

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

In the Matter of the Accusation Against:

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

Pharmacy License No. PHY 46007

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

Pharmacist License No. RPH 42817

Case No. 5267

OAH No. 2015101085

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary 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 May 26, 2016.

It is so ORDERED on April 26, 2016.

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



By

Amy Gutierrez, Pharm.D.
Board President

1 KAMALA D. HARRIS
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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**
14 **2865 East Coast Hwy., Suite 150**
Corona del Mar, CA 92625

OAH No. 2015101085

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

15 **Pharmacy Permit No. PHY 46007**

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

18 **Pharmacist License No. RPH 42817**

19 Respondents.
20

21
22 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
23 entitled proceedings that the following matters are true:

24 PARTIES

25 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.
26 She brought this action solely in her official capacity and is represented in this matter by Kamala
27 D. Harris, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney
28 General.

1 no force or effect, except for this paragraph, it shall be inadmissible in any legal action between
2 the parties, and the Board shall not be disqualified from further action by having considered this
3 matter.

4 15. The parties understand and agree that Portable Document Format (PDF) and facsimile
5 copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format
6 (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

7 16. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
8 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
9 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
10 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary
11 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a
12 writing executed by an authorized representative of each of the parties.

13 17. In consideration of the foregoing admissions and stipulations, the parties agree that
14 the Board may, without further notice or formal proceeding, issue and enter the following Order:

15 **ORDER**

16 IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 46007, issued to Respondent
17 Community Infusion Services Inc., doing business as CDM Drugs (Respondent CDM Drugs) is
18 surrendered and accepted by the Board of Pharmacy.

19 1. Respondent CDM Drugs surrenders Pharmacy Permit No. PHY 46007 as of the
20 effective date of this Decision. Respondent CDM Drugs shall relinquish the premises wall
21 license and renewal license to the Board within ten (10) days of the effective date of this
22 Decision.

23 2. The surrender of Respondent CDM Drugs' license and the acceptance of the
24 surrendered license by the Board shall constitute the imposition of discipline against Respondent
25 CDM Drugs. This Decision constitutes a record of discipline and shall become a part of
26 Respondent CDM Drugs' license history with the Board.

27 3. If Respondent CDM Drugs ever applies for licensure or petitions for reinstatement in
28 the State of California, the Board shall treat it as a new application for licensure. Respondent

1 CDM Drugs must comply with all the laws, regulations and procedures for licensure in effect at
2 the time the application or petition is filed, and all of the charges and allegations contained in
3 Accusation No. 5267 shall be deemed to be true, correct and admitted by Respondent CDM
4 Drugs when the Board determines whether to grant or deny the application or petition.

5 4. Respondent CDM Drugs shall pay the agency its costs of investigation and
6 enforcement in the amount of \$8,754.50, prior to issuance of a new or reinstated license.

7 **IT IS FURTHER HEREBY ORDERED** that Pharmacist License No. RPH 42817 issued
8 to Chad Trenor Kearns (Respondent Chad Kearns) is revoked. However, the revocation is stayed
9 and Respondent Kearns is placed on probation for five (5) years on the following terms and
10 conditions:

11 **1. Obey All Laws**

12 Respondent Chad Kearns shall obey all state and federal laws and regulations.

13 Respondent Chad Kearns shall report any of the following occurrences to the Board, in
14 writing, within seventy-two (72) hours of such occurrence:

- 15 • an arrest or issuance of a criminal complaint for violation of any provision of the
16 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
17 substances laws
- 18 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
19 criminal complaint, information or indictment
- 20 • a conviction of any crime
- 21 • discipline, citation, or other administrative action filed by any state or federal agency
22 which involves respondent's pharmacist license or which is related to the practice of
23 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
24 for any drug, device or controlled substance.

25 Failure to timely report such occurrence shall be considered a violation of probation.

26 **2. Report to the Board**

27 Respondent Chad Kearns shall report to the Board quarterly, on a schedule as directed by
28 the Board or its designee. The report shall be made either in person or in writing, as directed.

1 Among other requirements, Respondent Chad Kearns shall state in each report under penalty of
2 perjury whether there has been compliance with all the terms and conditions of probation. Failure
3 to submit timely reports in a form as directed shall be considered a violation of probation. Any
4 period(s) of delinquency in submission of reports as directed may be added to the total period of
5 probation. Moreover, if the final probation report is not made as directed, probation shall be
6 automatically extended until such time as the final report is made and accepted by the Board.

