AGREED BOARD ORDER #H-11-079-B

RE: IN THE MATTER OF
CVS/PHARMACY #7222
(PHARMACY LICENSE #24504)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy the matter of pharmacy license number 24504 issued to CVS/pharmacy #7222, 4131 Aldine Mail Rte., Houston, Texas 77039.

By letter dated January 5, 2012, the Texas State Board of Pharmacy gave preliminary notice to CVS/pharmacy #7222 of its intent to take disciplinary action with respect to pharmacy license number 24504 issued to CVS/pharmacy #7222. This action was taken as a result of an investigation which produced evidence indicating that CVS/pharmacy #7222 may have violated:

Section 565.001(a)(1), (2), (12) and (13); and Section 565.002(a)(3) and (6) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Subtitle J (2009);

Section 281.7(a)(12), (13) and (29)(A); Section 281.8(b)(4)(A); Section 291.31(1), (14) and (15); Section 291.32(c)(1)(E) and (F); Section 291.32(c)(2)(B), (C) and (D); Section 291.33(c)(7)(A)(iii) and (iv); Section 291.33(c)(7)(C); Section 291.34(c)(3)(D) and (O); and Section 295.3(b) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2010); and

Section 431.003; Section 431.021(a), (b) and (r); and Section 431.112(a)(1) of the Texas Food Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. (2009), in that, allegedly:

PREVIOUS HISTORY

On or about March 14, 2008, the Texas State Board of Pharmacy informed CVS/pharmacy #7222 of its investigation of a complaint alleging that on two separate occasions, two different patients received a refill of a prescription containing the correct medication but labeled with the name of a different drug for another patient. No disciplinary action was taken with regard to this matter.
COUNTS

(1) On or about September 1, 2010, Chukwuma Ikenna Okafor, while acting as an employee (staff pharmacist) of CVS/pharmacy #7222, 4131 Aldine Mail Rte., Houston, Texas 77039, dispensed zolpidem 10 mg tablets to patient A.B. on a refill of a prescription calling for lisinopril 40 mg tablets. The prescription vial was labeled lisinopril 40 mg tablets with directions to “take 1 tablet by mouth every day.” On September 9, 2010, patient A.B. took the incorrect drug and experienced adverse effects, resulting in an accident while operating a motor vehicle that caused the death of a passenger. The prescription was assigned prescription number 710691.

(2) On or about September 1, 2010, CVS/pharmacy #7222, 4131 Aldine Mail Rte., Houston, Texas 77039, failed to keep complete and accurate records of dispensing for the prescription described above in Count (1), in that the pharmacy’s records contain the following discrepancies:
   a. The patient’s medication profile indicates that the prescription was filled on September 1, 2010, when the prescription vial dispensed to the patient and other pharmacy records indicate that the prescription was filled on September 2, 2010;
   b. The patient’s medication profile indicates the name of a pharmacist different than the pharmacist named on the prescription vial as the dispensing pharmacist; and
   c. The patient’s medication profile inaccurately reflects the patient’s gender.

This case was initiated following the receipt of a Professional Liability Claim Report Form received by the Texas State Board of Pharmacy.

An informal conference was held in the office of the Texas State Board of Pharmacy on March 6, 2012, with Chukwuma Ikenna Okafor, R.Ph.; May Utti, R.Ph., Pharmacy Supervisor for CVS/pharmacy; and Nanette K. Beaird, Legal Counsel for CVS/pharmacy #7222, in attendance. The informal conference was heard by a Board panel comprised of: W. Benjamin Fry, R.Ph., Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin E. Arnold, General Counsel. Caroline K. Hotchkiss, Staff Attorney, was also in attendance.
At the aforementioned conference, Nanette K. Beaird stated she was present for and on behalf of CVS/pharmacy #7222. By Ms. Beaird’s appearance at the informal conference and by her signature on this Order, Nanette K. Beaird agrees that the Texas State Board of Pharmacy has jurisdiction in this matter and does hereby waive the right to notice of hearing, to a formal administrative hearing, and to judicial review of this Order.

