

1 KAMALA D. HARRIS
Attorney General of California
2 JAMES M. LEDAKIS
Supervising Deputy Attorney General
3 DESIREE I. KELLOGG
Deputy Attorney General
4 State Bar No. 126461
110 West "A" Street, Suite 1100
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 645-2996
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 5267

12 **COMMUNITY INFUSION SERVICES**
13 **INC., DBA CDM DRUGS**
2865 East Coast Hwy., Suite 150
14 Corona del Mar, CA 92625

A C C U S A T I O N

15 Pharmacy Permit No. PHY 46007

16 **CHAD TRENOR KEARNS**
1601 Anita Lane
17 Newport Beach, CA 92660

18 Pharmacist License No. RPH 42817

19 Respondents.

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22 Complainant alleges:

23 **PARTIES**

- 24 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
25 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 26 2. On or about July 3, 2002, the Board of Pharmacy issued Pharmacy Permit Number
27 PHY 46007 to Community Infusion Services Inc., doing business as CDM Drugs with Chad
28 Trenor Kearns designated as the Pharmacist-in-Charge (Respondent Community Infusion

1 Services Pharmacy.) The Pharmacy Permit was in full force and effect at all times relevant to the
2 charges brought herein and will expire on July 1, 2015, unless renewed.

3 3. On or about August 10, 1989, the Board of Pharmacy issued Pharmacist License
4 Number RPH 42817 to Chad Trenor Kearns (Respondent Chad Kearns). The Pharmacist License
5 was in full force and effect at all times relevant to the charges brought herein and will expire on
6 November 30, 2014, unless renewed.

7 JURISDICTION

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

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

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

16 7. Section 4300.1 of the Code states:

17 The expiration, cancellation, forfeiture, or suspension of a board-issued license
18 by operation of law or by order or decision of the board or a court of law, the
19 placement of a license on a retired status, or the voluntary surrender of a license by a
20 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.

21 STATUTORY PROVISIONS

22 8. Section 4022 of the Code states:

23 Dangerous drug" or "dangerous device" means any drug or device unsafe for
24 self-use in humans or animals, and includes the following:

25 (a) Any drug that bears the legend: "Caution: federal law prohibits
dispensing without prescription," "Rx only," or words of similar import.

26 (b) Any device that bears the statement: "Caution: federal law restricts this
27 device to sale by or on the order of a _____," "Rx only," or words of similar import,
28 the blank to be filled in with the designation of the practitioner licensed to use or
order use of the device.

1 (c) Any other drug or device that by federal or state law can be lawfully
2 dispensed only on prescription or furnished pursuant to Section 4006.

3 9. Section 4076(a)(7) of the Code states:

4 A pharmacist shall not dispense any prescription except in a container that
5 meets the requirements of state and federal law and is correctly labeled with all of the
6 following:

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8 The strength of the drug or drugs dispensed.

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

10 The pharmacist-in-charge shall be responsible for a pharmacy's compliance with
11 all state and federal laws and regulations pertaining to the practice of pharmacy.

12 11. Section 4127.7 of the Code states:

13 On or after July 1, 2005, a pharmacy shall compound sterile injectable products
14 from one or more nonsterile ingredients in one of the following environments:

15 (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The
16 cleanroom must have a positive air pressure differential relative to adjacent areas.

17 (b) An ISO class 5 cleanroom.

18 (c) A barrier isolator that provides an ISO class 5 environment for
19 compounding.

20 12. Section 4301 of the Code states in pertinent part:

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

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26 (f) The commission of any act involving moral turpitude, dishonesty, fraud,
27 deceit, or corruption, whether the act is committed in the course of relations as a
28 licensee or otherwise, and whether the act is a felony or misdemeanor or not.

.....

(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.

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13. Section 4306.5 of the Code states, 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.

....

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

14. Section 4342(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).

REGULATORY PROVISIONS

15. Title 16, California Code of Regulations, section 1735 (a) states in pertinent part:

“Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a drug product from chemicals or bulk drug substances

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16. Title 16, California Code of Regulations, section 1735.2 (d), (e) and (h) states:

(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:

- (1) Active ingredients to be used.
- (2) Equipment to be used.
- (3) Expiration dating requirements.

- 1 (4) Inactive ingredients to be used.
2 (5) Process and/or procedure used to prepare the drug.
3 (6) Quality reviews required at each step in preparation of the drug.
4 (7) Post-compounding process or procedures required, if any.

