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

In the Matter of the Accusation Against:
BROADWAY MEDICAL PHARMACY
1673 W. Broadway, Ste. 1
Anaheim, CA 92802
Pharmacy Permit No. PHY 48442
PHI THI LE VAN
817 N. Lenz Drive
Anaheim, CA 92805
Pharmacist License No. RPH 41632

Respondents.

Case No. 4822

DEFAULT DECISION AND ORDER

[Gov. Code, §11520]

FINDINGS OF FACT

1. On or about September 5, 2014, Complainant Virginia K. Herold, in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs, filed Accusation No. 4822 against Broadway Medical Pharmacy and Phi Thi Le Van (Respondents) before the Board of Pharmacy. (Accusation attached as Exhibit A.)

2. On or about March 20, 2007, the Board of Pharmacy issued Pharmacy Permit Number PHY 48442 to Broadway Medical Pharmacy (Respondent Pharmacy). The Pharmacy

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

3 3. On or about April 23, 1988, the Board issued Pharmacist License Number RPH
4 41632 to Phi Thi Le Van (Respondent Le Van). The Pharmacy Permit was in full force and effect
5 at all times relevant to the charges brought herein and will expire on August 31, 2015, unless
6 renewed. On October 24, 1991, with an effective date of November 21, 1991, in a matter
7 captioned, "In the Matter of the Accusation Against: Phi Thi Le Van, Tony Pham, doing business
8 as Broadway Medical Pharmacy," Case No. 1556, the Board issued a Decision and Order
9 revoking Respondent Le Van's license, staying the revocation, and placing the license on
10 probation for three years subject to certain terms and conditions. Respondent successfully
11 completed his probation, and his license was fully restored on November 21, 1994.

12 4. On or about September 26, 2014, Respondent was served by Certified and First Class
13 Mail copies of the Accusation No. 4822, Statement to Respondent, Notice of Defense, Request
14 for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6, and
15 11507.7) at Respondent's address of record which, pursuant to Business and Professions Code
16 section 4100, is required to be reported and maintained with the Board. Respondent's address of
17 record was and is: 1673 W. Broadway, Ste. 1, Anaheim, CA 92802.

18 5. Service of the Accusation was effective as a matter of law under the provisions of
19 Government Code section 11505, subdivision (c) and/or Business & Professions Code section
20 124.

21 6. Government Code section 11506 states, in pertinent part:

22 (c) The respondent shall be entitled to a hearing on the merits if the respondent
23 files a notice of defense, and the notice shall be deemed a specific denial of all parts
24 of the accusation not expressly admitted. Failure to file a notice of defense shall
constitute a waiver of respondent's right to a hearing, but the agency in its discretion
may nevertheless grant a hearing.

25 7. Respondent failed to file a Notice of Defense within 15 days after service upon them
26 of the Accusation, and therefore waived their right to a hearing on the merits of Accusation No.
27 4822.

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1 8. California Government Code section 11520 states, in pertinent part:

2 (a) If the respondent either fails to file a notice of defense or to appear at the
3 hearing, the agency may take action based upon the respondent's express admissions
4 or upon other evidence and affidavits may be used as evidence without any notice to
5 respondent.

6 9. Pursuant to its authority under Government Code section 11520, the Board finds
7 Respondents are in default. The Board will take action without further hearing and, based on the
8 relevant evidence contained in the Default Decision Evidence Packet in this matter, as well as
9 taking official notice of all the investigatory reports, exhibits and statements contained therein on
10 file at the Board's offices regarding the allegations contained in Accusation No. 4822, finds that
11 the charges and allegations in Accusation No. 4822, are separately and severally, found to be true
12 and correct by clear and convincing evidence.

13 10. Taking official notice of its own internal records, pursuant to Business and
14 Professions Code section 125.3, it is hereby determined that the reasonable costs for Investigation
15 and Enforcement is \$7,127.50 as of October 13, 2014.

16 DETERMINATION OF ISSUES

17 1. Based on the foregoing findings of fact, Respondent Broadway Medical Pharmacy
18 has subjected its Pharmacy Permit No. PHY 48442 to discipline, and Respondent Le Van has
19 subjected his Pharmacist License Number RPH 41632 to discipline

20 2. The agency has jurisdiction to adjudicate this case by default.

