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BEFOI	RE THE	
BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
	CALIFORNIA	
In the Matter of the Accusation Against:	Case No. 4771	
ADVANTACARE INFUSION		
5 Mandeville Ct., Ste. 100 Monterey, CA 93940	ACCUSATION	
Pharmacy License No. PHY 48323		
and		
DUNCAN LINCK MCCARTER		
1209 Ocean View Blvd. Pacific Grove, CA 93950		
Pharmacist License No. RPH 26117		
Respondents.		
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PARTIES		
1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity		
as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.		
2. On or about April 26, 2007, the Board of Pharmacy issued Pharmacy License No.		
PHY 48323 to AdvantaCare Infusion (Respondent AdvantaCare). The Pharmacy License was in		
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	1 ACCUSATION	
	Attorney General of California FRANK H. PACOE Supervising Deputy Attorney General NICHOLAS TSUKAMAKI Deputy Attorney General State Bar No. 253959 455 Golden Gate Avenue, Suite 11000 San Francisco, CA 94102-7004 Telephone: (415) 703-5188 Facsimile: (415) 703-5480 E-mail: Nicholas.Tsukamaki@doj.ca.gov Attorneys for Complainant  BEFOI BOARD OF DEPARTMENT OF C STATE OF C  In the Matter of the Accusation Against: ADVANTACARE INFUSION 5 Mandeville Ct., Ste. 100 Monterey, CA 93940  Pharmacy License No. PHY 48323 and  DUNCAN LINCK MCCARTER 1209 Ocean View Blvd. Pacific Grove, CA 93950  Pharmacist License No. RPH 26117  Respondents.  Complainant alleges:  PAR  1. Virginia Herold (Complainant) bring as the Executive Officer of the Board of Pharma 2. On or about April 26, 2007, the Boar PHY 48323 to AdvantaCare Infusion (Responde)	

full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2014, unless renewed.

3. On or about July 15, 1969, the Board of Pharmacy issued Pharmacist License Number RPH 26117 to Duncan Linck McCarter (Respondent McCarter). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2014, unless renewed. Since on or about August 20, 2007, and for all time periods relevant to the charges herein, Respondent McCarter served and/or was reflected in Board records as the Pharmacist-in-Charge (PIC) for Respondent AdvantaCare.

### JURISDICTION

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

"(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.

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"(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 4059 of the Code, in pertinent part, prohibits the furnishing of any dangerous drug or dangerous device except upon the prescription of an authorized prescriber.
  - 10. Section 4081, subdivision (a) of the Code states:

"All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices."

- 11. Section 4105 of the Code provides, in relevant part:
- "(a) 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.

"(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

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12. 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."

13. Section 4332 of the Code states:

"Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor."

- 14. Section 4333 of the Code states, in pertinent part, that 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.
- 15. 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.
  - 16. Section 4022 of the Code states, in pertinent part:
- "Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:
- "(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.
- "(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."
- 17. Health and Safety Code section 11165 provides, in pertinent part, for the establishment and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of and prescribing and dispensing of Schedule II, III, and IV controlled substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV controlled substance, the dispensing pharmacy or clinic transmit a report

19. California Code of Regulations, title 16, section 1714 provides, in relevant part:

"(b) 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.

. . .

- "(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist."
  - 20. California Code of Regulations, title 16, section 1715 provides, in pertinent part:
- "(a) 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.

. .

- "(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed."
  - 21. California Code of Regulations, title 16, section 1717, subdivision (b) provides:
- "(b) In addition to the requirements of Business and Professions Code section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:
- "(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.
- "(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

- "(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
- "(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained."

### COSTS

22. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

### FACTUAL BACKGROUND

- 23. On or about August 16, 2012, two Board inspectors conducted a routine inspection of AdvantaCare Infusion in Monterey, California. While at the facility, the inspectors noticed that the door to the licensed area was unlocked. Once inside the licensed area, the inspectors saw several dangerous drugs. One of the inspectors then asked Respondent AdvantaCare's administrative services manager to secure the licensed area, which she did with a key she had in her possession. Respondent AdvantaCare's administrative services manager is not a licensed pharmacist.
- 24. Later in the day on August 16, 2012, the inspectors met with Respondent McCarter. The inspectors requested that Respondent McCarter provide them with required policies and procedures, CURES reporting, records of acquisition and disposition, a Drug Enforcement Administration (DEA) biennial inventory, a copy of a prescription label, and a self-assessment of Respondent AdvantaCare's compliance with federal and state pharmacy law. With the exception of two (2) acquisition records for over the counter medications, Respondent McCarter was unable to provide the inspectors with any of the requested documents on August 16, 2012.
- 25. On or about August 20, 2012, one of the inspectors obtained from Respondent AdvantaCare's then current wholesaler a report of all the medication Respondent AdvantaCare had ordered between August 20, 2011, and August 20, 2012. The wholesaler's report indicates

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that Respondent AdvantaCare purchased numerous dangerous drugs in September 2011, December 2011, and July 2012.

