

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

In the Matter of the Accusation Against:

**PHARMEDIUM HEALTHCARE CORP
DBA PHARMEDIUM SERVICES LLC
12620 W. Airport Boulevard, Suite 130
Sugar Land, Texas 77478**

**Non-Resident Pharmacy Permit No. NRP
590**

**PHARMEDIUM SERVICES LLC
12620 W. Airport Boulevard, Suite 130
Sugar Land, Texas 77478**

**Non-Resident Sterile Compounding license
No. NSC 99221**

Case No. 4625

OAH No. 2015030385

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Repeval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on January 22, 2016.

It is so ORDERED on December 23, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 23, 2015

Pharmedium Healthcare Corp dba Pharmedium Services LLC
dba Pharmedium Services LLC
Pharmedium Services LLC
12620 W. Airport Boulevard, Suite 130
Sugar Land, TX 77478

Re: LETTER OF PUBLIC REPROVAL
In the Matter of the Accusation Against:
Pharmedium Healthcare Corp dba Pharmedium Services LLC,
Non-Resident Pharmacy Permit No. NRP 590
Non-Resident Sterile Compounding license No. NSC 99221

Dear Pharmedium Services Representative:

On September 13, 2014, the Board of Pharmacy, Department of Consumer Affairs, State of California, filed an Accusation against your Non-Resident Pharmacy Permit. The Accusation alleged, in relevant part, that you engaged in unprofessional conduct under Professions Code section 4301, 4033, for the unlicensed manufacture of medication in that you prepared injectable medication that was not provided directly to a consumer. The Accusation also alleged that you provided misbranded drugs pursuant to Business and Professions Code section 4169 and 4342 (a) in that section 111395 of the Health and Safety Code states that a drug is misbranded if it is an imitation of another drug, and they compounded a commercially available drug

The Accusation also alleged that during an Board investigation in June of 2012 it was determined that pursuant to Business and Professions Code section 4342 (a) in conjunction with Health and Safety Code section 11128 and California Code of Regulations section 1735.1 in that you sold drugs lacking in quality or strength; failed to provide a product statement on compounded medications in accordance with California Code of Regulations Section 1735.4(b); and that you improperly invoiced your product by listing your corporate headquarters address rather than your supplier facility address in violation of Business and Professions Code section 4059 (b).

Accordingly, in resolution of this matter under the authority provided under Business and Professions Code section 495, the Board of Pharmacy, Department of Consumer Affairs issues this letter of public reproof.

Sincerely,

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs

1 KAMALA D. HARRIS
Attorney General of California
2 KENT D. HARRIS
Supervising Deputy Attorney General
3 ELENA L. ALMANZO
Deputy Attorney General
4 State Bar No. 131058
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 322-5524
Facsimile: (916) 327-8643
7 *Attorneys for Complainant*

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

11 In the Matter of the Accusation Against:

12 **PHARMEDIUM HEALTHCARE CORP**
13 **DBA PHARMEDIUM SERVICES LLC**
14 **12620 W. Airport Boulevard, Suite 130**
Sugar Land, Texas 77478

15 **Non-Resident Pharmacy Permit No. NRP**
16 **590**

17 **PHARMEDIUM SERVICES LLC**
18 **12620 W. Airport Boulevard, Suite 130**
Sugar Land, Texas 77478

19 **Non-Resident Sterile Compounding license**
20 **No. NSC 99221**

20 Respondents.

Case No. 4625

OAH No. 2015030385

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL

[Bus. & Prof. Code § 495]

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

23 PARTIES

24 1. VIRGINIA HEROLD (Complainant) is the Executive Officer of the Board of
25 Pharmacy. She brought this action solely in her official capacity and is represented in this matter
26 by Kamala D. Harris, Attorney General of the State of California, by Elena L. Almanzo, Deputy
27 Attorney General.
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1 and court review of an adverse decision; and all other rights accorded by the California
2 Administrative Procedure Act and other applicable laws.

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

5 CULPABILITY

6 9. Respondents understand and agree that the charges and allegations in Accusation No.
7 4625, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident
8 Pharmacy Permit and non-resident Sterile Compounding license.

9 10. For the purpose of resolving the Accusation without the expense and uncertainty of
10 further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual
11 basis for the charges in the Accusation, and that Respondents hereby give up their right to contest
12 those charges.

13 11. Respondents agree that their Non-Resident Pharmacy Permit and Non-Resident
14 Sterile Compounding License are subject to discipline and they agree to be bound by the
15 Disciplinary Order below.