7 **3. Interview with the Board**

8 Upon receipt of reasonable prior notice, Respondent Chad Kearns shall appear in person for
9 interviews with the Board or its designee, at such intervals and locations as are determined by the
10 Board or its designee. Failure to appear for any scheduled interview without prior notification to
11 Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its
12 designee during the period of probation, shall be considered a violation of probation.

13 **4. Cooperate with Board Staff**

14 Respondent Chad Kearns shall cooperate with the Board's inspection program and with the
15 Board's monitoring and investigation of Respondent Chad Kearns' compliance with the terms and
16 conditions of his probation. Failure to cooperate shall be considered a violation of probation.

17 **5. Continuing Education**

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

20 **6. Notice to Employers**

21 During the period of probation, Respondent Chad Kearns shall notify all present and
22 prospective employers of the Decision in case number 5267 and the terms, conditions and
23 restrictions imposed on Respondent Chad Kearns by the Decision, as follows:

24 Within thirty (30) days of the effective date of this Decision, and within fifteen (15) days of
25 Respondent Chad Kearns undertaking any new employment, Respondent Chad Kearns shall
26 cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge
27 employed during respondent's tenure of employment) and owner to report to the Board in writing
28 acknowledging that the listed individual(s) has/have read the Decision in case number 5267, and

1 terms and conditions imposed thereby. It shall be Respondent Chad Kearns' responsibility to
2 ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

3 If Respondent Chad Kearns works for or is employed by or through a pharmacy
4 employment service, Respondent Chad Kearns must notify his direct supervisor, pharmacist-in-
5 charge, and owner at every entity licensed by the Board of the terms and conditions of the
6 Decision in case number 5267 in advance of the Respondent commencing work at each licensed
7 entity. A record of this notification must be provided to the Board upon request.

8 Furthermore, within thirty (30) days of the effective date of this Decision, and within fifteen
9 (15) days of Respondent Chad Kearns undertaking any new employment by or through a
10 pharmacy employment service, Respondent Chad Kearns shall cause his direct supervisor with
11 the pharmacy employment service to report to the Board in writing acknowledging that he has
12 read the Decision in case number 5267 and the terms and conditions imposed thereby. It shall be
13 Respondent Chad Kearns' responsibility to ensure that his employer(s) and/or supervisor(s)
14 submit timely acknowledgment(s) to the Board.

15 Failure to timely notify present or prospective employer(s) or to cause that/those
16 employer(s) to submit timely acknowledgments to the Board shall be considered a violation of
17 probation.

18 "Employment" within the meaning of this provision shall include any full-time,
19 part-time, temporary, relief or pharmacy management service as a pharmacist or any
20 position for which a pharmacist license is a requirement or criterion for employment,
21 whether the respondent is an employee, independent contractor or volunteer.

22 **7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
23 **Designated Representative-in-Charge, or Serving as a Consultant**

24 During the period of probation, Respondent Chad Kearns shall not supervise any intern
25 pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity
26 licensed by the Board nor serve as a consultant unless otherwise specified in this order.
27 Assumption of any such unauthorized supervision responsibilities shall be considered a violation
28 of probation.

1 **8. Reimbursement of Board Costs**

2 As a condition precedent to successful completion of probation, Respondent Chad Kearns
3 shall pay to the Board its costs of investigation and prosecution in the amount of \$2,500.00 in a
4 payment plan to be approved by the Board.

5 There shall be no deviation from the payment plan approved by the Board absent prior
6 written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed
7 shall be considered a violation of probation.

8 The filing of bankruptcy by Respondent Chad Kearns shall not relieve respondent of his
9 responsibility to reimburse the Board its costs of investigation and prosecution.

10 **9. Probation Monitoring Costs**

11 Respondent Chad Kearns shall pay any costs associated with probation monitoring as
12 determined by the Board each and every year of probation. Such costs shall be payable to the
13 Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the
14 deadline(s) as directed shall be considered a violation of probation.

15 **10. Status of License**

16 Respondent Chad Kearns shall, at all times while on probation, maintain an active, current
17 license with the Board, including any period during which suspension or probation is tolled.
18 Failure to maintain an active, current license shall be considered a violation of probation.

19 If Respondent Chad Kearns' license expires or is cancelled by operation of law or otherwise
20 at any time during the period of probation, including any extensions thereof due to tolling or
21 otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and
22 conditions of this probation not previously satisfied.

23 **11. License Surrender While on Probation/Suspension**

24 Following the effective date of this Decision, should Respondent Chad Kearns cease
25 practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of
26 probation, respondent may tender his license to the Board for surrender. The Board or its
27 designee shall have the discretion whether to grant the request for surrender or take any other
28 action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the

1 license, Respondent Chad Kearns will no longer be subject to the terms and conditions of
2 probation. This surrender constitutes a record of discipline and shall become a part of the
3 respondent's license history with the Board.

