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8	BEFORE THE BOARD OF PHARMACY	
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
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11	In the Matter of the Accusation Against:	Case No. 6193
12	NGUYEN LE DBA THANHS PHARMACY 633 N. Spring, Suite 5	
13	Los Angeles, CA 90012	ACCUSATION
14	Pharmacy Permit No. PHY 32480,	
15	and	·
16	NGUYEN LE 633 N. Spring, Suite 5	
17	Los Angeles, CA 90012	
18	Pharmacist License No. RPH 39548	
19	Respondents.	
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21	Complainant alleges:	
22	<u>PARTIES</u>	
23	1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity	
24	as the Executive Officer of the Board of Pharmacy (the "Board"), Department of Consumer	
25	Affairs.	
26	2. On or about August 28, 1985, the Board issued Pharmacist License Number RPH	
27	39548 to Respondent Nguyen Le ("Respondent Le"). The Pharmacist License was in full force	
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ŧ	(THANKS BUADMACV, NGUVEN LE and NGUVEN LE) ACCUSATION	

and effect at all times relevant to the charges brought herein and will expire on May 31, 2019, unless renewed.

3. On or about October 11, 1985, the Board issued Pharmacy Permit Number PHY 32480 to Respondent doing business as Thanhs Pharmacy ("Respondent Thanhs"). Respondent Le is and has been the Individual Licensed Owner and Pharmacist-in-Charge of Respondent Tranhs since October 11, 1985. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2017, unless renewed.

JURISDICTION

- 4. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 5. Section 4300 provides, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.
 - 6. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued 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 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."

- 7. Section 4307 of the Code states in pertinent part:
- "(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or

¹ Respondent Le and Respondent Thanhs shall be collectively referred to herein as "Respondents."

knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

- "(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
- "(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
- "(b) 'Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license' as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee."

STATUTORY PROVISIONS

8. Section 4036.5 of the Code states:

"'Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

9. Section 4040.5 of the Code states:

"'Reverse distributor' means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous drugs."

- 10. Section 4104 of the Code states:
- "(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

"(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."

11. Section 4301 of the Code states:

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

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

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

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12. Section 11165, subdivision (d), of the Health and Safety Code states:

"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.

interpretive services and translation 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."

- 16. California Code of Regulations, title 16, section 1707.6, states in part:
- "(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

"This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese. Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

"The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches."

- 17. California Code of Regulations, title 16, section 1714, states in part:
- "(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

- iii. California Code of Regulations, title 16, section 1714: dirty shelves; this was the second time Respondents were written up for this violation.
- iv. Health and Safety Code, section 11165: Failure to conduct CURES reporting; this was the second time Respondents were written up for this violation.

Complaint Against Respondent on October 15, 2015

21. On October 15, 2015, the Board received a complaint regarding Respondents from the PBM OptumRx ("Optum"). Optum performed an audit at Respondents' pharmacy and found one pharmacist (Respondent Le), no technician, expired medications on the shelves, prescriptions taped to the wall with patient information exposed to the public, no use of signature or delivery logs, no logging of refrigerator temperature, prescription back tags were not used, HIPAA² information was not posted or printed for patients, and improper disposal of HIPAA information because the pharmacist – Respondent Le – shreds documents by hand, and improper record keeping.

Inspection on July 28, 2016

- 22. On July 28, 2016, a Board inspector went to Respondents' pharmacy to perform an inspection. Respondent Le was present during the inspection.
- 23. The inspector went through the shelves of the pharmacy, and observed many expired drugs on the pharmacy shelves. She asked Respondent Le for an empty box, and he provided her with one. The inspector filled the box with drugs from one side of the shelving unit. Eventually, after spot checking four of the shelving units (about half the drug stock in the pharmacy), the inspector was able to fill an entire desktop and two large boxes with drugs that had expired. The drugs had expiration dates which were over six months old, and some of the drugs had expired in 2008. The inspector estimated that approximately 40% of the pharmacy's drug supply had expired. The inspector asked Respondent Le who his reverse distributor was, and he gave the inspector a job sheet dated 2010 for Reverse Distributors, Inc. Respondent Le stated he had not returned anything through them yet. Respondent Le stated he returns items to his wholesaler,

² "HIPAA" refers to the Health Insurance Portability and Accountability Act of 1996.