16 CIRCUMSTANCES IN MITIGATION

17 12. Respondents Pharmedium Healthcare Corp dba Pharmedium Services LLC and
18 Pharmedium Services LLC have never been the subject of any disciplinary action. Solely for the
19 purpose of resolving the Accusation, without the expense and uncertainty of further proceedings,
20 Respondents have acknowledged at an early state in the proceedings, that at a hearing,
21 Complainant could establish a factual basis for the charges in the Accusation.

22 CONTINGENCY

23 13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents
24 understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may
25 communicate directly with the Board regarding this stipulation and settlement, without notice to
26 or participation by Respondents or its counsel. By signing the stipulation, Respondents
27 understand and agree that they may not withdraw its agreement or seek to rescind the stipulation
28 prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation

1 as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reapproval
2 shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action
3 between the parties, and the Board shall not be disqualified from further action by having
4 considered this matter.

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

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

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

19 **DISCIPLINARY ORDER**

20 IT IS HEREBY ORDERED that Non-Resident Pharmacy Permit No. NRP 590 and Non-
21 Resident Sterile Compounding license Number NSC 99221 issued to Respondent Pharmedium
22 Healthcare Corp dba Pharmedium Services LLC and Pharmedium Services LLC (Respondents)
23 shall, by way of letter from the Board's Executive Officer, be publicly reapproved. The letter shall
24 be in substantially the same form as the letter attached as Exhibit B to this stipulation.

25 IT IS FURTHER ORDERED that Respondents shall pay \$27,353.50 within thirty (30) days
26 to the Board for its costs associated with the investigation and enforcement of this matter. If
27 Respondents fail to pay the Board costs as ordered, Respondents shall not be allowed to renew
28

1 their Non-Resident Pharmacy Permit or the Non-Resident Sterile Compounding License until
2 Respondents pay costs in full.

3 ACCEPTANCE

4 Respondents have carefully read the above Stipulated Settlement and Disciplinary Order for
5 Public Repeval and have fully discussed it with their attorney, Jeremy Meier. We understand the
6 stipulation and the effect it will have on their Non-Resident Pharmacy Permit and Non-Resident
7 Sterile Compounding License. We enter into this Stipulated Settlement and Disciplinary Order
8 for Public Repeval voluntarily, knowingly, and intelligently, and agree to be bound by the
9 Decision and Order of the Board of Pharmacy.

10
11 DATED: 11-3-15

William R. Smiley

12 REPRESENTATIVE
13 PHARMEDIUM HEALTHCARE CORP DBA
14 PHARMEDIUM SERVICES LLC
15 PHARMEDIUM SERVICES LLC
16 Respondents

17 I have read and fully discussed with Respondents Pharmedium Healthcare Corp dba
18 Pharmedium Services LLC and Pharmedium Services LLC the terms and conditions and other
19 matters contained in the above Stipulated Settlement and Disciplinary Order for Public Repeval.
20 I approve its form and content.

21 DATED: _____

22 JEREMY MEIER
23 Attorney for Respondent
24
25
26
27
28

1 their Non-Resident Pharmacy Permit or the Non-Resident Sterile Compounding License until
2 Respondents pay costs in full.

3 ACCEPTANCE

4 Respondents have carefully read the above Stipulated Settlement and Disciplinary Order for
5 Public Repeval and have fully discussed it with their attorney, Jeremy Meier. We understand the
6 stipulation and the effect it will have on their Non-Resident Pharmacy Permit and Non-Resident
7 Sterile Compounding License. We enter into this Stipulated Settlement and Disciplinary Order
8 for Public Repeval voluntarily, knowingly, and intelligently, and agree to be bound by the
9 Decision and Order of the Board of Pharmacy.

10
11 DATED: 11-3-15



12 REPRESENTATIVE
13 PHARMEDIUM HEALTHCARE CORP DBA
14 PHARMEDIUM SERVICES LLC
15 PHARMEDIUM SERVICES LLC
16 Respondents

17 I have read and fully discussed with Respondents Pharmedium Healthcare Corp dba
18 Pharmedium Services LLC and Pharmedium Services LLC the terms and conditions and other
19 matters contained in the above Stipulated Settlement and Disciplinary Order for Public Repeval.
20 I approve its form and content.