4 Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to
5 the Board within ten (10) days of notification by the Board that the surrender is accepted.
6 Respondent Chad Kearns may not reapply for any license from the Board for three (3) years from
7 the effective date of the surrender. Respondent Chad Kearns shall meet all requirements
8 applicable to the license sought as of the date the application for that license is submitted to the
9 Board, including any outstanding costs.

10 **12. Notification of a Change in Name, Residence Address, Mailing Address or**
11 **Employment**

12 Respondent Chad Kearns shall notify the Board in writing within ten (10) days of any
13 change of employment. Said notification shall include the reasons for leaving, the address of the
14 new employer, the name of the supervisor and owner, and the work schedule if known.
15 Respondent Chad Kearns shall further notify the Board in writing within ten (10) days of a
16 change in name, residence address, mailing address, or phone number.

17 Failure to timely notify the Board of any change in employer(s), name(s), address(es), or
18 phone number(s) shall be considered a violation of probation.

19 **13. Tolling of Probation**

20 Except during periods of suspension, Respondent Kearns shall, at all times while on
21 probation, be employed as a pharmacist in California for a minimum of thirty (30) hours per
22 calendar month. Any month during which this minimum is not met shall toll the period of
23 probation, i.e., the period of probation shall be extended by one month for each month during
24 which this minimum is not met. During any such period of tolling of probation, Respondent
25 Chad Kearns must nonetheless comply with all terms and conditions of probation.

26 Should Respondent Chad Kearns, regardless of residency, for any reason (including
27 vacation) cease practicing as a pharmacist for a minimum of thirty (30) hours per calendar month
28 in California, Respondent Chad Kearns must notify the Board in writing within ten (10) days of

1 the cessation of practice, and must further notify the Board in writing within ten (10) days of the
2 resumption of practice. Any failure to provide such notification(s) shall be considered a violation
3 of probation.

4 It is a violation of probation for Respondent Chad Kearns' probation to remain tolled
5 pursuant to the provisions of this condition for a total period, counting consecutive and non-
6 consecutive months, exceeding thirty-six (36) months.

7 "Cessation of practice" means any calendar month during which respondent is
8 not practicing as a pharmacist for at least thirty (30) hours, as defined by Business
9 and Professions Code section 4000 et seq. "Resumption of practice" means any
10 calendar month during which respondent is practicing as a pharmacist for at least
11 thirty (30) hours as a pharmacist as defined by Business and Professions Code section
12 4000 et seq.

13 14. **Violation of Probation**

14 If Respondent Chad Kearns has not complied with any term or condition of probation, the
15 Board shall have continuing jurisdiction over Respondent Chad Kearns, and probation shall
16 automatically be extended, until all terms and conditions have been satisfied or the Board has
17 taken other action as deemed appropriate to treat the failure to comply as a violation of probation,
18 to terminate probation, and to impose the penalty that was stayed.

19 If Respondent Chad Kearns violates probation in any respect, the Board, after giving
20 Respondent Chad Kearns notice and an opportunity to be heard, may revoke probation and carry
21 out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for
22 those provisions stating that a violation thereof may lead to automatic termination of the stay
23 and/or revocation of the license. If a petition to revoke probation or an accusation is filed against
24 Respondent Chad Kearns during probation, the Board shall have continuing jurisdiction and the
25 period of probation shall be automatically extended until the petition to revoke probation or
26 accusation is heard and decided.

1 **15. Completion of Probation**

2 Upon written notice by the Board or its designee indicating successful completion of
3 probation, Respondent Chad Kearns' license will be fully restored.

4 **16. Remedial Education**

5 Within sixty (60) days of the effective date of this Decision, Respondent Chad Kearns shall
6 submit to the Board or its designee, for prior approval, an appropriate program of remedial
7 education related to pharmacy law, operations and the role of a pharmacist in charge. The
8 program of remedial education shall consist of at least twenty (20) hours, which shall be
9 completed within the first year of probation at Respondent Chad Kearns' own expense. All
10 remedial education shall be in addition to, and shall not be credited toward, continuing education
11 (CE) courses used for license renewal purposes.

12 Failure to timely submit or complete the approved remedial education shall be considered a
13 violation of probation. The period of probation will be automatically extended until such
14 remedial education is successfully completed and written proof, in a form acceptable to the
15 Board, is provided to the Board or its designee.