5 (e) Where a pharmacy does not routinely compound a particular drug product,
6 the master formula record for that product may be recorded on the prescription
7 document itself.

8 ...

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

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19 17. Title 16, California Code of Regulations, section 1735.3 (a), (b) and (c), states:

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

- 21 (1) The master formula record.
22 (2) The date the drug product was compounded.
23 (3) The identity of the pharmacy personnel who compounded the drug product.
24 (4) The identity of the pharmacist reviewing the final drug product.
25 (5) The quantity of each component used in compounding the drug product.

26 (6) The manufacturer, expiration date and lot number of each component. If the
27 manufacturer name is demonstrably unavailable, the name of the supplier may be
28 substituted. Exempt from the requirements in this paragraph are sterile products
compounded on a one-time basis for administration within seventy-two (72) hours
and stored in accordance with standards for "Redispensed CSPS" found in Chapter
797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th
Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in
a health care facility licensed under section 1250 of the Health and Safety Code.

(7) A pharmacy assigned reference or lot number for the compounded drug
product.

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

1 (9) The quantity or amount of drug product compounded.

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

5 (c) Chemicals, bulk drug substances, drug products, and components used to
6 compound drug products shall be obtained from reliable suppliers. The pharmacy
7 shall acquire and retain any available certificates of purity or analysis for chemicals,
8 bulk drug substances, drug products, and components used in compounding.
9 Certificates of purity or analysis are not required for drug products that are approved
10 by the Food and Drug Administration.

11 ...
12 18. Title 16, California Code of Regulations, section 1735.4 (b) states:

13 A statement that the drug has been compounded by the pharmacy shall be
14 included on the container or on the receipt provided to the patient.

15 19. Title 16, California Code of Regulations, section 1735.5 states:

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

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

24 (c) The policy and procedure manual shall include the following:

25 (1) Procedures for notifying staff assigned to compounding duties of any
26 changes in processes or to the policy and procedures manual

27 (2) Documentation of a plan for recall of a dispensed compounded drug product
28 where subsequent verification demonstrates the potential for adverse effects with
continued use of a compounded drug product;

(3) The procedures for maintaining, storing, calibrating, cleaning, and
disinfecting equipment used in compounding, and for training on those procedures as
part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality,
and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate
expiration dates for compounded drug products.

20. Title 16, California Code of Regulations, section 1735.6 (a) states:

Any pharmacy engaged in compounding shall maintain written documentation
regarding the facilities and equipment necessary for safe and accurate compounded
drug products. Where applicable, this shall include records of certification(s) of

facilities or equipment.

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21. Title 16, California Code of Regulations, section 1735.7 (a) states:

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

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22. Title 16, California Code of Regulations, section 1735.8 (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.

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23. Title 16, California Code of Regulations, section 1751 (b)(4) states:

(b) Any pharmacy compounding sterile injectable drug products shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

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(4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.

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24. Title 16, California Code of Regulations, section 1751.4 (d) states:

Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase risk of contamination.

25. Title 16, California Code of Regulations, section 1751.6 (e)(1) states:

(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

- (A) Aseptic technique.
- (B) Pharmaceutical calculations and terminology.
- (C) Sterile product compounding documentation.
- (D) Quality assurance procedures.

1 (E) Aseptic preparation procedures.

2 (F) Proper gowning and gloving technique.

3 (G) General conduct in the controlled area.

4 (H) Cleaning, sanitizing, and maintaining equipment used in the controlled
5 area.

6 (I) Sterilization techniques.

7 (J) Container, equipment, and closure system selection.

8 26. Title 16, California Code of Regulations, section 1751.7 (b) and (c) states:

9 (b) Each individual involved in the preparation of sterile injectable products
10 must first successfully complete a validation process on technique before being
11 allowed to prepare sterile injectable products. The validation process shall be carried
12 out in the same manner as normal production, except that an appropriate
13 microbiological growth medium is used in place of the actual product used during
14 sterile preparation. The validation process shall be representative of all types of
15 manipulation, products and batch sizes the individual is expected to prepare. The
16 same personnel, procedures, equipment, and materials must be involved. Completed
17 medium samples must be incubated. If microbial growth is detected, then the sterile
18 preparation process must be evaluation, corrective action taken, and the validation
19 process repeated. Personnel competency must be revalidated at least every twelve
20 months, whenever the quality assurance program yields an unacceptable result, when
21 the compounding process changes, equipment used in the compounding of sterile
22 injectable drug products is repaired or replaced, the facility is modified in a manner
23 that affects airflow or traffic patterns, or whenever improper aseptic techniques are
24 observed. Revalidation must be documented.