21 DATED: 11-3-15


22 JEREMY MEIER
23 Attorney for Respondent
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ENDORSEMENT

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

Dated: 11/9/15

Respectfully submitted,
KAMALA D. HARRIS
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General


ELENA L. ALMANZO
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4625

1 KAMALA D. HARRIS
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2 KENT D. HARRIS
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3 ELENA L. ALMANZO
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7 *Attorneys for Complainant*

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9 **BOARD OF PHARMACY**
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11 **STATE OF CALIFORNIA**

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13 **DBA PHARMEDIUM SERVICES LLC**
14 **12620 W. Airport Boulevard, Suite 130**
15 **Sugar Land, Texas 77478**

A C C U S A T I O N

16 **Non-Resident Pharmacy Permit No. NRP**
17 **590**

18 **PHARMEDIUM SERVICES LLC**
19 **12620 W. Airport Boulevard, Suite 130**
20 **Sugar Land, Texas 77478**

21 **Non-Resident Sterile Compounding license**
22 **No. NSC 99221**

Respondent.

23 Complainant alleges:

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 August 4, 2004, the Board of Pharmacy issued Non-Resident Pharmacy
27 Permit Number NRP 590 to Pharmedium Healthcare Corp dba Pharmedium Services LLC
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1 (Respondent). The Non-Resident Pharmacy Permit was in full force and effect at all times
2 relevant to the charges brought herein and will expire on August 1, 2014, unless renewed.

3 3. On or about August 9, 2004, the Board of Pharmacy issued Non-Resident Sterile
4 Compounding license Number NSC 99221 to Pharmedium Services LLC (Respondent). The
5 Non-Resident Sterile Compounding license was in full force and effect at all times relevant to the
6 charges brought herein and will expire on August 1, 2015, 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 4300 of the Code states in pertinent part:

12 "(a) Every license issued may be suspended or revoked.

13 "(b) The board shall discipline the holder of any license issued by the
14 board, whose default has been entered or whose case has been heard by the board and
found guilty, by any of the following methods:

15 "(1) Suspending judgment.

16 "(2) Placing him or her upon probation.

17 "(3) Suspending his or her right to practice for a period not exceeding one
18 year.

19 "(4) Revoking his or her license.

20 "(5) Taking any other action in relation to disciplining him or her as the
board in its discretion may deem proper.

21 "(e) The proceedings under this article shall be conducted in accordance
22 with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the
Government Code, and the board shall have all the powers granted therein. The
23 action shall be final, except that the propriety of the action is subject to review by the
superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

24 6. Section 4300.1 of the Code states:

25 "The expiration, cancellation, forfeiture, or suspension of a board-issued
26 license by operation of law or by order or decision of the board or a court of law, the
placement of a license on a retired status, or the voluntary surrender of a license by a
27 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
28 a decision suspending or revoking the license."

1 7. Section 4301 of the Code states in pertinent part:

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

6 "(a) Gross immorality.

7 "(b) Incompetence.

8 "(c) Gross negligence.

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

12 "(g) Knowingly making or signing any certificate or other document that
13 falsely represents the existence or nonexistence of a state of facts.

14 "(j) The violation of any of the statutes of this state, or any other state, or
15 of the United States regulating controlled substances and dangerous drugs.

16 "(o) Violating or attempting to violate, directly or indirectly, or assisting
17 in or abetting the violation of or conspiring to violate any provision or term of this
18 chapter or of the applicable federal and state laws and regulations governing
19 pharmacy, including regulations established by the board or by any other state or
20 federal regulatory agency.

21 "(p) Actions or conduct that would have warranted denial of a license.

22 "(q) Engaging in any conduct that subverts or attempts to subvert an
23 investigation of the board.

24 "(r) The selling, trading, transferring, or furnishing of drugs obtained
25 pursuant to Section 256b of Title 42 of the United States Code to any person a
26 licensee knows or reasonably should have known, not to be a patient of a covered
27 entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the
28 United States Code.

 8. Section 4022 of the Code states

 "Dangerous drug" or "dangerous device" means any drug or device
unsafe for self-use in humans or animals, 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.

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

 "(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."

1 9. Section 4033 of the Code states in pertinent part:

2 (a)(1) "Manufacturer" means and includes every person who prepares,
3 derives, produces, compounds, or repackages any drug or device except a pharmacy
4 that manufactures on the immediate premises where the drug or device is sold to the
5 ultimate consumer

6 10. Section 4033 of the Code states in pertinent part:

7 (a)(1) "Manufacturer" means and includes every person who prepares,
8 derives, produces, compounds, or repackages any drug or device except a pharmacy
9 that manufactures on the immediate premises where the drug or device is sold to the
10 ultimate consumer.

