12	Respondents did not maintain pharmacy records and documentation on the premises and did not
13	obtain a waiver for off-site storage of records as provided for by California Code of Regulations,
14	title 16, section 1707, subdivision (a). The circumstances of this conduct are set forth above in
15	paragraphs 32 and 39.
16	FIFTH CAUSE FOR DISCIPLINE
17	(Failure to Provide Oral Consultation)
18	51. Respondent Yuen is subject to disciplinary action under sections 4301, subdivision
19	(o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section
20	1707.2, subdivision (b)(1)(B), in that Respondent Yuen failed to provide an oral consultation to a
21	patient who purchased from Respondent AMP a prescription with a change in directions. The
22	circumstances of this conduct are set forth above in paragraph 40.
23	SIXTH CAUSE FOR DISCIPLINE
24	(Failure to Maintain a Complete Written Policy and Procedure Manual for Compounding)
25	52. Respondents are subject to disciplinary action under sections 4301, subdivision (o)
26	and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section
27	1735.5, subdivisions (a) and/or (b), in that Respondents failed to maintain a complete and/or
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1	updated written policy and procedure manual for compounding. The circumstances of this
2	conduct are set forth above in paragraph 36.
3	SEVENTH CAUSE FOR DISCIPLINE
4	(Failure to Maintain Written Compounding Training Records for Pharmacy Personnel)
5	53. Respondents are subject to disciplinary action under sections 4301, subdivision (o)
6	and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section
7	1735.7, subdivisions (a) and/or (b), in that Respondents failed to maintain written compounding
8	training records for pharmacy personnel. The circumstances of this conduct are set forth above in
9	paragraphs 32 and 38.
10	EIGHTH CAUSE FOR DISCIPLINE
11	(Failure to Maintain a Written Quality Assurance Plan)
12	54. Respondents are subject to disciplinary action under sections 4301, subdivision (o)
13	and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section
14	1735.8, subdivision (a), in that Respondents failed to maintain a written quality assurance plan
15	designed to monitor and ensure the integrity, potency, quality, and labeled strength of
16	compounded drug products. The circumstances of this conduct are set forth above in paragraph
17	36.
18	NINTH CAUSE FOR DISCIPLINE
19	(Maintaining Outdated Products in Current Inventory)
20	55. Respondents are subject to disciplinary action under sections 4301, subdivision (o),
21	4113, subdivision (c), 4306.5, subdivision (a), and 4342 of the Code, and California Code of
22	Regulations, title 16, section 1714, subdivision (b) in that Respondent AMP maintained outdated
23	products in its current inventory. The circumstances of this conduct are set forth above in
24	paragraphs 30, 35, and 41.
25	TENTH CAUSE FOR DISCIPLINE
26	(Failure to Provide Expiration Dates for Compounded Drug Products)
27	56. Respondents are subject to disciplinary action under sections 4301, subdivision (o),
28	4113, subdivision (c), and 4306.5, subdivision (a) of the Code, and California Code of
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1	FIRST AMENDED ACCUSATION

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) 5 Respondents are subject to disciplinary action under sections 4301, subdivision (o) 57. 6 and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, sections 7 1735.2, subdivisions (d)(3) and (d)(5)-(d)(7), and 1735.3, subdivisions (a)(1), (a)(4), and (a)(8), in 8 that Respondent AMP's records for compounded drug products did not include the master 9 formula record, the identity of the pharmacist reviewing the final drug product, or the expiration 10 date of the final compounded drug product. The circumstances of this conduct are set forth above 11 in paragraphs 30, 31, and 37. 12

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TWELFTH CAUSE FOR DISCIPLINE

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

16 58. Respondents are subject to disciplinary action under sections 4301, subdivision (o),
17 4113, subdivision (c), and 4306.5, subdivision (a) of the Code, and Health and Safety Code
18 sections 11162.1, subdivisions (a)(1), (a)(2), (a)(7)(A), (a)(8), (a)(13), and (b), and 11164,
19 subdivision (a)(1) in that Respondents filled, compounded, and/or dispensed prescriptions for
20 controlled substances where the prescription form was missing certain required information and
21 features. The circumstances of this conduct are set forth above in paragraphs 42.a. and 44.

THIRTEENTH CAUSE FOR DISCIPLINE

23 || (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.

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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.

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DISCIPLINE CONSIDERATIONS

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

16 62. To determine the degree of discipline, if any, to be imposed on Respondent AMP,
17 Complainant alleges that on or about February 8, 2013, the Board issued Citation Number
18 CI 2011 51511 to Respondent AMP for violating section 4342, subdivision (a) of the Code
19 (action by Board to prevent sale of drugs lacking quality or strength). The Board ordered
20 Respondent AMP to pay a fine in the amount of \$500. That Citation is now final and is
21 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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1	64. To determine the degree of discipline, if any, to be imposed on Respondent Yuen,
2	Complainant alleges that on or about February 8, 2013, the Board issued Citation Number
3	CI 2012 55562 to Respondent Yuen for violating section 4342, subdivision (a) of the Code
4	(action by Board to prevent sale of drugs lacking quality or strength). The Board ordered
5	Respondent Yuen to pay a fine in the amount of \$750. That Citation is now final and is
6	incorporated by reference as if fully set forth.
7	PRAYER
8	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
9	and that following the hearing, the Board of Pharmacy issue a decision:
10	1. Revoking or suspending Pharmacy Permit Number PHY 46345 issued to Advance
11	Medical Pharmacy;
12	2. Revoking or suspending Pharmacist License Number RPH 43557 issued to James Po
13	Kwong Yuen;
14	3. Ordering James Po Kwong Yuen and Advance Medical Pharmacy to pay the Board of
15	Pharmacy the reasonable costs of the investigation and enforcement of this case pursuant to
16	Business and Professions Code section 125.3;
17	4. Taking such other and further action as deemed necessary and proper.
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19 20	DATED: 1/8/16 Uninia Accold
21	Executive Officer Board of Pharmacy
22	Department of Consumer Affairs State of California
23	Complainant
24	SF2013406710
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	FIRST AMENDED ACCUSATION

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