25 (c) Batch-produced sterile injectable drug products compounded from one or
26 more non-sterile ingredients shall be subject to documented end product testing for
27 sterility and pyrogens and shall be quarantined until the end product testing confirms
28 sterility and acceptable levels of pyrogens.

19 COST RECOVERY

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

24 DRUGS

25 28. Sodium Phosphorous is a dangerous drug pursuant to Business and Professions Code
26 section 4022.

27 29. Potassium Phosphorous is a dangerous drugs pursuant to Business and Professions
28 Code section 4022.

1 30. Calcium Gluconate is a dangerous drugs pursuant to Business and Professions Code
2 section 4022.

3 31. Sodium Chloride is a dangerous drugs pursuant to Business and Professions Code
4 section 4022.

5 **FACTUAL ALLEGATIONS**

6 32. Since July 3, 2002, Respondent Chad Kearns has been the Pharmacist-in-Charge of
7 Respondent Community Infusion Services Pharmacy.

8 33. On April 20, 2012, the Board notified Respondents that they needed to maintain
9 records of: (1) training and ongoing competence for the staff who were compounding drugs and
10 (2) cleaning logs for the sterile compounding area. The Board issued a notice of correction to
11 Respondents for their failure to identify drug products as compounded on their labels.

12 34. In 2013 and 2014, Respondents compounded and sold Total Parenteral Nutrition
13 (TPN) sterile injectable drug products which contained the following dangerous drug components
14 or ingredients, sodium phosphorous, potassium phosphorous, ascorbic folic acid, calcium
15 gluconate or sodium chloride.

16 35. From June 24, 2013 through April 22, 2014, Respondents compounded sterile
17 injectable batch products of sodium phosphate, potassium phosphate, calcium gluconate and
18 concentrated sodium chloride from non-sterile sources and added them to the TPN sterile
19 injectable drug products without compounding those dangerous drug products in either: (a) an
20 ISO class 5 laminar airflow hood within an ISO class 7 cleanroom with a positive air pressure
21 differential relative to the adjacent areas; (b) an ISO class 5 cleanroom or (c) a barrier isolator that
22 provides an ISO class 5 environment for compounding.

23 36. From June 24, 2013 through March 4, 2014, Respondents utilized a horizontal
24 laminar flow hood to compound TPN sterile injectable drug products. However, the horizontal
25 laminar flow hood used to compound those sterile injectable drug products had not been certified
26 since March 29, 2012, by a qualified technician who was familiar with the methods and
27 procedures for certifying laminar air flow hoods and clean room requirements in accordance with
28 standards adopted by the United States General Services Administration.

1 37. Respondents did not disinfect hard surfaces in the designated compounding area
2 weekly and after any unanticipated event that could increase risk of contamination.

3 38. Respondents did not possess records showing that they had conducted documented
4 end product testing to confirm sterility and acceptable levels of pyrogens for the components
5 compounded from non-sterile ingredients which were used to compound TPN sterile injectable
6 drug products. Respondents did not conduct that testing or quarantine the ingredients until the
7 end product testing confirmed sterility and acceptable levels of pyrogens. Respondents also failed
8 to produce and maintain documentation of the methodology used to test integrity, potency, quality
9 and strength of compounded drug products.

10 39. Respondents did not possess training records, performance evaluations or records
11 showing each individual involved in the preparation of sterile injectable drug products
12 successfully completed a validation process on technique before being allowed to prepare sterile
13 injectable drug products. Individuals involved in the preparation of sterile injectable drug
14 products did not successfully complete a validation process on technique before being allowed to
15 prepare sterile injectable drug products.

16 40. Similarly, Respondents did not possess updated compounding policies and
17 procedures, a compounding quality assurance plan or documentation of facilities and equipment
18 for compounding. The policy and procedure manual was not reviewed on an annual basis by the
19 pharmacist-in-charge and not updated whenever changes in processes were implemented.

