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

In the Matter of the Accusation Against:

Case No. 5879

OAH No. 2017040333

SOUTH FIGUEROA DRUGS, TONI GAYLE WALKER, Owner

Original Pharmacy Permit Number: PHY 40552

and

TONI GAYLE WALER,

Pharmacist License Number: RPH 33235

Respondents.

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy as the decision in the above-entitled matter, except that, pursuant to the provisions of Government Code section 11517, subdivision (c)(2)(C), the following technical changes are made:

- page four, paragraph #8: The date at the end of the paragraph should read "July 5, 2016", and not "July 5, 2017".
- page five, paragraph #11, at the beginning of the paragraph, the date should read "July 6, 2016", and not "July 6, 2017".

The technical changes made above do not affect the factual or legal basis of the Proposed Decision, which shall become effective at 5:00 p.m. on August 9, 2017.

It is so ORDERED on July 10, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

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

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Original Pharmacy Permit No. PHY 40552

and

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Respondents.

Case No. 5879

OAH No. 2017040333

PROPOSED DECISION

Ji-Lan Zang, Administrative Law Judge, Office of Administrative Hearings, State of California heard this matter on April 21, 2017, in Los Angeles, California.

Susan Melton Wilson, Deputy Attorney General, represented Virginia Herold (complainant), Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs.

Respondent Toni Gayle Walker (respondent Walker) represented herself individually and as the sole owner of South Figueroa Drugs (respondent Pharmacy).

Oral and documentary evidence was received. The record was closed and the matter was submitted for decision on April 21, 2017.

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FACTUAL FINDINGS

Parties and Jurisdiction

- 1. A. On August 20, 1979, the Board issued Pharmacist License Number RPH 33235 to respondent Walker. This license was valid at all times relevant to this matter, and will expire on January 31, 2019.
- B. On November 23, 1994, the Board issued Original Pharmacy Permit Number PHY 40552 to respondent Pharmacy. This permit was valid at all times relevant to this matter, and will expire on November 1, 2017.
- 2. On March 3, 2017, an Interim Suspension Order (ISO) was granted against respondent Pharmacy. The ISO suspended the operation of the respondent Pharmacy pending the final decision issued by the Board on the Accusation which is required to be filed under Business and Professions Code section 494, subdivision (f).
- 3. On March 16, 2017, complainant filed the Accusation in her official capacity. Respondent timely filed a Notice of Defense and a Request for Hearing on March 29, 2017. Thereafter, this hearing ensued.
- 4. Respondent Walker, during all times relevant to this matter, was 100 percent owner and Pharmacist-In-Charge (PIC) of respondent Pharmacy. She had no employees and operated respondent Pharmacy by herself.

The June 16, 2016 Inspection

- 5. On June 16, 2016, Board Inspectors Noelle Randall (Randall) and Connie Tang (Tang) conducted an unannounced inspection of respondent Pharmacy. They observed and took photographs of the exterior and interior of respondent Pharmacy and documented the following conditions:
- A. Piles of trash bags obstructed access to respondent Pharmacy's back room and completely blocked the back exit. Randall and Tang were unable to inspect a portion of the pharmacy due to the obstruction. Respondent Walker told Randall and Tang that the trash bags contained confidential patient documents, which she was going to take to a document destruction center for shredding.
- B. There were two refrigerators in the respondent Pharmacy. One refrigerator, which was not used for drug storage, was full of food and emitted a foul odor when it was opened. The other refrigerator, which was used for drug storage, had a large block of ice frozen around the internal freezer.
- C. The bathroom, which was located in respondent Pharmacy's backroom, was very dirty. Hardened yellow foam covered the walls under the sink and by the toilet. Pieces of the foam and paint and pieces were scattered on the floor by the toilet. The toilet's

water tank had no lid, and an object floated in the toilet's water bowl. The bathroom sink was dirty and crusted with a dark gray residue. When Tang turned on the water in the sink, the water was yellow in color.