21 3. The Board of Pharmacy is authorized to revoke Respondent Broadway Medical
22 Pharmacy's Pharmacy Permit and Respondent Le Van's Pharmacist License based upon the
23 following violations alleged in the Accusation which are supported by the evidence contained in
24 the Default Decision Evidence Packet in this case:

25 a. Respondents are subject to disciplinary action for unprofessional conduct under
26 Business and Professions Code section 4301, subdivision (o), for failing to maintain records of
27 manufacture, sale, acquisition and/or disposition of dangerous drugs in violation of Business and
28 Professions Code section 4081, subdivision (a), including a current inventory, as defined by
California Code of Regulations, title 16, section 1718, in that during inspections of Respondent

1 Pharmacy, the Board's investigator determined that from July 4, 2010 through July 4, 2012,
2 60,238 tablets of hydrocodone/apap 10/325 could not be accounted for by any records,
3 prescriptions could not be found in the pharmacy, and reverse distributor records could also not
4 be found in the pharmacy.

5 b. Respondents are subject to disciplinary action for unprofessional conduct under
6 Business and Professions Code section 4301, subdivision (o), for failing to initial orally
7 transmitted prescriptions as required by the pharmacist who reduced it to writing, in violation of
8 CCR, title 16, section 1717, subdivision (c).

9 c. Respondents are subject to disciplinary action for unprofessional conduct under
10 Business and Professions Code section 4301, subdivision (o), in that Respondents did not have
11 the required daily reports or an alternate system to document the refilling of controlled substance
12 prescriptions, in violation of Code of Federal Regulations, title 21, section 1306.22.

13 d. Respondents are subject to disciplinary action for unprofessional conduct under
14 Business and Professions Code section 4301, subdivision (j), in that Respondents dispensed 46
15 prescriptions more than 4 days early in violation of Health and Safety Code section 11153.

16 e. Respondents are subject to disciplinary action for unprofessional conduct under
17 Business and Professions Code section 4306.5 in that they failed to fulfill their corresponding
18 responsibility obligation, when they did not review patient profiles, and filled prescriptions for
19 patients coming from a distance with prescriptions by physicians prescribing the same therapy to
20 multiple patients and prescriptions for the same medications written for the same patient by
21 different physicians.

22 f. Respondents are subject to disciplinary action for unprofessional conduct under
23 Business and Professions Code section 4301, subdivision (j), in that Respondents failed to
24 maintain seven prescriptions in violation of Health and Safety Code section 11179.

25 g. Respondents are subject to disciplinary action for unprofessional conduct under
26 Business and Professions Code section 4301, subdivision (o), in that Respondents failed to
27 properly label drug containers dispensed to patients in violation of California Code of
28

1 Regulations, title 16, section 1707.5 and Business and Professions Code section 4076, subdivision
2 (a)(11).

3 h. Respondents are subject to disciplinary action for unprofessional conduct under
4 Business and Professions Code section 4301, subdivision (o), in that Respondents kept outdated
5 drugs on the pharmacy shelves in violation of Business and Professions Code section 4342.

6 i. Respondents are subject to disciplinary action for unprofessional conduct under
7 Business and Professions Code section 4301, subdivision (o), in that Respondents failed to
8 maintain a policy and procedure on theft and impairment in violation of Business and Professions
9 Code section 4104, subdivision (b).

10 j. Respondents are subject to disciplinary action for unprofessional conduct under
11 Business and Professions Code section 4301, subdivision (o), in that Respondents failed to
12 maintain a quality assurance policy and procedure available during inspection, in violation of
13 California Code of Regulations, title 16, section 1711, subdivision (c)(1).

14 k. Respondents are subject to disciplinary action for unprofessional conduct under
15 Business and Professions Code section 4301, subdivision (j), in that Respondents failed to submit
16 data to CURES weekly in violation of Health and Safety Code section 11165, subdivision (d).

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ORDER

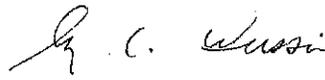
IT IS SO ORDERED that Pharmacy Permit No. PHY 48442 issued to Respondent Broadway Medical Pharmacy is revoked, and Pharmacist License No. RPH 41632 issued to Respondent Le Van is revoked.

Pursuant to Government Code section 11520, subdivision (c), Respondents may serve a written motion requesting that the Decision be vacated and stating the grounds relied on within seven (7) days after service of the Decision on Respondents. The agency in its discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

This Decision shall become effective on December 5, 2014.