After discussion of the matters previously outlined in this Order, and subsequent communications, Nanette K. Beaird, on behalf of CVS/pharmacy #7222, agreed to the entry of an Order disposing of the need for further disciplinary action in this matter. By her signature on this Order, Nanette K. Beaird neither admits nor denies the truth of the matters previously set out in this Order with respect to the above alleged violations.

Should this Order not be accepted by the Board, it is agreed that neither the presentation of the Order to the Board nor the Board’s consideration of the Order, will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participation in proceedings related to the matters set forth in the Order.

Nanette K. Beaird, on behalf of CVS/pharmacy #7222, understands that any failure to comply with the terms of this Order is a basis for discipline under the Texas Pharmacy Act.

At the conclusion of the aforementioned conference, and subsequent communications, it was agreed among the parties that CVS/pharmacy #7222 shall comply with the terms and conditions set forth in the ORDER OF THE BOARD below.
ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Texas State Board of Pharmacy (hereinafter referred to as "BOARD") does hereby ORDER that pharmacy license number 24504 held by CVS/pharmacy #7222 (hereinafter referred to as "Respondent") shall be, and such license is hereby suspended for a period of two (2) years, with such period to commence thirty (30) days after the entry of this Order. It is further ORDERED that such suspension be probated under the conditions that Respondent abide by and obey the terms of this Order, all Federal laws and laws of the State of Texas with respect to pharmacy, controlled substances, dangerous drugs, and all rules and regulations adopted pursuant to the above-mentioned statutes.

It is further ORDERED that Respondent shall pay a probation fee of one thousand two hundred dollars ($1,200). This probation fee is due ninety (90) days after the entry of this Order.

It is further ORDERED that Respondent shall develop and implement policies and procedures for a Continuous Quality Improvement Program for purposes of preventing and handling dispensing errors. The Continuous Quality Improvement Program shall include pharmacist peer review in compliance with guidelines approved by the BOARD. In addition, the policies and procedures for pharmacist peer review shall state that:

(1) The peer review committee will:
   • review incident reports;
   • determine what caused errors;
   • make recommendations to correct the problem that caused the errors; and
   • monitor the changes to determine if the changes have improved the operation of Respondent and reduced errors.
The peer review committee must be comprised of at least two employees of Respondent, including the pharmacist-in-charge and other pharmacist(s) or personnel who are employees of Respondent. The committee shall not be solely comprised of a district or regional manager/supervisor and the pharmacist-in-charge and shall not be used for personnel evaluation purposes.

The peer review committee will meet regularly, and no less than quarterly.

The peer review committee will make a record indicating:
- date of meeting
- location of meeting
- names of persons attending the meeting
- description of activities
- discussion of problems in Respondent’s operation (e.g., work flow, dispensing process)
- findings
- description of recommendations; and
- review of actions or changes relating to individuals, systems, or processes made as a result of previous recommendations.

Respondent shall submit a report and/or documentation of such policies and procedures to the BOARD, Enforcement Division, within ninety (90) days after the entry of this Order. Copies of forms used by Respondent to collect the data on errors committed at the pharmacy (i.e., incident report forms) must be submitted to the BOARD, as well as any other peer review forms that have been developed by Respondent. Additionally, records of the peer review committee, as described in subparagraph (4) above, shall be maintained for two (2) years at the location of Respondent and made available for inspection by BOARD employees.

It is further ORDERED that any cost associated with compliance with the terms of this Order shall be the responsibility of Respondent.
It is further ORDERED that Respondent shall allow the staff of the BOARD, Enforcement Division, to directly contact Respondent on any matter regarding the enforcement of this Order.

It is finally ORDERED that failure to comply with any of the terms and conditions in this Order constitutes a violation and shall be grounds for further disciplinary action against the Texas pharmacy license held by Respondent.
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And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 8th day of May, 2012.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Nanette K. Beaird, Legal Counsel for CVS/pharmacy #7222
Gardere Wynne Sewell, LLP
600 Congress Avenue, Suite 3000
Austin, Texas 78701

APPROVED AS TO FORM:

Karstin E. Arnold, General Counsel
Texas State Board of Pharmacy