20 41. Respondents did not possess complete compounding records identifying all
21 individuals who compounded the TPN sterile injectable drug products and the dates that those
22 drug products were compound by them. Additionally, Respondents did not record the lot
23 numbers and expiration dates for the dangerous drug components which were made from non-
24 sterile sources. Also, there was a variance between the compounding records for TPN sterile
25 injectable drug products in that the compounding record stated RX number 1144 contained 15 ml
26 of potassium phosphate while the worksheets stated that they contained 4 ml of sodium phosphate
27 and RX number 711 contained 4 ml of potassium phosphate while the worksheet stated that it
28 contained 25 ml of sodium phosphate. Moreover, Respondents did not possess and produce the

1 prescriptions with the master formulas recorded on them for TPN sterile injectable drug products
2 compounded by them.

3 42. Respondents did not accurately label certain TPN sterile injectable drug products in
4 that they were labeled as containing 15 ml of potassium phosphate, but actually contained 4 ml of
5 sodium phosphate.

6 43. In or about March 2014, Respondents maintained numerous expired dangerous drugs
7 on the shelves of the pharmacy, including bulk quantities of the dangerous drug components used
8 to compound drugs.

9 44. Respondents assigned a beyond use date of 365 days for a topical gel compounded by
10 them (Rx number 132517) without adequate testing to support that beyond use date.
11 Additionally, calcium gluconate compounded from a non sterile source and used in the TPN
12 sterile injectable drug products was assigned beyond use dates of 365 days without adequate
13 testing to support those beyond use dates.

14 45. Respondents did not record that a topical gel (Rx number 132517) was compounded on
15 the label of the container when it had been compounded by Respondents.

16 46. On March 4, 2014, Respondent Chad Kearns informed the Board that he did not
17 compound any sterile injectable drug products from non-sterile components when he had done so.
18 On May 2, 2014, Respondent Chad Kearns informed the Board that he had purchased sterile
19 dangerous drug components to compound the TPN sterile injectable drug products when he had in
20 fact compounded those components from non-sterile sources. Respondent Chad Kearns also
21 informed the Board that he had purchased an injectable ascorbic acid product from two
22 manufacturers when he had not purchased that product from them.

23 **FIRST CAUSE FOR DISCIPLINE**

24 **(Inadequate Record-Keeping)**

25 47. Respondents are subject to disciplinary action under Code section 4301(o) for
26 violating Pharmacy Law and regulations, as set forth in paragraphs 32 through 46, which are
27 incorporated herein by reference and as described below:
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- 1 a. California Code of Regulations, title 16, sections 1735.7(a) and 1751.6(e)(1):
2 Failure to maintain training records for compounding staff.
- 3 b. California Code of Regulations, title 16, section 1735.5(a): Failure to
4 maintain current written policies and procedures for compounding.
- 5 c. California Code of Regulations, title 16, section 1735.5(b): Failure to
6 review policy and procedures manual on an annual basis and update it.
- 7 d. California Code of Regulations, title 16, section 1735.6(a): Failure to
8 maintain written documentation of facilities and equipment for compounding.
- 9 e. California Code of Regulations, title 16, section 1735.8(a): Failure to
10 maintain a compounding quality assurance plan.
- 11 f. California Code of Regulations, title 16, section 1735.5(c)(4) : Failure to
12 produce and maintain documentation of the methodology used to test integrity, potency, quality,
13 and labeled strength of compounded drug products.
- 14 g. California Code of Regulations, title 16, section 1735.3: Failure to produce
15 and maintain complete records or any records of compounded drugs, including failing to record
16 the lot number, the expiration date of all components, the pharmacist who verified the
17 compounded drugs and the identity of the pharmacy staff who compounded the drug product.
- 18 h. California Code of Regulations, title 16, section 1735.2(d) and (e): Failure
19 to produce and maintain current prescriptions with the master formulas recorded on them for TPN
20 sterile injectable drug products.
- 21 i. California Code of Regulations, title 16, section 1751.7(b) and (c): Failure
22 to produce and maintain records for each individual involved in the preparation of sterile
23 injectable drug products having completed a validation process on technique before being allowed
24 to compound sterile injectable drug products. Failure to produce and maintain records of end
25 product testing of batch-produced sterile injectable drug products compounded from one or more
26 non-sterile ingredients.
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1 2. Revoking or suspending Pharmacist License Number RPH 42817, issued to Chad
2 Trenor Kearns;

3 3. Ordering Community Infusion Services Inc., doing business as CDM Drugs and Chad
4 Trenor Kearns to pay the Board of Pharmacy the reasonable costs of the investigation and
5 enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

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DATED: 1/17/15


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

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