11 (2) Notwithstanding paragraph (1), "manufacturer" shall not mean a
12 pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for
13 delivery to another pharmacy for the purpose of delivering or administering the drug
14 to the patient or patients named in the prescription, provided that neither the
15 components for the drug nor the drug are compounded, fabricated, packaged, or
16 otherwise prepared prior to receipt of the prescription

17 11. Section 4059 of the Code states in pertinent part:

18 (a) A person may not furnish any dangerous drug, except upon the
19 prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or
20 naturopathic doctor pursuant to Section 3640.7. A person may not furnish any
21 dangerous device, except upon the prescription of a physician, dentist, podiatrist,
22 optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7..

23 (b) This section does not apply to the furnishing of any dangerous drug or
24 dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a
25 physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor
26 pursuant to Section 3640.7, or to a laboratory under sales and purchase records that
27 correctly give the date, the names and addresses of the supplier and the buyer, the
28 drug or device, and its quantity. This section does not apply to the furnishing of any
dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist
acting within the scope of his or her license under sales and purchase records that
correctly provide the date the device is provided, the names and addresses of the
supplier and the buyer, a description of the device, and the quantity supplied.

12. Section 4123 of the Code provides as follows:

Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a
prescription, for delivery to another pharmacy shall report that contractual
arrangement to the board. That information shall be reported by the pharmacy
performing the compounding services within 30 days of commencing that
compounding.

13. Section 4169 of the Code states in pertinent part:

(a) A person or entity may not do any of the following:

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew

1 or reasonably should have known were adulterated, as set forth in Article 2
(commencing with Section 11250) of Chapter 6 of Part 5 of Division 104 of the
2 Health and Safety Code.

3 (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew
4 or reasonably should have known were misbranded, as defined in Section 11335 of
the Health and Safety Code.

5 14. Section 4342 of the Code provides as follows:

6 (a) The board may institute any action or actions as may be provided by
7 law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical
8 preparations and drugs that do not conform to the standard and tests as to quality and
9 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.

10 (b) Any knowing or willful violation of any regulation adopted pursuant
11 to Section 4006 shall be subject to punishment in the same manner as is provided in
Sections 4336 and 4321.

12 15. Health and Safety Code section 111395 provides as follows:

13 Any drug is misbranded in any of the following cases:

14 (a) It is an imitation of another drug.

15 (b) It is offered for sale under the name of another drug.

16 (c) The contents of the original package have been, wholly or partly,
17 removed and replaced with other material in the package.

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

22 17. California Code of Regulations Section 1735.2 provides in pertinent part:

23 (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt
24 by a pharmacy of a valid prescription for an individual patient where the prescriber has approved
25 use of a compounded drug product either orally or in writing. Where approval is given orally, that
approval shall be noted on the prescription prior to compounding.

26 18. California Code of Regulations Section 1735.4 provides:

27 (a) In addition to the labeling information required under Business and
28 Professions Code section 4076, the label of a compounded drug product shall contain

1 the generic name(s) of the principal active ingredient(s).

2 (b) A statement that the drug has been compounded by the pharmacy
3 shall be included on the container or on the receipt provided to the patient.

4 (c) Drug products compounded into unit-dose containers that are too
5 small or otherwise impractical for full compliance with subdivisions (a) and (b) shall
6 be labeled with at least the name(s) of the active ingredient(s), concentration or
7 strength, volume or weight, pharmacy reference or lot number, and expiration date.

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FIRST CAUSE FOR DISCIPLINE
(Unlicensed Manufacturing.)

19. Respondents are subject to disciplinary action under sections 4301 and 4033 for the
unlicensed manufacture of medication in that they prepared injectable medication that was not
provided directly to a consumer. The circumstances are as follows:

20. Documents provided on May 10, 2012 and November 27, 2012 indicated
Pharmedium Services LLC sold the following injectable products: #48 25mg nicardipine
hydrochloride 0.1mg/ml in 5% dextrose 250ml AVIVA bags, #24 3ml 4% sodium citrate
syringes, and #1 0.2% ropivacaine HCL 550ml injection to John Muir Medical Center Concord
Campus Pharmacy (HSP 42916) between 3/8/12 and 10/17/12. Documents provided on 5/10/12
and 7/19/12 indicated Pharmedium Services LLC sold the following injectable products:#160
nicardipine hydrochloride 0.1mg/ml in 0.9% sodium chloride 10ml syringes, #96 4mg
norepinephrine bitartrate (16mcg/ml), #12 150mg amiodarone HCL in 5% dextrose, #72 1.25g
vancomycin HCL in 5% dextrose, #24 1.5g vancomycin HCL in 5% dextrose, #120 1g
magnesium sulfate in 5% dextrose, #500 10mg/ml rocuronium bromide, #550 20mg/ml
succinylcholine chloride, #400 5mg/ml ephedrine sulfate, #400 100mcg/ml phenylephrine HCL,
#30 5mg/ml labetalol, #300 5mg labetalol (no overwrap), #72 125mg diltiazem HCL in 5%
dextrose, #20 0.1% ropivacaine HCL in 0.9% sodium chloride, #216 2g cefazolin in 5% dextrose,
#36 50mg phenylephrine HCL (0.1mg/ml) in 5% dextrose, and #5 0.25% bupivacaine HCL in
0.9% sodium chloride to Community Hospital Monterey (HSP 30134) between 1/12/12 and

