AGREED BOARD ORDER #H-15-041-B

RE: IN THE MATTER OF CVS/PHARMACY #7198 (PHARMACY LICENSE #24503) BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 24503 issued to CVS/pharmacy #7198 (Respondent), 3811 Old Spanish Trail, Houston, Texas 77021.

By letter dated September 8, 2015, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 551.003(26); 565.001(a)(1), (2), (12) and (13); and 565.002(a)(3), (8), (9) and (12) of the Texas Pharmacy Act, Tex. Occ. CODE ANN. Title 3, Subtitle J (2013);

Sections 281.2(8); 281.7(a)(12) and (13); 281.8(a)(2); 291.31(1), (16), (17), (18) and (33); 291.32(a)(2)(H); 291.32(b)(2); 291.32(c)(1)(E) and (F); 291.32(c)(2)(B), (D) and (E); 291.33(c)(1)(A) and (B); and 295.3 of the Texas Pharmacy Board Rules, 22 Tex. ADMIN. CODE (2014);

Section 481.067 of the Texas Food, Drug, and Cosmetic Act, Tex. Health & SAFETY CODE ANN. (2013); and

Sections 13.182(a) and 13.202(c) of the Texas Controlled Substances Rules, 37 Tex. ADMIN. CODE ANN. Part 1 (2014), in that allegedly:

PREVIOUS HISTORY

- (1) On or about November 18, 2008, the Texas State Board of Pharmacy entered Agreed Board Order #B-07-026 in the matter of CVS/pharmacy #7198. The Order was based on allegations of audit shortages of alprazolam 2mg tablets over a period of 21 months, totaling 44,811 dosage units. The Order imposed a \$5,000 penalty and required the pharmacy to implement policies and procedures to detect shortages and prevent theft and loss of controlled substances.
- (2) On or about June 7, 2011, the Texas State Board of Pharmacy entered Agreed Board Order #H-10-050 in the matter of CVS/pharmacy #7198. The Order was based on allegations of audit shortages of hydrocodone/APAP 10 mg tablets and alprazolam 2mg tablets over a period of 12 months, totaling 40,080 dosage units, and allegations that a refill of a prescription for 90 Norvasc 10 mg tablets were dispensed two times without the

- authorization of the prescriber. The Order imposed a two-year probation, a \$4,000 administrative penalty, and required the pharmacy to implement a Continuous Quality Improvement Program.
- (3) On or about November 4, 2014, the Texas State Board of Pharmacy entered Agreed Board Order #H-13-061-B in the matter of CVS/pharmacy #7198. The Order was based on allegations that, while subject to the probationary period imposed by Agreed Board Order #H-10-050, six prescriptions were erroneously dispensed to an incorrect patient as a result of incorrectly verifying data entry, and allegations that the pharmacy failed to keep records of the errors. The Order imposed a two-year probation, a \$3,000 penalty, and required the pharmacy to implement a Continuous Quality Improvement Program.
- (4) On or about May 5, 2015, the Texas State Board of Pharmacy entered Agreed Board Order #H-15-005-B in the matter of CVS/pharmacy #7198. The Order was based on allegations that atenolol 100 mg tablets were erroneously dispensed on a partial fill of a prescription calling for azilsartan 80 mg tablets. The Order superseded Agreed Board Order #H-13-061-B, and imposed a two-year probation and required the pharmacy to implement of a Continuous Quality Control Program.

COUNTS

- (1) On or about May 2, 2013, through on or about May 1, 2014, CVS/pharmacy #7198, 3811 Old Spanish Trail, Houston, Texas 77021, failed to maintain complete and accurate records of purchases and disposals of 7,213 hydrocodone 10/650 mg tablets (-10.59%). Hydrocodone is a controlled substance listed in the Texas Controlled Substances Act: Hydrocodone.
- (2) On or about May 2, 2013, through on or about May 1, 2014, CVS/pharmacy #7198, 3811 Old Spanish Trail, Houston, Texas 77021, failed to maintain complete and accurate records of purchases and disposals of 3,070 diazepam 10 mg tablets (-22.45%). Diazepam is a controlled substance listed in the Texas Controlled Substances Act: Diazepam.
- (3) The audit shortages described above in Counts (1) and (2) reflect that CVS/pharmacy #7198, 3811 Old Spanish Trail, Houston, Texas 77021, failed to establish and maintain effective controls against the diversion and loss of controlled substances.
- (4) On or about July 28, 2014, Harsh Vardhan, while acting as an employee (pharmacist-in-charge) of CVS/pharmacy #7198, 3811 Old Spanish Trail, Houston, Texas 77021, dispensed oxcarbazepine 600 mg tablets to patient D.J. on a new electronic prescription calling for oxaprozin 600 mg tablets. The prescription vial was labeled 60 oxcarbazepine 600 mg tablets with directions to "take 1 tablet by mouth twice a day." Patient D.J. took three doses of the wrong drug and experienced adverse effects, including feeling dizzy and tired. The prescription was assigned number 1231370.

(5) On or about July 28, 2014, Harsh Vardhan, while acting as an employee (pharmacist-in-charge) of CVS/pharmacy #7198, 3811 Old Spanish Trail, Houston, Texas 77021, failed to provide verbal patient counseling to patient D.J. on the prescription described above in Count (4).

An informal conference was held in the Board's office on October 7, 2015, with Roger Francis, Area Vice President, CVS Health; James T. Greer, Area Loss Prevention Director, CVS Health; Rosamaend Oglesbee, Regional Diversion Manager, CVS Health; Roger Patatanian, Pharmacy Supervisor, CVS Health; and Carol P. Geisler, Legal Counsel-Healthcare Services, CVS Health, Legal Counsel for Respondent, in attendance. The informal conference was heard by a Board panel comprised of: Phyllis A. Stine, Board Member; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin Arnold, General Counsel. Tyler Vance, Staff Attorney, was also in attendance.

By appearing at the informal conference and by signing this Order, Respondent's counsel neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

- (1) Effective thirty days (30) the entry of this Order, Agreed Board Order #H-15-005-B, entered on May 5, 2015, shall be set aside and be of no further force and effect, and this Order shall supersede Agreed Board Order #H-15-005-B.
- (2) Respondent's license shall be placed on probation for a period of three (3) years, with such period to commence thirty (30) days after the entry of this Order. During the period of probation, Respondent shall abide by the terms of this Order, and shall not violate any pharmacy or drug statute or rule of this state, another state, or the United States with respect to pharmacy, controlled substances, and dangerous drugs.
- (3) Respondent shall pay a probation fee of one thousand two hundred dollars (\$1,200) due one hundred twenty (120) days after the entry of this Order.

- (4) Respondent shall pay an administrative penalty of sixteen thousand five hundred dollars (\$16,500) due one hundred twenty (120) days after the entry of this Order.
- (5) During the period of probation described above, Respondent shall employ a pharmacist approved by Board staff to serve as a management consultant to conduct quarterly visits and submit quarterly audit reports confirming compliance with the requirements of this Order and the laws and rules governing the practice of pharmacy. Respondent shall authorize and ensure that the consultant provides a written quarterly report within fifteen (15) days of the end of the quarter as designated by Board staff. Respondent shall not hold any individual providing reports in good faith liable in any manner for the contents of such reports. Upon written request, modification of this requirement may be determined by Board staff.
- (6) During the period of probation described above, Respondent shall continue the Continuous Quality Improvement Program as set forth in Agreed Board Order #H-15-005-B, entered on May 5, 2015.
- (7) Respondent shall be responsible for all costs relating to compliance with the requirements of this Order.
- (8) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.
- (9) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, Tex. Occ. Code Ann., Title 3, Subtitle J (2015), and Texas Pharmacy Board Rules, 22 Tex. ADMIN. Code (2015).

| Agreed Board Order #H-13-041-B CVS/pharmacy #7198 Page 5 | |
|----------------------------------------------------------------|--|
| And it is so ORDERED. | |
| THIS ORDER IS A PUBLIC RECORD. | |

MEMBER, DEXAS STATE BOARD OF PHARMACY

SIGNED AND ENTERED ON THIS 2nd day of February , 2016

| ATTEST: | | |
|-------------|----------------------------------------|--|
| | 12/1 | |
| | 136/01/6 | |
| | 2018/18/ | |
| Gay Dodson | n, R.Ph., Executive Director/Secretary | |
| Texas State | Board of Pharmacy | |

APPROVED AS TO FORM AND AGREED TO:

Carol P. Geisler, Legal Counsel - Healthcare Services
For and on behalf of CVS/pharmacy #7198
CVS Health
2211 Sanders Road
Northbrook, Illinois 60062

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel Texas State Board of Pharmacy