Bergen, and he throws away³ whatever he cannot return. The inspector advised Respondent Le to be aware of the expiration dates of his stock and not to dispense drugs which were outdated. She also asked him to go through the entire pharmacy and remove all expired products from the dispensing shelves and keep all the expired items in a separate area so he would not accidently dispense them. The inspector instructed Respondent Le to send the medications to a licensed reverse distributor or back to the wholesaler.

- During the inspection, Respondent Le could not find any self-assessment completed after 2006, which means he could not find the ones he should have completed in 2011, 2013, and 2015. In a statement he prepared at the end of the inspection, Respondent Le admitted that he last completed a self-assessment in 2006. The inspector asked Respondent Le to complete a selfassessment and send it to her within 14 days.
- During the inspection, the shelves in the pharmacy were very dirty, and the pharmacy was cluttered.
- Respondent Le informed the inspector that he was submitting CURES⁴ reports 26. monthly. The inspector informed Respondent Le that he was required to submit CURES report weekly, and Respondent Le seemed shocked at this information.
- The inspector asked Respondent Le for copies of Respondents' policies and procedures. After reviewing Respondents' policies, the inspector determined that Respondents did not have policies and procedures for the following: Interpretive services, absence of a pharmacist, technician job duties, impairment, and theft. In a statement he prepared at the end of the inspection, Respondent Le admitted that he did not have policies or procedures for Quality Assurance, temporary absence of a pharmacist, or interpretive services.

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27 28 ⁴ "CURES" stands for Controlled Substance Utilization Review and Evaluation System. CURES is a database of Schedule II, III and IV controlled substance prescriptions dispensed in California serving the public health, regulatory oversight agencies, and law enforcement. CURES assists the government in reducing prescription drug abuse and diversion without affecting legitimate medical practice or patient care.

Throwing medications in the trash is not an appropriate method of disposing of drugs in a pharmacy.

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- 28. The inspector observed that Respondents' prescription labels were not in sans serif font. She talked to Respondent Le about the size and font, and asked him to fix it immediately and to send her proof within 14 days.
- 29. The inspector also noted there was no "point to your language" poster in the pharmacy; she asked Respondent Le to obtain one and post it in the pharmacy.
- 30. At the end of the inspection, the inspector issued Respondents a notice of non-compliance for the following:
 - i. California Code of Regulations, title 16, section 1715: No self-assessment since 2006; this was the third time Respondents were written up for this violation.
 - ii. Code of Federal Regulations, title 21, section 1306.22: No controlled substance printout being done every three days; this was the second time Respondents were cited for this violation.
 - iii. Section 4342 of the Code: Large amount of expired products; this was the third time Respondents were written up for this violation.
 - iv. California Code of Regulations, title 16, section 1714: dirty shelves; this was the third time Respondents were written up for this violation.
 - v. Health and Safety Code, section 11165: Failure to conduct CURES reporting; this was the third time Respondents were written up for this violation.
 - vi. California Code of Regulations, title 16, section 1793.7: No technician job description.
 - vii. Section 4104 of the Code: No policy for theft and impairment.
 - viii. California Code of Regulations, title 16, section 1707.5: No policy for interpretive services; label not compliant.
 - ix. California Code of Regulations, title 16, section 1707.6: No point to your language sign.
 - x. California Code of Regulations, title 16, section 1714.1: No policy for temporary absence of a pharmacist.
- 31. All Respondents were to submit to the Board proof of compliance with the issues outlined in the notice of non-compliance by August 11, 2016. As of September 20, 2016,

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Respondents did not show proof of correction or compliance with the following items: complete a self-assessment; controlled substance printout every three days; proper disposal of expired medications; create a policy on theft and impairment; create a policy on interpretive services; edit label to comply with regulations; create a policy regarding the temporary absence of a pharmacist; draft technician job duties.

Inspection on November 8, 2016

- 32. On November 8 2016, two Board inspectors went to Respondents' pharmacy to perform a follow-up inspection and to inquire why Respondent failed to comply with the inspector's previous request for proof of compliance.
- 33. During this inspection, Respondent Le admitted that he had not completed a new self-assessment.
 - 34. Respondent Le also admitted that he had not written a policy for interpretive services.
- 35. The inspectors also observed that Respondents failed to post the "point to your language" sign.
- 36. Respondents' prescription labels were the same as the labels Respondents were using during the inspection on July 28, 2016. Respondents' prescription labels were not in sans serif font. The inspector asked Respondent Le to contact his software vendor, Care Company, to change the label.
- 37. Respondents also failed to properly dispose of the expired medications. Respondent Le indicated that he kept the expired medications in four boxes at the front of the pharmacy.
- 38. The two inspectors inspected the medications on the pharmacy shelves. They observed that many of the medications on the pharmacy's shelves were expired. The inspectors pulled approximately 20% to 25% of the pharmacy stock off the shelves because they were expired. Some of these medications expired in 2008.
- 39. During the inspection, the pharmacy was cluttered and there were many items on the ground. One inspector wiped the shelving with a wet paper towel to remove the stuck layer of dirt which was on the shelves. The other inspector's hands were black after pulling medications off the shelves.

Respondent Le failed to complete the necessary self-assessments before July 1 of every odd-numbered year.

Complainant realleges paragraphs 19-40, above, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violating California Statutes Applicable to Pharmacy – Respondent Le)

- 45. Respondent Le's Pharmacist License is subject to disciplinary action pursuant to section 4301, subdivision (j), in that Respondent Le exhibited unprofessional conduct by failing to comply with the provisions of the following California statutes:
- (a) Health and Safety Code, section 111295, as it relates to Health and Safety Code, section 111285: On or about July 28, 2016, and November 8, 2016, Respondent Le held large amounts of expired and adulterated products on the shelves of his pharmacy. These expired medications were ready to be dispensed.
- (b) Health and Safety Code, section 11165, subdivision (d): On or about July 28, 2016, Respondent Le was not reporting his CURES data within seven days after he dispensed controlled substances.
- (c) Section 4104, subdivision (b), of the Code: On or about July 28, 2016, and November 8, 2016, Respondent Le did not have written policies and procedures for addressing theft, diversion, or self-use of dangerous drugs among licensed individuals employed by or with the pharmacy.

Complainant realleges paragraphs 19-40, above, as if fully set forth herein.

OTHER MATTERS

46. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 32480 issued to Nguyen Le, dba Thanhs Pharmacy, while Nguyen Le was an owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Nguyen Le shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 32480 is placed on probation or until Pharmacy Permit Number PHY 32480 is reinstated if it is revoked.

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Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 39548 issued to Nguyen Le, Nguyen Le shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 39548 is placed on probation or until Pharmacist License Number RPH 39548 is reinstated if it is revoked.

DISCIPLINE CONSIDERATIONS

To determine the degree of discipline, if any, to be imposed on Respondent Thanhs, 48. Complainant alleges that on or about August 5, 2010, in a prior action, the Board issued Citation Number CI 2009 41745 and ordered Respondent Thanhs to pay a fine of \$5,000.00 for violating the following statutes and regulations: Business and Professions Code, sections 4076, subdivisions (a) & (11)(A), and 4342, subdivision (a); Health and Safety Code, section 11165, subdivision (b); Code of Federal Regulations, title 21, section 1306.22; California Code of Regulations, title 16, sections 1715, subdivision (a), 1711, subdivision (c)(1), 1714, subdivision (c), 1707.2, and 1717, subdivision (b). That Citation is now final and is incorporated by reference as if fully set forth.

PRAYER

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

- Revoking or suspending Pharmacy Permit Number PHY 32480, issued to Nguyen Le, 1. dba Thanhs Pharmacy;
- 2. Revoking or suspending Pharmacist License Number RPH 39548, issued to Nguyen Le:
- 3. Prohibiting Nguyen Le, dba Thanhs Pharmacy, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 32480, is placed on probation or until Pharmacy Permit Number PHY 32480 is reinstated if Pharmacy Permit Number PHY 39226 issued to Issued to Nguyen Le, dba Thanhs Pharmacy, is revoked;
- 4. Prohibiting Nguyen Le from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number