7/11/12. All products were sold without a valid license to manufacture FDA approved drugs and without receipt of a valid prescription for an individual patient. The following table shows the injectable medications sold:

Compounded medication furnished to a sample of licensed hospitals in California

| Drug | Dates | Invoice #/ Document # | Sold to | Total Quantity |
|---|--|--------------------------|---------|----------------|
| nicardipine 0.1mg/ml 10ml syringe | 1/12/12 | A571580 | CH-M * | 160 |
| | 1/31/12 | A579832 | | |
| | 2/2/12 | A581416 | | |
| | 3/12/12 | A598834 | | |
| | 4/6/12 | A611130 | | |
| | 4/11/12 | A613149 | | |
| | 5/8/12 | A624220 | | |
| | 6/25/12 | A643900 | | |
| 4mg norepinephrine bitartrate (16mcg/ml) | 1/31/12 | A579832 | CH-M | 96 |
| | 6/25/12 | A643900 | | |
| | 7/11/12 | A651062 | | |
| 150mg amiodarone in 5% dextrose | 1/31/12 | A579832 | CH-M | 12 |
| 1.25g vancomycin in 5% dextrose | 1/31/12 | A579832 | CH-M | 72 |
| | 6/25/12 | A643900 | | |
| | 7/5/12 | A648371 | | |
| 1.5g vancomycin in 5% dextrose | 1/31/12 | A579832 | CH-M | 24 |
| 1g magnesium sulfate in 5% dextrose | 1/31/12 | A579832 | CH-M | 120 |
| | 3/12/12 | A598834 | | |
| | 7/11/12 | A651062 | | |
| 10mg/ml rocuronium bromide | 1/31/12 | A579832 | CH-M | 500 |
| | 2/2/12 | A581416 | | |
| | 3/12/12 | A598834 | | |
| | 4/6/12 | A611130 | | |
| | 5/8/12 | A624220 | | |
| | 7/5/12 | A648371 | | |
| | 7/11/12 | A651062 | | |
| | 20mg/ml succinylcholine chloride | 1/31/12 | | |
| 2/2/12 | | A581416 | | |
| 3/12/12 | | A598834 | | |
| 4/6/12 | | A611130 | | |
| 5/8/12 | | A624220 | | |
| 7/5/12 | | A648371 | | |

| | | | | | | |
|----|---|---|---------|--------|-----|---------|
| | | 7/11/12 | A651062 | | | |
| 1 | 5mg/ml ephedrine sulfate | 2/2/12 | A581416 | CH-M | 400 | |
| 2 | | 3/12/12 | A598834 | | | |
| 3 | | 4/6/12 | A611130 | | | |
| 4 | | 5/8/12 | A624220 | | | |
| 5 | | 7/5/12 | A648371 | | | |
| 6 | 100mcg/ml phenylephrine HCL | 7/11/12 | A651062 | CH-M | 400 | |
| 7 | | 2/2/12 | A581416 | | | |
| 8 | | 3/12/12 | A598834 | | | |
| 9 | | 4/6/12 | A611130 | | | |
| 10 | | 5/8/12 | A624220 | | | |
| 11 | 5mg/ml labetalol (no overwrap) | 7/5/12 | A648371 | CH-M | 300 | |
| 12 | | 7/11/12 | A651062 | | | |
| 13 | | 2/2/12 | A581416 | | | |
| 14 | | 3/12/12 | A598834 | | | |
| 15 | | 4/6/12 | A611130 | | | |
| 16 | 125mg diltiazem HCL in 5% dextrose | 5/8/12 | A624220 | CH-M | 72 | |
| 17 | | 6/25/12 | A643900 | | | |
| 18 | | 7/11/12 | A651062 | | | |
| 19 | 0.1% ropivacaine HCL in 0.9% sodium chloride | 4/11/12 | A613149 | CH-M | 20 | |
| 20 | | 2g cefazolin in 5% dextrose | 5/8/12 | | | A624220 |
| 21 | | | 6/25/12 | | | A643900 |
| 22 | 7/11/12 | | A651062 | | | |
| 23 | 50mg phenylephrine HCL in 5% dextrose | 6/25/12 | A643900 | CH-M | 36 | |
| 24 | | 7/11/12 | A651062 | | | |
| 25 | 0.25% bupivacaine HCL in 0.9% sodium chloride | 7/5/12 | A648371 | CH-M | 5 | |
| 26 | | 25mg nicardipine (0.1mg/ml) in 5% dextrose 250ml AVIVA bag | 3/9/12 | | | 558459 |
| 27 | | | 6/1/12 | | | 594179 |
| 28 | | | 8/29/12 | | | 629096 |
| | 10/17/12 | | 649014 | | | |
| | 4% sodium citrate 3ml | 8/29/12 | 629096 | JMCC-C | 24 | |
| | | | | | | |