It is so ORDERED November 5, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 
STAN C. WEISSER
Board President

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DOJ Matter ID:SD2013705613

Attachment:
Exhibit A: Accusation

Exhibit A

Accusation

1 KAMALA D. HARRIS
Attorney General of California
2 LINDA K. SCHNEIDER
Supervising Deputy Attorney General
3 ANTOINETTE B. CINCOTTA
Deputy Attorney General
4 State Bar No. 120482
110 West "A" Street, Suite 1100
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 645-2095
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 4822

12 **BROADWAY MEDICAL PHARMACY**
13 1673 W. Broadway, Ste. 1
14 Anaheim, CA 92802

ACCUSATION

15 Pharmacy Permit No. PHY 48442

16 **PHI THI LE VAN**
17 817 N. Lenz Drive
Anaheim, CA 92805

18 Pharmacist License No. RPH 41632

19 Respondents.

20 Complainant alleges:

21 **PARTIES**

22 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
23 as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

24 2. On or about March 20, 2007, the Board of Pharmacy issued Pharmacy Permit
25 Number PHY 48442 to Broadway Medical Pharmacy (Respondent Pharmacy). The Pharmacy
26 Permit was in full force and effect at all times relevant to the charges brought herein and will
27 expire on March 1, 2015, unless renewed.

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9. Section 4076 of the Code states in relevant part:

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

...

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

....

10. Section 4081 of the Code states in relevant part:

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

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11. Section 4104 of the Code states in relevant part:

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(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

....

12. Section 4301 of the Code states in relevant part:

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

...

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

...

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

...

13. Section 4113(c) of the Code states:

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

14. Section 4306.5 of the Code states, in relevant part:

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

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

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

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15. Section 4342 of the Code states, in relevant part:

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

....

16. Health and Safety Code section 11153(a) states:

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

....

17. Health and Safety Code section 11165 states in relevant part:

...

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

1 (4) National Drug Code (NDC) number of the controlled substance
dispensed.

2 (5) Quantity of the controlled substance dispensed.

3 (6) International Statistical Classification of Diseases, 9th revision (ICD-9)
4 or 10th revision (ICD-10) Code, if available.

5 (7) Number of refills ordered.

6 (8) Whether the drug was dispensed as a refill of a prescription or as a first-
7 time request.

8 (9) Date of origin of the prescription.

9 (10) Date of dispensing of the prescription.

10

11 REGULATIONS

12 18. California Code of Regulations (CCR), title 16, section 1707.3 states:

13 Prior to consultation as set forth in section 1707.2, a pharmacist shall review a
14 patient's drug therapy and medication record before each prescription drug is
15 delivered. The review shall include screening for severe potential drug therapy
16 problems.

17 19. CCR, title 16, section 1707.5 states:

18 (a) Labels on drug containers dispensed to patients in California shall
conform to the following format:

19 (1) Each of the following items shall be clustered into one area of the label
20 that comprises at least 50 percent of the label. Each item shall be printed in at least
a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point
typeface, and listed in the following order:

21 (A) Name of the patient

22 (B) Name of the drug and strength of the drug. For the purposes of this
23 section, "name of the drug" means either the manufacturer's trade name of the
drug, or the generic name and the name of the manufacturer.

24 (C) The directions for the use of the drug.

25 (D) The condition or purpose for which the drug was prescribed if the
26 condition or purpose is indicated on the prescription.

27 (2) For added emphasis, the label shall also highlight in bold typeface or
28 color, or use blank space to set off the items listed in subdivision (a)(1).

///

1 (3) The remaining required elements for the label specified in section 4076
2 of the Business and Professions Code, as well as any other items of information
3 appearing on the label or the container, shall be printed so as not to interfere with
4 the legibility or emphasis of the primary elements specified in paragraph (1) of
5 subdivision (a). These additional elements may appear in any style, font, and size
6 typeface.

7 (4) When applicable, directions for use shall use one of the following
8 phrases:

9 (A) Take 1 [insert appropriate dosage form] at bedtime

10 (B) Take 2 [insert appropriate dosage form] at bedtime

11 (C) Take 3 [insert appropriate dosage form] at bedtime

12 (D) Take 1 [insert appropriate dosage form] in the morning

13 (E) Take 2 [insert appropriate dosage form] in the morning

14 (F) Take 3 [insert appropriate dosage form] in the morning

15 (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1
16 [insert appropriate dosage form] at bedtime

17 (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2
18 [insert appropriate dosage form] at bedtime

19 (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3
20 [insert appropriate dosage form] at bedtime

21 (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert
22 appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the
23 evening

24 (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert
25 appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the
26 evening

27 (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert
28 appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the
evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert
appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the
evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert
appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the
evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert
appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the
evening, and 3 [insert appropriate dosage form] at bedtime

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(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

20. CCR, title 16, section 1711 states in relevant part:

...