- 26. On or about August 21, 2012, Respondent McCarter told one of the inspectors that he had ordered dangerous drugs for himself and his family. On the same day, the inspector faxed to Respondent McCarter a letter requesting (1) copies of invoices of acquisition for any and all purchases of dangerous drugs between August 22, 2009, and August 21, 2012; and (2) copies of prescriptions/invoices for disposition of any and all dangerous drugs for the same time period.
- 27. On or about August 27, 2012, Respondent McCarter provided one of the inspectors with some, but not all, of the invoices for the dangerous drugs listed on Respondent AdvantaCare's then current wholesaler's report. The inspector then asked Respondent McCarter for invoices from Respondent AdvantaCare's previous wholesaler beginning on August 22, 2009. Respondent McCarter was unable to provide the inspector with these earlier invoices. The inspector also asked Respondent McCarter for dispensing records. Respondent McCarter was only able to produce one prescription record. The inspector then asked Respondent McCarter if he could provide any other records. Respondent McCarter told the inspector that no other records were available at that time. Furthermore, with one exception, Respondent McCarter did not provide the inspector with any prescriptions for the dangerous drugs he had ordered for himself and his family. Nor did Respondent McCarter maintain medication profiles for patients who had prescriptions filled in the pharmacy.
- 28. On or about September 7, 2012, one of the inspectors requested and received from Respondent AdvantaCare's previous wholesaler a summary of prescription medications purchased by Respondent AdvantaCare between August 22, 2009, and August 20, 2012. The summary indicates that on or about December 31, 2009, Respondent AdvantaCare purchased one (1) sixteen ounce bottle of Cheratussin AC. Cheratussin contains codeine, a Schedule V controlled substance and dangerous drug. Neither prescription information nor dispensing information for the Cheratussin AC was readily retrievable by Respondent McCarter during the pharmacy inspection on August 16, 2012.

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### FIRST CAUSE FOR DISCIPLINE

# (Furnishing a Dangerous Drug Without a Prescription)

29. Respondents are subject to disciplinary action under sections 4301, subdivision (j) and/or (o), 4113, subdivision (c), and 4059 of the Code, in that Respondents furnished dangerous drugs without a prescription of an authorized prescriber. The circumstances of Respondents' conduct are set forth above in paragraphs 26-28.

### SECOND CAUSE FOR DISCIPLINE

# (Failure to Maintain and Preserve Records of Dangerous Drugs)

30. Respondents are subject to disciplinary action under sections 4301, subdivision (j) and/or (o), 4081, 4113, subdivision (c), 4332, and 4333 of the Code, and California Code of Regulations, title 16, sections 1707.1, subdivision (a)(1)(B) and 1717, subdivision (b), in that Respondents failed to maintain prescriptions and other records of the sale, acquisition, or disposition of dangerous drugs, to make those records available for inspection, and to preserve those records for at least three years from the date of making. The circumstances of Respondents' conduct are set forth above in paragraphs 24-28.

### THIRD CAUSE FOR DISCIPLINE

# (Failure to Report Controlled Substance Prescriptions to CURES)

31. Respondents are subject to disciplinary action under sections 4301, subdivision (j) and/or (o) and 4113, subdivision (c) of the Code, and Health and Safety Code section 11165, in that Respondents failed to transmit controlled substances dispensing data to CURES.

### FOURTH CAUSE FOR DISCIPLINE

# (Failure to Retain Records of Dangerous Drugs on Licensed Premises)

32. Respondents are subject to disciplinary action under sections 4301, subdivision (j) and/or (o), 4105, subdivisions (a) and (c), and 4113, subdivision (c) of the Code, in that Respondents failed to retain on the licensed premises in a readily retrievable form records or other documentation of the acquisition and disposition of dangerous drugs for three years from the date of making. The circumstances of Respondents' conduct are set forth above in paragraphs 24, 27, and 28.

# FIFTH CAUSE FOR DISCIPLINE 1 2 3 4 5 6 7 set forth above in paragraph 27. 8 9 10 11 12 13 14 15 35. 16 17 18 19 EIGHTH CAUSE FOR DISCIPLINE 20 21 36. 22 23

# (Failure to Maintain Patient Medication Profiles)

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 1707.1, in that Respondents failed to maintain medication profiles for all patients who had prescriptions filled in Respondents' pharmacy. The circumstances of Respondents' conduct are

### SIXTH CAUSE FOR DISCIPLINE

# (Failure to Safely and Properly Secure Drugs)

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 1714, subdivision (b), in that Respondents failed to safely and properly secure drugs. The circumstances of Respondents' conduct are set forth above in paragraph 23.

### SEVENTH CAUSE FOR DISCIPLINE

# (Possession of Pharmacy Key by Non-Pharmacist)

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 1714, subdivision (d), in that on or about August 16, 2012, a non-pharmacist employee of Respondents' pharmacy was in possession of a key to the pharmacy.

### (Failure to Complete and Retain a Self-Assessment)

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 1715, subdivisions (a) and (d), in that Respondent McCarter failed to complete and retain a self-assessment of Respondent AdvantaCare's compliance with federal and state pharmacy law. The circumstances of Respondents' conduct are set forth above in paragraph 24.

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# WHEREFORE, Complainant requand that following the hearing, the Board. 1. Revoking or suspending Ph. Infusion (Respondent AdvantaCare); 2. Revoking or suspending Ph. McCarter (Respondent McCarter); 3. Ordering Respondent AdvantaCare); enforcement of this case pursuant to Bu.

# **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 License No. PHY 48323 issued to AdvantaCare nfusion (Respondent AdvantaCare);
- 2. Revoking or suspending Pharmacist License No. RPH 26117 issued to Duncan Linck McCarter (Respondent McCarter);
- 3. Ordering Respondent AdvantaCare and Respondent McCarter to jointly and severally be responsible 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 is deemed necessary and proper.

DATED:	5/10/14	Diama Llevold
		YIRGINYA HEROLD
	•	Executiγe Φfficer
		Board of Pharmacy
		Department of Consumer Affairs
		State of California

Complainant

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