16 Following the completion of each course, the Board or its designee may require
17 Respondent Chad Kearns, at his own expense, to take an approved examination to test
18 Respondent Chad Kearns' knowledge of the course. If Respondent Chad Kearns does not achieve
19 a passing score on the examination, this failure shall be considered a violation of probation. Any
20 such examination failure shall require respondent to take another course approved by the Board in
21 the same subject area.

22 **17. Supervised Practice**

23 During the period of probation, Respondent Chad Kearns shall practice only under the
24 supervision of a licensed pharmacist not on probation with the Board. Upon and after the
25 effective date of this Decision, Respondent Chad Kearns shall not practice pharmacy and his
26 license shall be automatically suspended until a supervisor is approved by the Board or its
27 designee. The supervision shall be as follows:

- 28 • Daily Review- Supervisor's review of probationer's daily activities within

1 24 hours.

2 "Daily review" as this term is used herein shall not require that the supervising pharmacist
3 be engaged in physical supervision of Respondent Chad Kearns' activities in real time, but shall
4 require that the supervising pharmacist, by no later than close of business on each day following,
5 review all transactions performed by Respondent Chad Kearns and records associated with those
6 transactions to ensure compliance with state and federal statutes and regulations and with the
7 requirements of this Decision.

8 The Board, or its designee, retains the discretion to increase the level of supervision during
9 Respondent Chad Kearns' probation, if warranted by circumstances, or by violations or omissions
10 discovered during Daily Review, to any of the following:

- 11 • Continuous- At least 75% of a work week
- 12 • Substantial- At least 50% of a work week
- 13 • Partial- At least 25% of a work week

14 Within thirty (30) days of the effective date of this Decision, Respondent Chad Kearns shall
15 have his supervisor submit notification to the Board in writing stating that the supervisor has read
16 the Decision in case number 5267 and is familiar with the required level of supervision as
17 determined by the Board. It shall be Respondent Chad Kearns' responsibility to ensure that his
18 employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the
19 Board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely
20 acknowledgements to the Board shall be considered a violation of probation.

21 If Respondent Chad Kearns changes employment, it shall be Respondent Chad Kearns'
22 responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit
23 timely acknowledgement(s) to the Board. Respondent Chad Kearns shall have his new
24 supervisor, within fifteen (15) days after employment commences, submit notification to the
25 Board in writing stating the direct supervisor and pharmacist-in-charge have read the Decision in
26 case number 5267 and is familiar with the level of supervision as determined by the Board.
27 Respondent Chad Kearns shall not practice pharmacy and his license shall be automatically
28 suspended until the Board or its designee approves a new supervisor. Failure to cause the direct

1 supervisor and the pharmacist-in-charge to submit timely acknowledgements to the Board shall
2 be considered a violation of probation.

3 Within ten (10) days of leaving employment, Respondent Chad Kearns shall notify the
4 Board in writing.

5 During suspension, Respondent Chad Kearns shall not enter any pharmacy area or any
6 portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other
7 distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous
8 drugs and devices or controlled substances are maintained. Respondent Chad Kearns shall not
9 practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing,
10 compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be
11 a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing
12 or dispensing of dangerous drugs and controlled substances. Respondent Chad Kearns shall not
13 resume practice until notified by the Board.

14 During suspension, Respondent Chad Kearns shall not engage in any activity that requires
15 the professional judgment of a pharmacist. Respondent Chad Kearns shall not direct or control
16 any aspect of the practice of pharmacy. Respondent Chad Kearns shall not perform the duties of a
17 pharmacy technician or a designated representative for any entity licensed by the Board.

18 Subject to the above restrictions, Respondent Chad Kearns may continue to own or hold an
19 interest in any licensed premises in which he holds an interest at the time this Decision becomes
20 effective unless otherwise specified in this order.

21 Failure to comply with this suspension shall be considered a violation of probation.

22 **18. No Ownership of Licensed Premises**

23 Respondent Chad Kearns shall not own, have any legal or beneficial interest in, or serve as
24 a manager, administrator, member, officer, director, trustee, associate, or partner of any business,
25 firm, partnership, or corporation currently or hereinafter licensed by the Board. Respondent Chad
26 Kearns shall sell or transfer any legal or beneficial interest in any entity licensed by the Board
27 within ninety (90) days following the effective date of this Decision and shall immediately
28 thereafter provide written proof thereof to the Board. Failure to timely divest any legal or

1 beneficial interest(s) or provide documentation thereof shall be considered a violation of
2 probation.