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

....

21. CCR, title 16, section 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly accepted pharmaceutical practice in the compounding or dispensing of a prescription.

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22. CCR, title 16, section 1717, states in relevant part:

...

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

...

23. CCR, title 16, section 1718, states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

24. CCR, title 16, section 1761 states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

25. Code of Federal Regulations (CFR), title 21, section 1306.22 states:

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued. No prescription for a controlled substance listed in Schedule III or IV authorized to be refilled may be refilled more than five times.

(b) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document or electronic prescription record. If entered on another document, such as a medication record, or electronic prescription record, the document or record must be uniformly maintained and readily retrievable.

(c) The following information must be retrievable by the prescription number:

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- (1) The name and dosage form of the controlled substance.
- (2) The date filled or refilled.
- (3) The quantity dispensed.
- (4) The initials of the dispensing pharmacist for each refill.
- (5) The total number of refills for that prescription.

(d) If the pharmacist merely initials and dates the back of the prescription or annotates the electronic prescription record, it shall be deemed that the full face amount of the prescription has been dispensed.

(e) The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original paper prescription or annotates the electronic prescription record with the date, quantity of refill, number of additional refills authorized, and initials the paper prescription or annotates the electronic prescription record showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA registration number of the practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

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1 (2) Any such proposed computerized application must also provide online
2 retrieval (via computer monitor or hard-copy printout) of the current refill history
3 for Schedule III or IV controlled substance prescription orders (those authorized
4 for refill during the past six months). This refill history shall include, but is not
5 limited to, the name of the controlled substance, the date of refill, the quantity
6 dispensed, the identification code, or name or initials of the dispensing pharmacist
7 for each refill and the total number of refills dispensed to date for that prescription
8 order.

9 (3) Documentation of the fact that the refill information entered into the
10 computer each time a pharmacist refills an original paper, fax, or oral prescription
11 order for a Schedule III or IV controlled substance is correct must be provided by
12 the individual pharmacist who makes use of such an application. If such an
13 application provides a hard-copy printout of each day's controlled substance
14 prescription order refill data, that printout shall be verified, dated, and signed by
15 the individual pharmacist who refilled such a prescription order. The individual
16 pharmacist must verify that the data indicated are correct and then sign this
17 document in the same manner as he would sign a check or legal document (e.g.,
18 J.H. Smith, or John H. Smith). This document shall be maintained in a separate file
19 at that pharmacy for a period of two years from the dispensing date. This printout
20 of the day's controlled substance prescription order refill data must be provided to
21 each pharmacy using such a computerized application within 72 hours of the date
22 on which the refill was dispensed. It must be verified and signed by each
23 pharmacist who is involved with such dispensing. In lieu of such a printout, the
24 pharmacy shall maintain a bound log book, or separate file, in which each
25 individual pharmacist involved in such dispensing shall sign a statement (in the
26 manner previously described) each day, attesting to the fact that the refill
27 information entered into the computer that day has been reviewed by him and is
28 correct as shown. Such a book or file must be maintained at the pharmacy
employing such an application for a period of two years after the date of dispensing
the appropriately authorized refill.

(4) Any such computerized application shall have the capability of
producing a printout of any refill data that the user pharmacy is responsible for
maintaining under the Act and its implementing regulations. For example, this
would include a refill-by-refill audit trail for any specified strength and dosage
form of any controlled substance (by either brand or generic name or both). Such a
printout must include name of the prescribing practitioner, name and address of the
patient, quantity dispensed on each refill, date of dispensing for each refill, name
or identification code of the dispensing pharmacist, and the number of the original
prescription order. In any computerized application employed by a user pharmacy
the central recordkeeping location must be capable of sending the printout to the
pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator
requests a copy of such printout from the user pharmacy, it must, if requested to do
so by the Agent or Investigator, verify the printout transmittal capability of its
application by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized
application experiences system down-time, the pharmacy must have an auxiliary
procedure which will be used for documentation of refills of Schedule III and IV
controlled substance prescription orders. This auxiliary procedure must ensure that
refills are authorized by the original prescription order, that the maximum number
of refills has not been exceeded, and that all of the appropriate data are retained for
online data entry as soon as the computer system is available for use again.

