

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matters of)
CVS/pharmacy # 220)
264 East Main Street)
Marlboro, Massachusetts)
Registration No. 17722)
_____)

Docket Nos. DS-08-009
DS-07-055

ORDER OF PROBATION

The **Board of Registration in Pharmacy** (Board) and **CVS/pharmacy** (Registrant), a subsidiary of CVS Corporation (now CVS/Caremark), with corporate headquarters located at One CVS Drive in Woonsocket, Rhode Island, entered into that certain Agreement with the Board dated February 9, 2006 (Agreement) in resolution of certain complaints pending before the Board regarding Registrant, the complaint docket numbers being listed on Exhibit A attached to the Agreement.

Pursuant to Paragraphs 1. and 3. of the Agreement, Registrant's non-compliance with any Agreement term constitutes sufficient grounds for the Board to place the registration of the pharmacy where the conduct or violations occurred on **PROBATIONARY STATUS**, without the requirement of further proceedings pursuant to Mass. Genl. Laws c. 30A, for a minimum period of one year with terms and conditions to be determined by the Board.

A. STATEMENT OF ALLEGATIONS

1. CVS/pharmacy # 220 is licensed by the Board (Registration No. 17722) to operate as a pharmacy at 264 East Main Street in Marlboro, Massachusetts (Pharmacy).
2. At all times relevant to these proceedings and continuing as the date of this Order, a pharmacist (MP) acted as the pharmacist Manager of Record of the Pharmacy, pursuant to Mass. Genl. Laws. c. 112, s. 39 and Board regulation 247 CMR 6.07.
3. Commencing on or about February 7, 2005, Registrant employed an individual (FG) to perform pharmacy technician duties at the Pharmacy.
4. On March 14, 2007, a quality related event (QRE) occurred at the Pharmacy (Complaint Docket No. DS 07 055 received by the Board on April 5, 2007).

5. The Board requested a response to Complaint No. DS 07 055 by letter to MP dated April 25, 2007.
6. On May 8, 2007, the Board received a response to Complaint No. DS 07 055 that included a statement (unsigned/undated) from CVS pharmacist JH (signed Statement provided on June 15, 2007), with attached document identifying FG as the individual performing the "data entry" involved in the QRE. JH was working at the Pharmacy on March 17, 2007 and spoke with the patient's representative by telephone on that date when the patient's representative contacted the Pharmacy after discovering the QRE. According to the May 23, 2007 Statement of the verifying pharmacist (PF): "[T]he prescription was entered into the computer system by technician [FG]."
7. On or about June 15, 2007, a Board investigator telephoned MP and inquired as to the registration status of FG since Board records did not reflect FG to be registered by the Board as a pharmacy technician as of that date.
8. Later in the day on June 15, 2007, MP advised the Board investigator that FG had worked 2763 hours at the Pharmacy and that as of June 15, 2007, FG "is being removed from the pharmacy until she is certified with the state." (MP June 15, 2007 Statement faxed to the Board investigator on June 15, 2007)
9. According to a letter (undated; received on July 6, 2007) to the Board Investigator from the Pharmacy Supervisor of the Pharmacy (AM), FG worked 2,760 hours in the Pharmacy and "failed to get state licensed."
10. As of June 15, 2007, FG had never been registered by the Board as a pharmacy technician or applied to the Board for registration as a pharmacy technician.
11. An individual may act and be designated as a pharmacy technician trainee for NOT more than 1000 hours, pursuant to Board regulation 247 CMR 8.03(3).
12. No person may act as a pharmacy technician without being so registered by the Board, pursuant to Mass. Genl. Laws. c. 112, s. 24E.
13. The performance of pharmacy technician trainee duties by FG for a period of approximately 2760 hours grossly exceeded the 1000 hour pharmacy technician trainee limitation of Board regulation 247 CMR 8.03(3).

14. As set forth in Board regulations 247 CMR 6.07(1)(d) through 6.07(1)(g), the responsibilities of a pharmacist MOR include:

(d) the establishment, monitoring and enforcement of policies and procedures which encourage acceptable standards of practice consistent with Board regulations at 247 CMR 2.00 et seq., and all other applicable state and federal regulations;

(e) the establishment, monitoring and enforcement of policies and procedures which maintain the standards of professional practice as such standards relate to the dispensing of pharmaceuticals, including proper supervision of technicians, and the delegation of authority to another pharmacist when not on duty;

(f) the maintenance of adequate staff in the pharmacy or pharmacy department in order to ensure that the practice of pharmacy shall be carried out in accordance with Board regulations at 247 CMR 2.00 et seq. and all other applicable state and federal regulations; and

(g) the maintenance of records relating to the responsibilities of pharmacy technicians as outlined in 247 CMR 8.02(6).

15. On July 24, 2007, Board investigators conducted an on-site inspection of the Pharmacy (the Inspection) and observed five pharmacy support personnel performing pharmacy services in the Pharmacy under the supervision of one pharmacist. Specifically, one pharmacy intern (VD), two pharmacy technicians (BM and KM), and two pharmacy technician trainees (PN and SB) were observed to be performing pharmacist support services under the supervision of one pharmacist (MP). The ratio of one pharmacist to five support personnel (1:5) exceeds the pharmacy support personnel supervisory ratios that may be utilized by a pharmacist, in violation of the pharmacy support personnel ratio requirements required per Board Regulation 247 CMR 8.06(3)(a).

16. During the Inspection, Board investigators interviewed an individual in the Pharmacy ("Pharmacy Trainer" BL) who stated he was responsible for the training of pharmacy technicians, pharmacy technician trainees and interns at fourteen (14) district pharmacies. BL stated he had developed an electronic spreadsheet to track training data. BL stated various individuals had acted as "Pharmacy Trainers" of the Pharmacy prior to his January 2006 hire date and during a subsequent four month period when he worked for Registrant in California. BL had not included FG on his spreadsheet.

17. During the Inspection, Board investigators interviewed FG, who was working in a non-pharmacy position. FG stated that she wore a name badge identifying

her as a "Pharmacy Associate" during her employment in the Pharmacy performing pharmacy technician trainee duties.

18. A pharmacy technician trainee is required to wear a name tag with the individual's name and the title "Pharmacy Technician Trainee", in accordance with Board regulation 247 CMR 8.03(2)(a).

B. AGREEMENT TERMS

In accordance with the terms of the Agreement:

1. By March 9, 2006, managers of record for each of Registrant's pharmacies, together with appropriate CVS management, were required to have commenced monthly reviews of pharmacy staffing to insure compliance with 247 CMR 8.06 (Par.2.c.(2)(d)/Agreement p.6);
2. By March 9, 2006, Registrant was required to have commenced quarterly meetings of pharmacy personnel at each pharmacy for the purpose of reviewing medication error incidents, including root cause analysis findings (Par. 2.c.(2)(e)/Agreement p.6);
3. By May 9, 2006, Registrant was required to have developed and presented an in-service training at each pharmacy in the Commonwealth on various topics to all pharmacists, pharmacy interns and pharmacy technicians, with appropriate and timely written assessment of comprehension and compliance by pharmacists, pharmacy interns and pharmacy technicians by Registrant with records of such training and assessment to be maintained by Registrant; including the specific topic: "Pharmacy practice and proper delegation of pharmacy duties and responsibilities to support personnel in compliance with the Supervisory requirements of 247 CMR 8.06(3)" (Par. 2.c.(3)(a)(ii)/Agreement p.7); and
4. By May 9, 2006, Registrant was required to have conducted an on-site visit of each pharmacy in the Commonwealth and pharmacy supervisors were to have conducted an "Every Visit Review" (EVR) evaluation for each pharmacy; which evaluations were to be conducted monthly and include verification of licensure status; specifically, Registrant's EVR evaluation forms were expected to include the verification to the effect: "Are all Support Staff appropriately Licensed, Certified or Registered if required by State Regulations ?" (Par. 2.d./Agreement p.7).

The terms of the Agreement clearly identify pharmacy personnel training, pharmacy staffing oversight, and regulatory compliance monitoring as crucial areas of concern regarding Registrant's operation of pharmacies in the Commonwealth. In addition to the specific requirements set forth above, the Agreement also required Registrant to engage the Institute for Safe Medication Practices (ISMP) to evaluate Registrant's policies and procedures in these specific areas; assess the implementation and ongoing compliance of

Registrant's pharmacies with Registrant's policies and procedures; and make recommendations to Registrant for improvements to existing policies, procedures and training programs. Registrant is required to implement ISMP recommendations as set forth in the Agreement.

The Board's purpose in requiring the monthly and quarterly meetings, staff trainings, on-site visits, monthly EVR evaluations, and ISMP assessment, as mandated by the Agreement, was intended to insure regulatory compliance at all pharmacies regarding Registrant's pharmacy staffing practices, a main area of Board concern. Registrant's employment of a non-licensed individual to perform pharmacy technician services for this extended period of time without detection by Registrant constitutes grounds for the Board to act regarding the Pharmacy pursuant to Paragraph 3. of the Agreement.

C. ORDER

The monthly EVR process utilized by Registrant failed to identify an unregistered individual over the approximately eighteen month period since the date the Agreement was executed by Registrant and the Board. As noted, FG began employment with Registrant performing pharmacy technician trainee duties almost a year prior to the date of the Agreement. FG would likely already have been employed in excess of the 1000 hour maximum regulatory limit as of the date of the Agreement. Neither the MOR nor any pharmacy supervisor or any employee as acting as "Pharmacy Trainer" assigned to the Pharmacy during FG's employment apparently was charged with the specific duty of verifying FG's registration status over the lengthy period FG provided pharmacy support services in the Pharmacy. The exact roles and reporting responsibilities of the MOR, pharmacy supervisor, and "pharmacy trainer" in this matter were not apparent and not effective in overseeing compliance in an area of crucial importance to quality assurance and patient safety.

The pharmacy operations described herein underscore the Board's continuing concerns as to the implementation, effectiveness and adequacy of Registrant's compliance monitoring programs in achieving uniform practice standards and ensuring regulatory compliance in its operations of pharmacies in the Commonwealth. The observed variations in pharmacy supervisor monitoring of pharmacy operations in general and pharmacy staffing in particular and lack of apparent responsibility of the MOR at each pharmacy regarding pharmacy personnel regulatory compliance raise issues as to the adequacy and effectiveness of Registrant's EVR process. The employment of a non-registered individual functioning as a pharmacy technician trainee without detection by the Pharmacy MOR, any pharmacy supervisor overseeing the Pharmacy, or any other person employed by Registrant with assigned oversight responsibility over the approximately two and a half year period of FG's employment at any time prior to the date the Board investigator advised Registrant of FG's unlicensed status highlights shortcomings in Registrant's EVR supervisory evaluation process and current corporate compliance program in general.

Pursuant to Paragraphs 1. and 3. of the Agreement, based on the conduct and operations of the Pharmacy in employing FG to perform pharmacy technician trainee duties at the Pharmacy for approximately 2,760 hours during the period from on or about February 7, 2005 (such employment the Board notes commenced approximately twelve months prior to the February 9, 2006 date of the Agreement) and continuing through June 15, 2007 (the date on which the Board Investigator inquired as to the licensure status of FG), without being registered by the Board as a pharmacy technician, in accordance with Mass. Genl. Laws. c. 112, ss. 24C and 24E; 247.CMR 8.02 and 8.03; the Board hereby places the Pharmacy (Registration No. 17722) on **PROBATIONARY STATUS** for a minimum twelve-month period, effective as of the Date of this Order (Probation Period).

The Board hereby ORDERS:

1. Within ten (10) days of the Date of this Order, the Pharmacy must file an application (*Change of Manager*) for a replacement MOR with the Board; and
2. Within fifteen (15) days of the Date of this Order, Registrant must develop a compliance monitoring program with specific focus on corporate compliance monitoring of training and licensure/registration status of all pharmacy personnel. Within forty-five (45) days of the Date of this Order, Registrant shall implement the compliance program and submit a report to the Board detailing the implementation of the program at each pharmacy in the Commonwealth, such report to include specific titles of responsible individuals, MOR responsibilities (per Mass. Genl. Laws c. 112, s. 39 and 247 CMR 6.01 and 6.07), and specific actions required and by whom (title) when non-compliance is identified.

The Board will not review any petition for termination of the Probation Period filed sooner than twelve months from the date of this Order. As a condition precedent to the filing of any petition for termination of the Probation Period, the Pharmacy MOR, pharmacy supervisor(s) and any other Pharmacy representatives deemed appropriate by the Board may be required to appear before the Board regarding any such petition.

On September 18, 2007, the Board voted in favor of a motion to issue this **Order of Probation** by the following vote: In Favor: George A. Cayer, R.Ph., Joel R. Berman, R.Ph., William Gouveia, R.Ph., M.S., Michael Tocco, R.Ph., M.Ed., Kathy J. Fabiszewski, Ph.D., N.P., Donald D. Accetta, M.D., Marilyn Barron, M.S.W., Public Member, and Steven Budish, Public Member. Opposed: None. Abstained: None. Recused: James T. DeVita, R.Ph. Absent: Karen Ryle, R.Ph., M.S. and Sophia Pasedis, Pharm.D.

RIGHT TO APPEAL

Registrant is hereby notified of the right to appeal this Order, pursuant to G.L. c. 112, s. 64 and G.L. c. 30A, ss. 14 and 15, within thirty (30) days of receipt of this Order.

BOARD OF REGISTRATION
IN PHARMACY

By: 

Sophia Pasedis, R.Ph., Pharm.D.
President Elect

Date: September 19, 2007

DECISION ID NO 1635