| | | | | | |
|---|--|---------|--------|--------|---|
| 1 | syringe | | | | |
| 2 | 0.2% ropivacaine HCL 550ml injection | 8/29/12 | 629096 | JMCC-C | 1 |

3 *Ch-M= Community Hospital Monterey
 4 **JMMC-C=John Muir Medical Center-Concord

5
 6 SECOND CAUSE FOR DISCIPLINE

7 (Selling Misbranded Drugs)

8 21. Respondents are subject to disciplinary action under section Business and Professions
 9 Code section 4169, in that they sold drugs which were misbranded as more specifically set forth
 10 above in paragraph 11 and the table set forth above.

11 THIRD CAUSE FOR DISCIPLINE

12 (Manufacture and sale of Commercially Available Drugs)

13 22. Respondents are subject to disciplinary action under section 4342 (a) in that
 14 section 111395 of the Health and Safety Code states that a drug is misbranded if it is an imitation
 15 of another drug, and on or about March 8, 2012 and October 17, 2012, Pharmedium Services
 16 LLC compounded and sold to John Muir Medical Center Concord Campus Pharmacy (HSP
 17 42916) #48 bags of 25mg nicardipine hydrochloride 250ml (0.1mg/ml) in 5% dextrose. The
 18 commercially available product, Cardene, is 20mg nicardipine hydrochloride 200ml (0.1mg/ml)
 19 in 4.8% dextrose.

20 FOURTH CAUSE FOR DISCIPLINE

21 (Manufacture and Sale of Unapproved Drugs)

22 23. Respondents are subject to disciplinary action under section 4342 (a) in that
 23 Respondent sold injectables without FDA approval and without the receipt of a valid prescription.
 24 The circumstances are as follows:

25 24. On or about Specifically, between January 12, 2012 and July 11, 2012,
 26 Pharmedium Services LLC sold to Community Hospital Monterey (HSP 30134) #160 10ml
 27
 28

1 syringes of injectable nicardipine hydrochloride 0.1mg/ml in 0.9% sodium chloride, an
2 unapproved drug.

3 FIFTH CAUSE FOR DISCIPLINE
4 (selling adulterated drugs)

5 25. Respondents are subject to disciplinary action under section 4342 (a) in conjunction
6 with Health and Safety Code section 11128 and California Code of Regulations section 1735.1 in
7 that Respondent sold drugs lacking in quality or strength. The circumstances are as follows:

8 26. Documents provided on May 10, 2012 and June 20, 2012 indicated Pharmedium
9 Services LLC compounded Batch Number 12117009S on 4/26/2012 with a labeled strength of
10 50mg nicardipine 0.2mg/ml in 250ml 0.9% sodium chloride, when quantitative analysis indicated
11 the actual product strength was beyond the industry accepted range of +/- 10% with
12 concentrations of nicardipine 0.173, 0.169, and 0.173 mg/ml. Expected concentration should be
13 nicardipine 0.180-0.220 mg/ml. This quantitative analysis report indicated a potency of "P" for
14 pass.
15

16 SIXTH CAUSE FOR DISCIPLINE
17 (Not Compounding pursuant to a Patient Specific Prescription)

18 27. Respondents are subject to disciplinary action under California Code of
19 Regulations Section 1735.2 in that documents provided on May 10, 2012 and November 27, 2012
20 indicated Pharmedium Services LLC sold the following injectable products: #48 25mg
21 nicardipine hydrochloride 0.1mg/ml in 5% dextrose 250ml AVIVA bags, #24 3ml 4%
22 sodiumcitrate syringes, and #1 0.2% ropivacaine HCL 550ml injection to John Muir Medical
23 Center Concord Campus Pharmacy (HSP 42916) between 3/8/12 and 10/17/12. Documents
24 provided on 5/10/12 and 7/19/12 indicated Pharmedium Services LLC sold the following
25 injectable products: #160 nicardipine hydrochloride 0.1mg/ml in 0.9% sodium chloride 10ml
26 syringes, #96 4 mgnorepinephrine bitartrate (16mcg/ml), #12 150mg amiodarone HCL in 5%
27
28