- D. A thick layer of dark dust covered the surfaces of respondent Pharmacy's inventory shelves, the right side of the main pharmacy counter, a white plastic shelving unit in the main pharmacy area, a plastic set of drawers under the pharmacy counter, and the refrigerator in the front of the pharmacy.
- E. The counter of the main pharmacy area was cluttered with prescription documents, many of which were dirty and or stained. Many of those documents were also bound together by rubber bands and did not seem to be organized by date or prescription number. The main pharmacy counter was also slanted downward, in a semi-collapsed state.
- F. There were many boxes and bags of paper and/or trash on the floor of the main pharmacy area, including pharmacy mail and wholesaler invoices which were piled on boxes on the floor.
 - G. The sink in the main pharmacy area was full of dishes.
- H. At least two unidentifiable substances, along with two loose tablets, were found on the floor adjacent to one of respondent Pharmacy's inventory shelves.
- I. Both inspectors observed insects in the pharmacy. Tang noted gnats flying around the trash bags in the respondent Pharmacy's back room. Additionally, a larger bug, which Randall believed to be cockroach, crawled out from a stack of prescriptions as she was reviewing them.
- J. Reused containers were found in a drawer, some with patient labels from the respondent Pharmacy.
- 6. During the June 6, 2016 inspection, the following interactions occurred between the inspectors and respondent Walker:
- A. Randall asked to review the most recent Community Pharmacy Self-Assessment¹ completed by respondent Walker. Respondent Walker was not able to locate a Community Pharmacy Self-Assessment completed prior to July 2015.

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¹ California Code of Regulations, title 16, section 1715, requires the PIC of each pharmacy to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law before July 1 of every odd-numbered year.

- B. Randall asked to review a biennial inventory of controlled substances.² The most recent inventory of controlled substances respondent Walker made available for review was completed on September 23, 2013. She could not locate a biennial inventory of controlled substances completed within the last two years.
- C. Respondent Pharmacy did not have a posted sign or other means to identify the language of a patient with limited or no English proficiency.³ When Randall asked respondent Walker for a written policy and procedure to assist patients with limited or no English proficiency, respondent Walker stated that respondent Pharmacy did not have such a policy and did not have the ability to provide interpretation services.
- 7. At the end of the inspection, Randall provided a written inspection report to respondent Walker and orally reviewed the report with her. Both the written and oral directives required respondent Pharmacy to correct the deficiencies described above by June 30, 2016.
- 8. On June 30, 2016, Randall called respondent Walker regarding her compliance in correcting these deficiencies. Respondent Walker told Randall that she was cleaning respondent Pharmacy and expected it be in good condition by July 5, 2017.

The July 6, 2016 Inspection

9. On July 6, 2016, Randall and Tang returned to the pharmacy. When the inspectors arrived at approximately 10:30 a.m., they could not obtain access to respondent Pharmacy because the security gate was locked from the inside. Although the inspectors heard a radio, they could not find respondent Walker. Tang also called respondent Pharmacy but received no response. The inspectors waited for approximately one hour and fifteen

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 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.

² Code of Federal Regulations, title 21, section1304.11, requires a pharmacy to take a new inventory of all stocks of controlled substances on hand at least every two years.

³ California Code of Regulations, title 16, section 1707.5, subdivision (d), requires the pharmacy to have policies and procedures in place to help patients with limited or no English proficiency understand the information on drug labels. The regulation states, in pertinent part:

minutes before calling respondent Pharmacy again and received a busy signal. The inspectors then returned to respondent Pharmacy and found respondent Walker inside the pharmacy.

- 10. During the July 6, 2016 inspection, the inspectors found respondent Pharmacy to be in a condition substantially similar to the condition they found on June 16, 2016, as follows:
- A. Although respondent Walker had removed some of the trash bags that had obstructed the back door during the prior inspection, many trash bags were not removed such that the rear door remained obstructed. The inspectors were able to reach a file cabinet which had been previously completely blocked, but they could not open it because it was still partially blocked by the trash bags.
 - B. The bathroom appeared unchanged in condition from the prior inspection.
 - C. The unidentified substances remained on the floor.
- D. Insects, including spiders, were observed on the premises, along with spray poison and ant traps.
- E. The premises remained dirty, with dirt and dried liquids on inventory shelves and trash on the floor. There were boxes and bags of papers on the floor in the main pharmacy area.
- F. The prescription documents and records on the main pharmacy counter seemed unchanged from the prior inspection. The prescription documents were in no discernable order and prescription documents for Schedule II controlled substances were comingled with prescription documents for other schedules.⁴ Respondent Walker told the inspector that she was in the process of ordering a new document retrieval system, but admitted that it would be difficult to quickly retrieve pharmacy records for a particular patient or drug given the current disarray.
- 11. At the end of the July 6, 2017 inspection, Randall again gave a written inspection report to respondent Walker and orally reviewed the report with her. Both the written and oral directives required respondent Walker to provide photographs showing that respondent Pharmacy had been brought to a clean and orderly condition by July 8, 2016, and to provide a written statement or a plan, addressing any cleanliness issues she was unable to resolve, by the same date.