1 (g) When filing refill information for original paper, fax, or oral
2 prescription orders for Schedule III or IV controlled substances, a pharmacy may
3 use only one of the two applications described in paragraphs (a) through (e) or (f)
4 of this section.

5 (h) When filing refill information for electronic prescriptions, a pharmacy
6 must use an application that meets the requirements of part 1311 of this chapter.

7 **COSTS**

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

12 **DRUGS**

13 27. **Hydrocodone bitartate/acetaminophen**, also known by the brand names Vicodin,
14 Norco, Zydone, Maxidone, Lortab, Lorcet, Hydrocet, Co-Gesic, and Anexsia, is a narcotic
15 Schedule III controlled substance as designated by Health and Safety Code section 11056(e)(4),
16 and is a dangerous drug pursuant to Business and Professions Code section 4022. Hydrocodone is
17 used as a narcotic analgesic in the relief of pain.

18 **FACTUAL ALLEGATIONS**

19 28. From January 4, 2007 and at all times mentioned, Respondent Van was the owner and
20 Pharmacist-in-Charge of Respondent Broadway Medical Pharmacy.

21 **July 8, 2011 Inspection**

22 29. On July 8, 2011, Board Inspectors went to Broadway Medical Pharmacy to perform
23 an inspection. Pharmacist in charge and owner Phi Le Van was present and the only one working.

24 29. During the July 18, 2011 inspection, the inspectors requested pharmacy records, and
25 noted the following:

26 • There was no Quality Assurance policy and procedure retrievable and no Internet
27 access available during the inspection;

28 • There was no theft and/or diversion policy available during the inspection;

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- 1 • Daily reports containing controlled and non-controlled medications were not
2 initialed/signed by the pharmacist;
- 3 • Telephone orders were not reduced to writing and initialed by the pharmacist;
- 4 • There were no patient-centered labels with a description of the drug being dispensed;
5 and
- 6 • The pharmacy contained many expired drugs.

7 **March 29, 2013 Inspection**

8 30. On March 29, 2013, the Board's inspectors conducted a second inspection of
9 Respondent Broadway Medical Pharmacy. Respondent Van was present. During the inspection,
10 Respondent Van admitted that Respondents do not submit CURES every week.

11 31. Respondents were unable to locate the following prescriptions: 376614, 376923,
12 377573, 378033, 378617, 382714, 388092, 388447, 388514, 388515, 388647, 388773, 388984,
13 389131, 389132, 389261, 389438, 389439, 389675, 389720, 389875, 389886, 389935, 390103,
14 390244, 390599, 390633, 390734, 390764, 390938, 391119, 391450, 391603, 391748, 391908,
15 392062, 392133, 392278, 392279, 392339, 392360, 392551, 392552.

16 **April 2, 2013 Inspection**

17 32. On April 2, 2013, the Board's inspectors conducted a third inspection of Respondent
18 Broadway Medical Pharmacy. Respondents were unable to identify their reverse distributor and
19 did not provide any reverse distributor records.

20 33. Respondents filled controlled substance prescriptions for patients who used multiple
21 pharmacies to fill their controlled substance prescriptions, and patients who used multiple
22 prescribers to obtain the same controlled substances. Respondents did not review CURES data to
23 determine patients' history of controlled substance use or call the Drug Enforcement
24 Administration to verify a prescriber's status to prescribe controlled substances. Respondents did
25 not verify or otherwise research whether these prescriptions were written for a legitimate medical
26 purpose before filling them.

27 34. Respondents dispensed 46 prescriptions more than 4 days early, and the pharmacy
28 was missing 60,238 tablets of hydrocodone/APAP 10/325.

1 CFR, title 21, section 1306.22 as set forth in paragraphs 28 to 35, which are incorporated here by
2 this reference.

3 **FOURTH CAUSE FOR DISCIPLINE**

4 **(Unprofessional Conduct – Failure to Properly Verify Prescriptions)**

5 39. Respondents are subject to disciplinary action for unprofessional conduct under Code
6 section 4301, subdivision (j), in that Respondents dispensed 46 prescriptions more than 4 days
7 early in violation of Health and Safety Code section 11153 as set forth in paragraphs 28 to 35,
8 which are incorporated here by this reference.

9 **FIFTH CAUSE FOR DISCIPLINE**

10 **(Unprofessional Conduct – Failing to Exercise Professional Judgment and/or**
11 **Corresponding Responsibility)**

12 40. Respondents are subject to disciplinary action for unprofessional conduct under Code
13 section 4306.5 in that they failed to fulfill their corresponding responsibility obligation, when they
14 did not review patient profiles, and filled prescriptions for patients coming from a distance with
15 prescriptions by physicians prescribing the same therapy to multiple patients and prescriptions for
16 the same medications written for the same patient by different physicians, as set forth in
17 paragraphs 28 to 35, which are incorporated here by this reference.

18 **SIXTH CAUSE FOR DISCIPLINE**

19 **(Unprofessional Conduct – Failure to Maintain Prescriptions)**

20 41. Respondents are subject to disciplinary action for unprofessional conduct under Code
21 section 4301, subdivision (j), in that Respondents failed to maintain seven prescriptions in
22 violation of Health and Safety Code section 11179 as set forth in paragraphs 28 to 35, which are
23 incorporated here by this reference.

24 **SEVENTH CAUSE FOR DISCIPLINE**

25 **(Unprofessional Conduct – Failure to Properly Label Prescriptions)**

26 42. Respondents are subject to disciplinary action for unprofessional conduct under Code
27 section 4301, subdivision (o), in that Respondents failed to properly label drug containers
28 dispensed to patients in violation of California Code of Regulations, title 16, section 1707.5 and

1 Code section 4076, subdivision (a)(11), as set forth in paragraphs 28 to 35, which are
2 incorporated here by this reference.

3 **EIGHTH CAUSE FOR DISCIPLINE**

4 **(Unprofessional Conduct – Maintaining Expired Drugs)**

5 43. Respondents are subject to disciplinary action for unprofessional conduct under Code
6 section 4301, subdivision (o), in that Respondents kept outdated drugs on the pharmacy shelves in
7 violation of Code section 4342 as set forth in paragraphs 28 to 35, which are incorporated here by
8 this reference.

9 **NINTH CAUSE FOR DISCIPLINE**

10 **(Unprofessional Conduct – Failing to Maintain a Policy
11 and Procedure on Theft and Impairment)**

12 44. Respondents are subject to disciplinary action for unprofessional conduct under Code
13 section 4301, subdivision (o), in that Respondents failed to maintain a policy and procedure on
14 theft and impairment in violation of Code section 4104, subdivision (b) as set forth in paragraphs
15 28 to 35, which are incorporated here by this reference.

16 **TENTH CAUSE FOR DISCIPLINE**

17 **(Unprofessional Conduct – Failure to Maintain a
18 Quality Assurance Policy and Procedure During Inspection)**

19 45. Respondents are subject to disciplinary action for unprofessional conduct under Code
20 section 4301, subdivision (o), in that Respondents failed to maintain a quality assurance policy
21 and procedure available during inspection, in violation of CCR, title 16, section 1711, subdivision
22 (c)(1), as set forth in paragraphs 28 to 35, which are incorporated here by this reference.

23 **ELEVENTH CAUSE FOR DISCIPLINE**

24 **(Unprofessional Conduct – Failure to Submit Data to CURES Weekly)**

25 46. Respondents are subject to disciplinary action for unprofessional conduct under Code
26 section 4301, subdivision (j), in that Respondents failed to submit data to CURES weekly in
27 violation of Health and Safety Code section 11165, subdivision (d), as set forth in paragraphs 28
28 to 35, which are incorporated here by this reference.

1 **FACTORS IN AGGRAVATION**

2 47. By Order of the Board effective November 21, 1991, Respondent Le Van's
3 pharmacist license was revoked based on the charges and allegations set forth in Accusation No.
4 1556. Accusation No. 1556 charged Respondent with unprofessional conduct based on her
5 conviction of violation of Code section 4047.5, failing to properly label a prescription, and section
6 4047.9(a), and failing to inform the person receiving the drug Carisoprodol (Generic Soma) of the
7 harmful effects of the drug. The revocation of Respondent's pharmacist license was stayed, and
8 the license was placed on probation for a period of three years subject to certain terms and
9 conditions. Respondent Le Van successfully completed the probationary term on November 21,
10 1994.

11 **PRAYER**

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

- 14 1. Revoking or suspending Pharmacy Permit Number PHY 48442 issued to Respondent
- 15 Broadway Medical Pharmacy;
- 16 2. Revoking or suspending Pharmacist License No. RPH 41632 issued to Respondent
- 17 Phi Thi Le Van;
- 18 3. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the
- 19 investigation and enforcement of this case, pursuant to Business and Professions Code section
- 20 125.3; and
- 21 4. Taking such other and further action as deemed necessary and proper.

22
23 DATED: _____

9/5/14

Virginia Herold

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

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