1 dextrose, #72 1.25 gvancomycin HCL in 5% dextrose, #24 1.5g vancomycin HCL in 5%
2 dextrose, #120 1 gmagnesium sulfate in 5% dextrose, #500 10mg/ml rocuronium bromide, #550
3 20mg/ml succinylcholine chloride, #400 5mg/ml ephedrine sulfate, #400 100mcg/ml
4 phenylephrine HCL, #30 5mg/ml labetalol, #300 5mg labetalol (no overwrap), #72 125mg
5 diltiazem HCL in 5% dextrose, #20 0.1% ropivacaine HCL in 0.9% sodium chloride, #216 2g
6 cefazolin in 5% dextrose, #36 50mg phenylephrine HCL (0.1mg/ml) in 5% dextrose, and #5
7 0.25% bupivacaine HCL in 0.9% sodium chloride to Community Hospital Monterey (HSP
8 30134) between 1/12/12 and 7/11/12. All products were sold without receipt of a valid
9 prescription for an individual patient and without a license to manufacture FDA approved drugs.
10 As set forth more specifically above in paragraph 11, table 1.
11

12 SEVENTH CAUSE FOR DISCIPLINE
13 (Selling a Mislabeled Drug Product)

14 28. Respondents are subject to disciplinary action under section 4169 (a) (3) in that
15 Respondent sold drugs which were misbranded. The circumstances are as follows:

16 29. On or about July 19 2012, at Community Hospital Monterey (HSP
17 30134), the labels on nicardipine hydrochloride 0.1mg/1ml 0.9% sodium chloride 10ml syringes
18 provided by Pharmedium Services LLC stated "Use as Directed. Rx Only", "Store at Room
19 Temp.", and indicated a 90-day expiration date. Pharmedium Services LLC stated in writing on
20 6/5/12 "the labeled statement of use is: See Manufacturer's Package Insert. Use as directed. Rx
21 Only." The "Drug Presentation" screen provided by Pharmedium Services LLC to Community
22 Hospital Monterey on 7/19/12 provided Drug Manufacturer's Package Inserts for Emcure
23 Pharmaceuticals and Sun Pharmaceuticals. Both manufacturer's package inserts stated "vials
24 must be diluted before infusion" and "the diluted solution is stable for 24 hours at room
25 temperature". No patient specific directions were provided.
26
27
28

1 EIGHTH CAUSE FOR DISCIPLINE
2 (No Compounding Statement on Products)

3 30. Respondents are subject to disciplinary action under California Code of Regulations
4 Section 1735.4(b) in that they failed to provide a product statement on compounded medications.
5 The circumstances are as follows:

6 31. On or about July 19, 2012, during an inspection of Community Hospital Monterey
7 (HSP 30134), nicardipine syringes compounded and sold by Pharmedium Services LLC found in
8 the inventory did not contain a compounded drug product statement.
9

10 NINTH CAUSE FOR DISCIPLINE
11 (Failure to Report Contracts)

12 32. Respondents are subject to disciplinary action under section 4123 for failure to report
13 its contractual arrangement to compound drugs for other pharmacies. The circumstances are as
14 follows:

15 33. Documents provided on June 5, 2012 indicated Pharmedium Services LLC
16 contracted with pharmacies in California to "compound injectable sterile drugs for parenteral use
17 pursuant to California's Business and Professions Code Section 4123" and the drugs for
18 parenteral therapy were not compounded pursuant to a prescription but by invoice at wholesale,
19 as set forth more specifically in paragraph 11 and table 1, above.
20

21 TENTH CAUSE FOR DISCIPLINE
22 (Improper Invoicing)

23 34. Respondents are subject to disciplinary action under section 4059 (b) for improper
24 invoicing in that they failed to properly list the address of their supplier. The circumstances are as
25 follows:

26 35. Documents provided on July 19, 2012 and November 27, 2012 indicated
27 Pharmedium Services LLC invoiced from 39797 Treasury Center, Chicago, IL 60694 and 43
28

1 Distribution Blvd., Edison, NJ 08817 which were not the address of the supplier in each instance.
 2 Pharmedium Services LLC was in violation for the eleven invoices with an incorrect supplier
 3 address. See Table 2 below.