⁴ Code of Federal Regulations, title 21, section 1304.04, subdivision (h), requires a pharmacy to maintain inventories and records of all controlled substances listed in Schedule I and II separately from all other records of the pharmacy. Additionally, paper prescriptions for Schedule II controlled substances must be maintained in a separate prescription file.

- 12. On July 7, 2016, respondent sent Randall eleven photographs. These photographs are close-up shots of various areas of respondent Pharmacy, but it is impossible to discern from these photographs any changes in the pharmacy's condition. On August 2, 2016, respondent Walker sent an electronic mail message stating that she had disposed of the "confidential trash." However, she did not provide any written statement or plan addressing how she would correct all the deficiencies described above.
- 13. Randall wrote an Investigation Report, dated January 4, 2017, based on the events described above. At the administrative hearing, she testified consistently with the contents of the report.
- 14. At the administrative hearing, respondent Walker stipulated to all five causes for discipline alleged in the Accusation except for the fourth cause, failure to comply with requirements for storage of controlled substances. She claimed that she had maintained paper prescriptions for Schedule II controlled substances in a separate prescription file.

Prior Discipline

- 15. On May 6, 2010, the Board issued Administrative Citations No. CI 200944168 and No. CI 200940588 against respondents. The citations involved three separate violations. First, the Board cited respondents for violation of Professions Code section 4105, subdivision (a), failure to retain prescription records on the licensed premises in a retrievable form. This violation resulted in a \$250 fine. Second, the Board cited respondents for violation of California Code of Regulations, title 16, section 1761, subdivision (a), obtaining uncertain and erroneous prescriptions on the internet and dispensing the prescriptions to patients without insuring that the prescriptions had been authorized by the physicians. This violation resulted in a \$4,750 fine. Third, respondents were cited for violating Business and Professions Code section 4067, dispensing dangerous drugs or controlled substances based on internet prescriptions that were not issued pursuant to a good faith prior examination of the patients for which the medications were intended. This third violation, involving 2,092 internet prescriptions, resulted in a fine of \$52,300,000.
- 16. On March 14, 2012, following an administrative hearing, a Proposed Decision was issued reducing the total fines for both citations to \$55,050. On April 26, 2012, the Board adopted the Proposed Decision, effective May 28, 2012.

Evidence of Mitigation/Rehabilitation

- 17. Respondent Walker received her pharmacist license from the Pharmacy School at the University of Southern California in 1979. She has been continuously employed as a pharmacist since that time.
- 18. Respondent Walker testified that she had served her community for the past 23 years, but she experienced "burn out." She stated that will not be working as a pharmacist again, regardless of the outcome of this proceeding.

Cost Recovery

- 19. Complainant submitted evidence of the costs of investigation and enforcement of this matter, summarized as follows: 8.5 hours of legal services at rates ranging from \$120 to \$170 per hour for a subtotal of \$1,395; and 31 hours of investigative services at the rate of \$121 per hour for a subtotal of \$6,927.25. The total costs of investigation and enforcement of this matter are \$8,322.25.
- 20. Since the ISO was issued against respondent Pharmacy, respondent Walker has been unemployed. She receives \$760 monthly in social security income. Her monthly expenses include \$500 in rent, \$200 in food and gas, and \$108 in car insurance.

LEGAL CONCLUSIONS

- 1. The standard of proof for the Board to prevail on the Accusation is clear and convincing evidence to a reasonable certainty. (See *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.) Clear and convincing evidence requires proof that is so clear as to leave no substantial doubt and that is sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478, 487.)
- 2. First Cause for Discipline (Failure to Maintain Pharmacy in a Clean and Orderly Condition). Respondents are subject to disciplinary action, pursuant to Business and Professions Code section 4300 for unprofessional conduct, as defined in Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivisions (b) and (c). During the June 16, 2016 inspection, respondent Pharmacy's premises, fixtures, and equipment were found to be in a dirty and disorderly condition. Despite written and oral directives to correct these deficiencies, respondent Pharmacy's premises, fixtures, and equipment were found to be in substantially similar conditions during a second inspection on July 6, 2016. (Factual Findings 5, 7 to 14.)
- 3. Second Cause for Discipline (Failure to Comply with the Self-Assessment Form Requirement). Respondents are subject to disciplinary action, pursuant to Business and Professions Code section 4300 for unprofessional conduct, as defined in Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1715, subdivision (a), in that respondent Walker was unable to produce a current self-assessment form during the June 16, 2016 inspection. (Factual Finding 6A.)
- 4. Third Cause for Discipline (Failure to Comply with the Requirement to Provide Interpretive Services). Respondents are subject to disciplinary action, pursuant to Business and Professions Code section 4300 for unprofessional conduct, as defined in Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1707.5, subdivision (d). During the June 16,

2016 inspection, respondent Pharmacy did not have any signs or other means posted for a patient with limited English proficiency to identify his or her language. Respondent Walker admitted to having no ability to provide interpretation service and no policies or procedures to address the provision of such services. (Factual Finding 6C.)

- 5. Fourth Cause for Discipline (Failure to Comply with Requirements for Storage of Controlled Substances). Respondents are subject to disciplinary action, pursuant to Business and Professions Code section 4300 for unprofessional conduct, as defined in Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Code of Federal Regulations, title 21, section 1304.04, subdivision (h). Although respondent Walker denied this cause of discipline, she provided no evidence to support her contention that paper prescriptions for Schedule II controlled substances were kept in a separate file. Randall's credible testimony and her investigation report established that, during the July 6, 2016 inspection, respondent Pharmacy's prescription documents for Schedule II controlled substances were comingled with prescriptions for other schedules. (Factual Finding 10F.)
- 6. Fifth Cause for Discipline (Failure to Comply with Inventory Requirements for Controlled Substances). Respondents are subject to disciplinary action, pursuant to Business and Professions Code section 4300 for unprofessional conduct, as defined in Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Code of Federal Regulations, title 21, section 1304.11, in that respondent Pharmacy did not have a biennial inventory of controlled substances completed after September 23, 2013. (Factual Findings 6B.)
- 7. The Board's Disciplinary Guidelines (Rev. 10/2007) (Guidelines) set forth categories of violations and recommended penalties. Violations of Business and Professions section 4301, subdivisions (j) and (o), constituting unprofessional conduct that involves serious potential harm or greater disregard for pharmacy law and public safety, are Category II violations. The minimum penalty is revocation stayed and three years' probation. The maximum penalty is revocation.
- 8. The Guidelines specify that, in determining whether the minimum, maximum or an intermediate penalty is to be imposed in a given case, the following factors should be considered: (1) actual or potential harm to the public; (2) actual or potential harm to any consumer; (3) prior disciplinary record; (4) prior warnings; (5) number and or variety of current violations; (6) the nature and severity of the act(s) or offense(s), or crime(s); (7) aggravating evidence; (8) mitigating evidence; (9) rehabilitation evidence; (10) compliance with terms of any criminal sentence, parole, or probation; (11) overall criminal record; (12) if applicable, evidence of dismissal proceedings pursuant to section 1203.4 of the Penal Code; (13) the time that has elapsed since commission of the act(s) or offenses(s); (14) whether the conduct was intentional or negligent; and (15) financial benefit to the respondent from the misconduct. (Guidelines, p. 3.)
- 9. In respondents' case, although there was no evidence of actual harm to any patients, the potential harm of the violations were immense. Respondent Pharmacy was in

such a filthy and dirty state that the medications stored on the premises could have been contaminated. Prescriptions for dangerous controlled substances were disorganized and comingled with other types of prescription, thereby increasing the risk of dispensing the wrong medication. The fact that respondent Walker, as the sole owner and PIC of respondent Pharmacy, allowed it to fall into this state suggests that she lacks basic competence as a pharmacist. The nature of the misconduct in this case, therefore, is serious, and the number and variety of the violations are numerous and repeated. Even when prior warnings were given after the June 16, 2016 inspection, respondents failed to heed them by complying with Randall's oral and written directives. Respondents also have a prior record of discipline, with two prior citations. At the hearing, respondent Walker presented little rehabilitation evidence and showed no interest in retaining her individual pharmacist's license or the pharmacy permit for respondent Pharmacy. In light of these factors, the protection of public health, safety, and welfare requires the revocation of respondent Walker's individual pharmacist's license and respondent Pharmacy's pharmacy permit.

- 10. Because the discipline imposed on respondent Pharmacy's pharmacy permit is revocation, pursuant to Business and Professions Code section 4307, respondent Walker, as the individual licensed owner, shall be prohibited from serving as a manager, administrator, owner, member officer, director, associate, or partner of a Board licensee, until the pharmacy permit is reinstated.
- Under Business and Professions Code section 125.3, the Board may recover 11. costs "not to exceed the reasonable costs of the investigation and enforcement" of this matter. As set forth in Factual Finding 20, the costs claimed are \$8,322.25. In Zuckerman v. State Board of Chiropractic Examiners (2002) 29 Cal.4th 32, the Supreme Court rejected a constitutional challenge to a cost provision similar to Business and Professions Code section 125.3. In so doing, however, the Court directed the administrative law judge and the agency to evaluate several factors to ensure that the cost provision did not deter individuals from exercising their right to a hearing. Thus, an agency must not assess the full costs where it would unfairly penalize the respondent who has committed some misconduct, but who has used the hearing process to obtain the dismissal of some charges or a reduction in the severity of the penalty; the agency must consider a respondent's subjective good faith belief in the merits of his or her position and whether the respondent has raised a colorable challenge; the agency must consider a respondent's ability to pay; and the agency may not assess disproportionately large investigation and prosecution costs when it has conducted a disproportionately large investigation to prove that a respondent engaged in relatively innocuous misconduct. (Id. at p. 45).
- 12. In this case, as set forth in Factual Finding 20, respondent Walker relies on social security for her monthly income of \$760. Her monthly expenses include \$500 in rent. These circumstances warrant a 75 percent reduction in actual costs. Therefore, the reasonable costs of investigation and enforcement are \$2,080.56. Given the nature of the order below, it would be unnecessarily punitive to require respondents to pay the Board's costs at this time. However, it is reasonable to require respondents to pay the Board's costs

if respondent Walker's individual pharmacist's license and/or respondent Pharmacy's pharmacy permit are ever reinstated.

ORDER

- 1. Original Pharmacy Permit Number PHY 40552, issued to respondent Pharmacy, South Figueroa Drugs, is revoked. Respondent Toni Gayle Walker, as the owner respondent Pharmacy, shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent Walker shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five days of disposition.
- 2. Respondent Toni Gayle Walker is prohibited from serving as a manager, administer, owner, member, officer, associate or partner of a licensee until Original Pharmacy Permit PHY 40522 is reinstated.
- 3. Pharmacist License Number RPH 33235, issued to respondent Toni Gayle Walker is revoked. Respondent Walker shall relinquish her wall license and pocket renewal license to the board within 10 days of the effective date of this decision. Respondent Walker may not reapply or petition the board for reinstatement of her revoked license for three years from the effective date of this decision.
- 4. As a condition precedent to reinstatement of respondent Toni Gayle Walker's revoked license and/or respondent South Figueroa Drugs' pharmacy permit, respondents shall reimburse the board for its costs of investigation and prosecution in the amount of \$2,080.56. Said amount shall be paid in full prior to the reapplication or reinstatement of respondent Walker's license and/or respondent Pharmacy's pharmacy permit, unless otherwise ordered by the Board.

DATED: May 22, 2017

JI-LAN ZANG

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Administrative Law Judge
Office of Administrative Hearings

| | XAVIER BECERRA | | | |
|----------|---|--|--|--|
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| 7 | BEFORE THE BOARD OF PHARMACY | | | |
| 8 | DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA | | | |
| 9 | STATE OF C | ALIFORNIA | | |
| 10 | In the Matter of the Accusation Against: | Case No. 5879 | | |
| 11 | | | | |
| 12 | SOUTH FIGUEROA DRUGS, TONI GAYLE WALKER, Owner | ACCUSATION | | |
| 13 | 1503 W. Martin Luther King Jr. Blvd Los Angeles, CA 90062 | | | |
| 14 | | | | |
| 15 | Original Pharmacy Permit No. PHY 40552 | | | |
| 16 | AND | · | | |
| 17 | TONI GAYLE WALKER 1503 W. Martin Luther King Jr. Blvd. Los Angeles, CA 90062 | | | |
| 18 | Pharmacist License No. RPH 33235 | | | |
| 19 | | | | |
| 20 | Respondent. | | | |
| 21 | | · · | | |
| - 22 | | | | |
| 23 | <u>PARTIES</u> | | | |
| 24 25 | : | gs this Accusation solely in her official capacity | | |
| 25 | as the Executive Officer of the Board of Pharma | | | |
| 26 | | about November 23, 1994, the Board of | | |
| 27 | Pharmacy issued Original Pharmacy Permit Nu | | | |
| 28 | Drugs(Respondent Pharmacy). Toni Gayle Walker is and has been 100% owner, as an individua | | | |
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(SOUTH FIGUEROA DRUGS, TONI GAYLE WALKER) ACCUSATION

licensed owner, as well as Pharmacist-In-Charge of Respondent Pharmacy at all times since the permit was issued in 1994. The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2017, unless renewed.

3. Toni Gayle Walker - On or about August 20, 1979, the Board of Pharmacy issued Pharmacist License Number RPH 33235 to Toni Gayle Walker (Respondent Walker). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2019, unless renewed.

JURISDICTION

- 4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 5. Section 118, subdivision (b), of the Code provides that the suspension/expiration/surrender/cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.
 - 6. Section 4300 of the Code states:
 - "(a) Every license issued may be suspended or revoked.
- "(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - "(1) Suspending judgment.
 - "(2) Placing him or her upon probation.
 - "(3) Suspending his or her right to practice for a period not exceeding one year.
 - "(4) Revoking his or her license.
- "(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
- "(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is

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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.

8. Section 4307 of the Code states at sub-division (a) that:

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, or partner of any partnership, corporation, 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, or partner had knowledge or 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, or partner 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.
 - 9. Section 4105 of the Code states:
- "(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.
- "(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.
- "(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

- "(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.
- "(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.
- (2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter."
 - 10. Business and Professions Code section 4081 provides in pertinent 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 ... 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.
- (b) The owner, officer, and partner of a pharmacy ... shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section."
 - 11. California Code of Regulations, title 16, section 1707.5, provides in pertinent part:
- (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.
 - 12. California Code of Regulations, title 16, section 1714 provides:
- (a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to impatients of the hospital) shall contain an area which is suitable for confidential patient counseling.
- (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.
- (c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.
- (d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous

drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

- (e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.
- (f) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.
- (g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.
- 13. California Code of Regulations, title 16, section 1715. (Self-Assessment of a Pharmacy by the Pharmacist-in-Charge) provides:
- (a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
 - (1) A new pharmacy permit has been issued, or
- (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
 - (3) There is a change in the licensed location of a pharmacy to a new address.
- (c) The components of this assessment shall be on Form 17M-13 (Rev. 01/11) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on

Form 17M-14 (Rev. 01/11) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

- (d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.
 - 14. Code of Federal Regulations, title 21, section 1304.11 states in pertinent part:
- (b) Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (3) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.
- (c) After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.
- 15. Code of Federal Regulations, title 21, section 1304.04(h) states in pertinent part, that each registered pharmacy shall maintain the inventories and records of controlled substances as follows: (1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy. (2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescriptions file.

COST RECOVERY

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

FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

17. The following allegations are common to all causes for discipline in this matter:

A. Respondent South Figueroa Drugs (Respondent Pharmacy) is a small retail pharmacy in the city of Los Angeles, which Toni Gayle Walker has solely owned and operated as pharmacist-in-charge since 1994.

June 16, 2016 Inspection

- B. During a routine Board inspection on June 16, 2016, Board Inspectors observed and documented the following conditions at South Figueroa Pharmacy:
 - 1. Trash Bags Blocked Rear Door There were many trash bags piled in the back room. The pile of trash bags blocked the back door to the pharmacy and obstructed access to most of the back room, so that the Inspectors were not able to inspect the portion of the pharmacy blocked by the pile of trash bags. Respondent Walker stated the bags contained confidential HIPAA documents to be shredded.
 - 2. Insects The Inspector observed several insects in the pharmacy, including spiders, spider webs, gnats (particularly in the area where black trash bags were piled) and a large insect she believed was a cockroach.
 - 3. Trash and Clutter Piles of paperwork, boxes, and trash bags cluttered the aisles, partially blocking medication shelves and what appeared to be the dispensing counter.
 - 4. **Dust and Dirt** There was a thick layer of dirt or dust coating many of the pharmacy's medication inventory shelves. There was also a layer of dirt or dust on the right side of the counter in the main pharmacy area, on and surrounding a computer, which appeared unused. Additionally, there was a significant amount of dirt on a white plastic shelving unit in the main pharmacy area on a plastic set of drawers under the pharmacy counter.
 - 5. Reused Containers One of the drawers in the plastic set of drawers under the main counter contained empty prescription containers, possibly retained for re-use (prohibited under California Code of Regulations Section 1717 (a)).
 - 6. Collapsed Counter/ Disorganized Records The counter in the main pharmacy area was very cluttered with many unorganized prescription documents. The counter was also slanted downward. Respondent Walker stated the counter had collapsed and she was in the

process of reorganizing prescription documents that had fallen or become disorganized in the collapse. Many prescription documents were rubber banded in large stacks that did not seem to be in order by date or prescription number.

- 7. Unidentified Substance There was an unidentified brown and white substance on the floor adjacent to one of the pharmacy shelves.
- 8. Foul Order/Rotted Food There were two refrigerators in the pharmacy, one behind the front counter and one under the counter in the main pharmacy area. The refrigerator behind the front counter was full of food and had a strong foul odor when opened. Respondent Walker stated this refrigerator was not used for drug storage. The refrigerator under the counter in the main pharmacy area had a large block of ice frozen around the internal freezer. Respondent Walker stated the second refrigerator was used for drug storage.
- 9. **Foul Bathroom** The pharmacy bathroom was extremely unclean. The tank cover of the un-flushed toilet was off. There was a significant amount of crusted dirt in the bathroom sink. Water that flowed from the faucet was yellow in color.
- C. Respondent Walker was alone at the pharmacy during the inspection and advised Inspectors that Respondent Pharmacy had no other employees.
- D. Verbal and written instructions were given to Respondent Walker to correct deficiencies referenced above which were observed during the June 16, 2016 inspection and to clean up the pharmacy by June 30, 2016.
 - E. Additional violations observed during the June 16 inspection included the following:
 - 1. Respondent Pharmacy did not have, and/or Respondent Walker could not locate, a current self-assessment completed, per requirements of California Code of Regulations, title 16, section 1715(a)).
 - 2. Respondent Pharmacy did not have, and/or Respondent Walker could not locate, a biennial inventory of controlled substances completed after September 23, 2013 (per requirements of Code of Federal Regulations, title 21, section 1304.11).

- 3. Respondent Pharmacy did not have any policy or procedure in place to address the provision of interpretative services, a posted sign or other means to identify a patient's language, or the ability to provide translations services(per requirements of title 16, California Code of Regulations, section 1707.5(d)).
- 4. Respondents did not maintain inventories and records for all Schedule I and II controlled substances separately from all other records in the pharmacy; nor were paper prescriptions for Schedule II controlled substances maintained in a separate prescription file. Rather, Inspectors observed that prescription documents for Schedule II controlled substances were commingled with prescription documents for other schedules (violating requirements of Code of Federal Regulations, title 21, section 1304.04(h)).

July 6, 2016 Inspection

- F. On or about July 6, 2016, Board Inspectors returned to Respondent Pharmacy to determine whether the premises had been brought into compliance. However, Inspectors found the pharmacy premises in a *substantially similar condition*, and documented the following observations of the premises at that time:
 - 1. Trash Bags Blocking Back Door Respondent Walker stated she had removed some of the boxes and bags from the floor in the main pharmacy, and removed a portion of the black trash bags. However black bags *still* obstructed the rear door. Because a portion of the trash bags were removed from the back room, Inspectors were able to reach a file cabinet which had been previously completely blocked but could not open it because it was still partially obstructed by the filled trash bags.
 - 2. Bathroom The bathroom appeared unchanged from the previous inspection.
 - 3. Unidentified Substance There was still a pile of an unidentified substance on the floor adjacent to the inventory shelves.
 - 4. Insects The Inspector observed several spider webs, several ant traps, and two bottles of Raid Ant and Roach spray. There were also flat black insects in the internal freezer sections of the front refrigerator.
 - 5. Filthy Premises and Storage Areas One of the pharmacy's inventory shelves

contained dirt and what appeared to be dried liquid in a drop formation. The Inspector observed trash on the floor near Respondent Walker's desk including soda bottles. Some of the pharmacy's inventory shelves remained very dusty and dirty. There were still boxes and bags containing papers on the floor in the main pharmacy area. The Inspector also observed and photographed an unknown black substance in an upper corner of the pharmacy, which was directly overhead as she stood in the patient accessible entry area.

- 6. **Prescription Records on the Floor** The prescription documents and records on the main pharmacy counter seemed unchanged from the previous inspection. The Inspector also noticed several prescription documents were on the floor under the pharmacy counter.
- G. Inspectors provided written and verbal instructions to Respondent Walker at the time of the July 6, 2016 inspection including a written Inspection Report specifying items in need of correction. Respondent Walker was asked to provide photos to Inspectors showing that the pharmacy had been brought to a clean and orderly condition by July 8, 2016, and provide a written statement with a plan to promptly address any of the cleanliness issues she was unable to resolve by July 8, 2016.
- H. On or about July 7, 2016, Board Inspectors received a set of eleven (11) photographs from Respondents, which were not sufficient to show substantial changes or compliance. On or about August 2, 2016, Respondent Walker sent an electronic mail message stating she had disposed of "the confidential trash." However, no written statement or plan addressing all issues of concern identified in the Inspection Report was received prior to the filing of this accusation.

CAUSES FOR DISCIPLINE

FIRST CAUSE FOR DISCIPLINE

(Failed to Maintain Pharmacy in a Clean and Orderly Condition)

18. Respondent Pharmacy is subject to disciplinary action under Code section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1714 (b) and (c) as follows:

- A. June 16, 2016 During an inspection on June 16, 2016, Board Inspectors found that the fixtures and equipment on the pharmacy premises were not maintained in a clean and orderly condition.
- B. July 6, 2016 Despite specific instructions to remediate problems identified during the June 16, 2016 inspection, Respondent failed to provide documentation indicating she brought fixtures and equipment on the pharmacy premises into a clean and orderly condition.

SECOND CAUSE FOR DISCIPLINE

(Failed to Comply With Self Assessment Form Requirements)

19. Respondents Walker and Pharmacy are subject to disciplinary action under Code section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1715, subdivision (a) (which requires that a pharmacy must complete a new self-assessment form before July 1 or every odd numbered year) in that during a Board inspection on or about June 16, 2016, Respondents were unable to produce a current, properly completed self assessment form.

THIRD CAUSE FOR DISCIPLINE

(Failed to Comply With Requirement to Provide Interpretive Services)

20. Respondents Walker and Pharmacy are subject to disciplinary action under Code section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1707.5(d) (requiring the pharmacy to implement procedures to assist patients with limited English language proficiency) in that during a Board inspection on or about June 16, 2016, Respondents admitted that no policies or procedures were in place to address the provision of interpretative services, no sign or other means was used to identify a patient's language, and that Respondent had no ability to provide translations services.

FOURTH CAUSE FOR DISCIPLINE

(Failed to Comply With Requirements for Storage of Controlled Substance Records)

21. Respondent Pharmacy is subject to disciplinary action under Code section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with

Code of Federal Regulations, title 21, section 1304.04(h), in that Respondent did not maintain inventories and records for all Schedule I and II controlled substances separately from all other records in the pharmacy; nor were paper prescriptions for Schedule II controlled substances maintained in a separate prescription file. Rather, Inspectors observed that prescription documents for Schedule II controlled substances were comingled with prescription documents for other schedules.

FIFTH CAUSE FOR DISCIPLINE

(Failed to Comply With Inventory Requirements for Controlled Substances)

22... Respondents Walker and Pharmacy are subject to disciplinary action under Code section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Code of Federal Regulations, title 21, section 1304.11, in that Respondent Pharmacy did not have or could not locate, a biennial inventory of controlled substances completed after September 23, 2013.

OTHER MATTERS

- 23. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 40552 issued to South Figueroa Drugs, Toni Gayle Walker, as the individual licensed owner, 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 40552 is placed on probation or until Pharmacy Permit Number PHY 40552 is reinstated if it is revoked.
- 24. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
 Number PHY 40552 issued to South Figueroa Drugs, while Toni Gayle Walker has been the
 individual licensed owner, and had knowledge of or knowingly participated in any conduct for
 which the licensee was disciplined, she 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 40552 is placed on probation or until Pharmacy Permit Number
 PHY 40552 is reinstated if it is revoked.

DISCIPLINE CONSIDERATIONS

25. Prior Citation – Respondent Walker - On or about May 6, 2010 Administrative Citation/Assessment of Fine No. CI 2009 44168 was issued to Respondent Walker for violating codes and regulations as set forth below, resulting in the issuance of a fine exceeding \$52,300,000.00. The citation matter was resolved and is now final.

| Code/Regulation(s) Violated | Description |
|---|---|
| Business and Professions Code section 4067 | Internet dispensing without a prescription |
| California Code of Regulations, title 16, section 1761(a) | Dispensing pursuant to a prescription with significant error or omission |
| Business and Professions Code section 4105(a) | Failure to retain prescription records on the licensed premises in a retrievable form |

26. Prior Citation – Respondent South Figueroa Drugs – On or about May 6, 2010 Administrative Citation/Assessment of Fine No. CI 2009 40588 was issued to Respondent South Figueroa Drugs for violating codes and regulations as set forth below, resulting in the issuance of a fine exceeding \$52,305,000. The citation matter was resolved and is now final

| Code/Regulation(s) Violated | Description |
|---|---|
| Business and Professions Code section 4067 | Internet dispensing without a prescription |
| California Code of Regulations, title 16, section 1761(a) | Dispensing pursuant to a prescription with significant error or omission |
| Business and Professions Code section 4105(a) | Failure to retain prescription records on the licensed premises in a retrievable form |

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:

- 1. Revoking or suspending Original Pharmacy Permit Number PHY 40552, issued to South Figueroa Drugs, Toni Gayle Walker, Owner;
- 2. Revoking or suspending Pharmacist License Number RPH 33235, issued to Toni Gayle Walker;

(SOUTH FIGUEROA DRUGS, TONI GAYLE WALKER) ACCUSATION