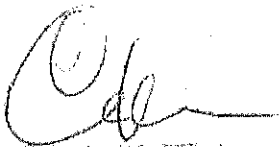
3 19. **Restricted Practice**

4 Respondent shall not prepare, oversee or participate in the preparation of sterile
5 compounded drug products during probation. Respondent shall submit proof satisfactory to the
6 board of compliance with this term of probation. Failure to abide by this restriction or to timely
7 submit proof to the board of compliance therewith shall be considered a violation of probation.
8 Respondent may resume the preparation, oversight or participation in the preparation of sterile
9 compounded drug products if he successfully completes at his own expense, thirty (30) hours of
10 in-person, remedial education in the area of compounding sterile drug products which has been
11 preapproved by the Board or its designee and submits satisfactory proof of such completion to the
12 Board or its designee.

13 ACCEPTANCE

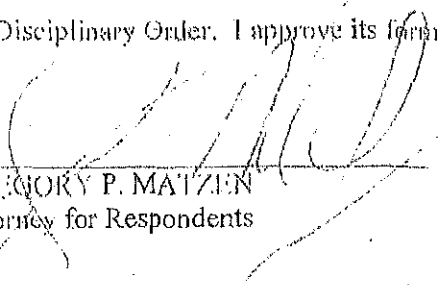
14 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
15 discussed it with my attorney, Gregory P. Matzen. I understand the stipulation and the effect it
16 will have on the Pharmacy Permit and Pharmacist License. I enter into this Stipulated Settlement
17 and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the
18 Decision and Order of the Board of Pharmacy.

19
20 DATED: 3/3/16


21 CHAD TRENOR KEARNS, as an individual and
22 as the authorized agent on behalf of COMMUNITY
23 INFUSION SERVICES INC., DOING BUSINESS
24 AS CDM DRUGS
25 Respondents

24 I have read and fully discussed with Respondents the terms and conditions and other
25 matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and
26 content.

27 DATED: 3/2/16


28 GREGORY P. MATZEN
Attorney for Respondents

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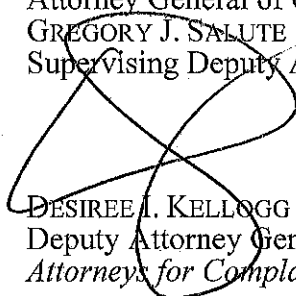
ENDORSEMENT

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

DATED: 3/10/16

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General


DESIREE L. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5267

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Attorneys for Complainant

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14 **2865 East Coast Hwy., Suite 150**
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A C C U S A T I O N

15 **Pharmacy Permit No. PHY 46007**

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

18 **Pharmacist License No. RPH 42817**

19 Respondents.
20

21
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
self-use in humans or animals, and includes the following:

24 (a) Any drug that bears the legend: "Caution: federal law prohibits
25 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
dispensed only on prescription or furnished pursuant to Section 4006.

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

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

5

6 The strength of the drug or drugs dispensed.

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

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

10 11. Section 4127.7 of the Code states:

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

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

14 (b) An ISO class 5 cleanroom.

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

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

18 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
19 misrepresentation or issued by mistake. Unprofessional conduct shall include, but
is not limited to, any of the following:

20

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

23

24 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
25 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
26 pharmacy, including regulations established by the board or by any other state or
27 federal regulatory agency.
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2 13. Section 4306.5 of the Code states, in pertinent part:

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

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

9
10 (c) Acts or omissions that involve, in whole or in part, the failure to consult
11 appropriate patient, prescription, and other records pertaining to the performance of
12 any pharmacy function.

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

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

21 REGULATORY PROVISIONS

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

23 "Compounding" means any of the following activities occurring in a licensed
24 pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a
25 prescription:

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

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

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

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

- (4) Inactive ingredients to be used.
- (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.

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

...

(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.

....

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

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

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

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be 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.

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.

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:

....

(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.

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
area.

5 (I) Sterilization techniques.

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

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

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

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

28 COST RECOVERY

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

33 DRUGS

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

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

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:
28

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.

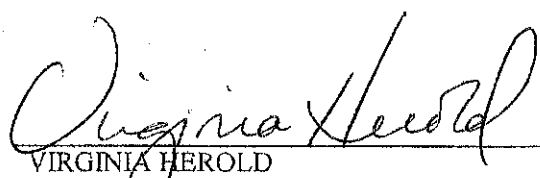
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2. Revoking or suspending Pharmacist License Number RPH 42817, issued to Chad
Trenor Kearns;

3. Ordering Community Infusion Services Inc., doing business as CDM Drugs and Chad
Trenor Kearns 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: 1/17/15



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

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