| Date | PO#: | Record #: | Type of Record: | Pharmadium address | Hospital customer |
|---------|---------|-----------|-----------------|--|-------------------|
| 1/12/12 | RX8524 | A571580 | Invoice | 39797 Treasury Center, Chicago, IL 60694 | CH-M |
| 1/31/12 | RX8555 | A579832 | Invoice | 39797 Treasury Center, Chicago, IL 60694 | CH-M |
| 2/2/12 | RX8564 | A581416 | Invoice | 39797 Treasury Center, Chicago, IL 60694 | CH-M |
| 3/12/12 | RX8x642 | A598834 | Invoice | 39797 Treasury Center, Chicago, IL 60694 | CH-M |
| 4/6/12 | RX8709 | A611130 | Invoice | 39797 Treasury Center, Chicago, IL 60694 | CH-M |
| 4/11/12 | RX8717 | A613149 | Invoice | 39797 Treasury Center, Chicago, IL 60694 | CH-M |
| 5/8/12 | RX8771 | A624220 | Invoice | 39797 Treasury Center, Chicago, IL 60694 | CH-M |
| 6/25/12 | RX8861 | A648371 | Invoice | 39797 Treasury | CH-M |

| | | | | | |
|----------|----------|------------------|--------------|--|--------|
| | | | | Center, Chicago, IL 60694 | |
| 7/5/12 | RX8885 | A648371 | Invoice | 39797 Treasury Center, Chicago, IL 60694 | CH-M |
| 7/11/12 | RX8904 | A651062 | Invoice | 39797 Treasury Center, Chicago, IL 60694 | CH-M |
| 10/17/12 | 101212FJ | WEB0649014- A | Packing Slip | 43 Distribution Blvd., Edison, NJ 08817 | JMMC-C |

DISCIPLINE CONSIDERATIONS

36. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 14, 2011, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 47609 for violating Business and Profession Code section 4123 and ordered Respondent, Pharmedium Healthcare Corp dba Pharmedium Services LLC, to pay a fine of \$4,460.00. That Citation is now final and is incorporated by reference as if fully set forth.

PRAAYER

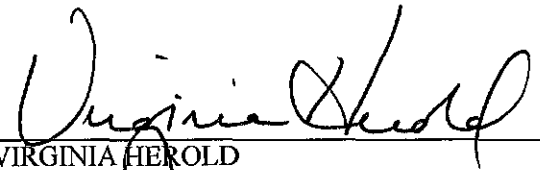
WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 590, issued to Pharmedium Healthcare Corp dba Pharmedium Services LLC;
2. Revoking or suspending Non-Resident Sterile Compounding license Number NSC 99221 to Pharmedium Services LLC;
3. Ordering Pharmedium Healthcare Corp. and Pharmedium Services LLC 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;

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

DATED: 9/13/14



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

SA2013110653
11452689.docx

Exhibit B

Letter of Public Repeal in Case No. 4625

Date: _____

Pharmedium Healthcare Corp dba Pharmedium Services LLC
dba Pharmedium Services LLC
Pharmedium Services LLC
12620 W. Airport Boulevard, Suite 130
Sugar Land, TX 77478

Re: LETTER OF PUBLIC REPROVAL
In the Matter of the Accusation Against:
Pharmedium Healthcare Corp dba Pharmedium Services LLC,
Non-Resident Pharmacy Permit No. NRP 590
Non-Resident Sterile Compounding license No. NSC 99221

Dear Pharmedium Services Representative:

On September 13, 2014, the Board of Pharmacy, Department of Consumer Affairs, State of California, filed an Accusation against your Non-Resident Pharmacy Permit. The Accusation alleged, in relevant part, that you engaged in unprofessional conduct under Professions Code section 4301, 4033, for the unlicensed manufacture of medication in that you prepared injectable medication that was not provided directly to a consumer. The Accusation also alleged that you provided misbranded drugs pursuant to Business and Professions Code section 4169 and 4342 (a) in that section 111395 of the Health and Safety Code states that a drug is misbranded if it is an imitation of another drug, and they compounded a commercially available drug

The Accusation also alleged that during an Board investigation in June of 2012 it was determined that pursuant to Business and Professions Code section 4342 (a) in conjunction with Health and Safety Code section 11128 and California Code of Regulations section 1735.1 in that you sold drugs lacking in quality or strength; failed to provide a product statement on compounded medications in accordance with California Code of Regulations Section 1735.4(b); and that you improperly invoiced your product by listing your corporate headquarters address rather than your supplier facility address in violation of Business and Professions Code section 4059 (b).

Accordingly, in resolution of this matter under the authority provided under Business and Professions Code section 495, the Board of Pharmacy, Department of Consumer Affairs issues this letter of public reproval.

Sincerely,

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs