## COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY	BOARD OF REGISTRATION IN PHARMACY
In the Matter of CVS/pharmacy ) Store #'s 2162, 838, 1873 & 1251 ) MA Reg. Nos. 2687, 2786, 2880 ) & 3422 )	Docket Nos. DS-06-146 DS-06-155 DS-07-007 DS-08-017 DS-08-024 DS-08-027

## CONSENT AGREEMENT

This Consent Agreement is entered into by and among the Board of Registration in Pharmacy (Board), CVS Pharmacy, Inc. (CVS) and CVS/pharmacy #2162 located at 300 Longwood Avenue, Boston, Massachusetts (Registrant no. 2687), CVS/pharmacy #838, located at 427 East Main Street, Westfield, Massachusetts (Registrant no. 2786), CVS/pharmacy #1873, located at 435 West Central Street, Franklin, Massachusetts (Registrant No. 2880), CVS/pharmacy #1251, located at 842 S. Franklin Street, Holbrook, Massachusetts (Registrant no. 3422) (collectively, Registrants). The Board, CVS and the Registrants do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the file of Registrants which is maintained by the Board:

- 1. The parties enter into this Consent Agreement (Agreement) in order to resolve complaints pending against Registrants before the Board as Docket Nos. DS-06-155, DS-06-146, DS-07-007, DS-08-017, DS-08-024, and DS-08-027 (Complaints).
- 2. Registrant No. 2687 acknowledges that on May 2 and May 8, 2006, Board investigators visited Registrant No. 2687 and observed multiple pharmacy practices and conditions that were non-compliant with the requirements of M.G.L. c. 112, § 39; 247 CMR 6.03(1) and 9.01(3); and United States Pharmacopoeia (USP) Standards 795 and 797.
- 3. Registrant No. 2687 acknowledges the occurrence of medication errors, specifically:
  - a. On or about April 26, 2006, Registrant No. 2687 improperly filled prescriptions for a pediatric patient by dispensing:
    - two vials of Humulin R 100 units/ml instead of two vials of Humulin N 100 units/ml as prescribed; with administration resulting; and

- ii. a compounded insulin prescription requiring dilution of Humolog 100 units/ml to Humulog 10 units/ml without following required USP 797 aseptic techniques;
- b. On or about May 12, 2006, Registrant No. 2687 improperly filled a prescription for a pediatric patient by dispensing Prednisolone 15mg per 5mL with directions to take four teaspoonfuls two times per day instead of Prednisolone 5mg per 5mL with directions to be taken once a day as prescribed; and
- c. On or about August 17, 2006, Registrant No. 2687 improperly filled a prescription for a pediatric patient by dispensing amitriptyline 100mg tablets (3) instead of amitriptyline 10mg tablets (3) as prescribed.
- 4. Registrant No. 2786 acknowledges that it hired reda and permitted him to work in a capacity as a pharmacy technician with an expired registration. reda worked for Registrant No. 2787 with an expired registration until on or about April 27, 2007.
- Registrant No. 2880 acknowledges that in or about August 2007, it granted access to its pharmacy department on several occasions to an unauthorized individual, free On or about August 13, 2007, after having been granted access to the pharmacy department by Registrant No. 2880, freda diverted 1200 doses of Norco 10/325 mg (Hydrocodone/APAP 10/325).
- 6. Registrant No. 3422 acknowledges that Registrant hired pharmacy technician trainee, J. H. Registrant No. 3422 permitted [reda to work at CVS/pharmacy #1251 in the capacity of a pharmacy technician trainee after she had attained the maximum 1000-hour limitation on the period of employment permitted by the Board. On or about August 22, 2007, Registrant No. 3422 reported the theft of 600 tablets of Hydrocodone 10 mg/660 mg tablets from its pharmacy. After an internal investigation, Registrant No. 3422 determined its employee, [reda to work at CVS/pharmacy #1251 in the capacity of a pharmacy technician trainee after she had attained the
- 7. It is the desire and the intent of CVS, Registrants and the Board to completely resolve the Complaints without formal proceedings before the Board. Accordingly, CVS and Registrants acknowledge and agree to the following:
  - a. Registrants' Pharmacy Registration Nos. 2687, 2786, 2880 and 3422 are hereby placed on PROBATION for a minimum one-year period (Probation Period), commencing on the Effective Date of the Agreement. Termination of the Probation Period shall be governed by Paragraph 10 hereof.
  - b. During the Probation Period, Registrant No. 2687 acknowledges and agrees that it may not compound prescription products until such time as it:
    - i. demonstrates USP 795 and/or 797 compliance to the Board satisfaction,

which may include certification as a compounding pharmacy by an entity with recognized compounding expertise approved by the Board;

- ii. the Board or its designated agent conducts an inspection of Registrant any proposed compounding activities; and
- iii. Registrant obtains written approval from the Board prior to compounding any prescription products. Compounding by Registrant prior to receiving Board approval to commence compounding shall be a basis for discipline for violation of this Agreement
- c. Registrant No. 2687 will use good faith efforts to provide appropriate pediatric dosing spoons or devices with all new pediatric prescriptions.
- d. Registrants agree that they shall comply with all laws and regulations governing the practice of pharmacy, and not engage in any continued or further conduct and actions alleged in Paragraphs 2 through 6 above.
- 8. CVS agrees that it has developed and will maintain a Massachusetts Regulatory Compliance Monitoring Program designed to insure that all CVS pharmacies licensed by the Board are operating in compliance with applicable state and federal laws and regulations, including, but not limited to, Board regulations 247 CMR 2.00 15.00 and applicable USP Standards as they relate to, among other things, professional standards for the practice of pharmacy, performance of pharmacist support functions by pharmacy technicians and unlicensed pharmacy personnel, pharmacy registration requirements and Manager of Record responsibilities.

The Massachusetts Regulatory Compliance Monitoring Program is part of CVS' overall corporate compliance program which includes, but is not limited, to:

- a. Written standards of conduct, as well as written policies and procedures that promote the commitment of CVS to regulatory compliance.
- b The designation of a chief compliance officer (CCO) and a corporate compliance committee (Compliance Committee), charged with the responsibility of operating and monitoring the Compliance Program.
- c. An ongoing, effective education and training program for all employees including pharmacy personnel.
- d. Various processes, including a hotline, email, written memorandum, newsletters, and other methods of information exchange, to receive information from both identified and anonymous sources and the adoption of procedures to encourage detection and reporting.

- e. A system to respond to allegations of non-compliance and the enforcement of appropriate disciplinary action against employees determined to have violated corporate compliance policies, applicable statutes and regulations relating to pharmacy practice.
- f. The use of audits and other evaluation techniques to monitor compliance.
- 9. CVS agrees that it will provide to the Board written confirmation by December 31, 2008 that the Massachusetts Regulatory Compliance Monitoring Program has been reviewed and approved by the Compliance Officer and has been built into the 2009 Workplan for the Compliance and Audit Group.
- 10. The Board will terminate the Probation Period at such time as the Registrants demonstrate to the satisfaction of the Board all of the following:
  - a. Registrants file a written application for termination of the Probation Period with the Board. The Registrants may be required to appear before the Board regarding such application;
  - b. Compliance with all terms and conditions of this Agreement; and
  - c. Compliance with any other requirements for licensure by the Board.
- 11. CVS and the Board agree that in return for CVS and Registrants' execution of this Agreement, the Board will not advance the prosecution of the Registrants pursuant to the Complaints and will dismiss the pending Order to Show Cause. Any and all rights of the Board to take action within the scope of its authority are expressly reserved.
- 12. CVS and Registrants understand and agree that its failure to satisfy the terms of the Agreement shall nullify the representation contained in paragraph 11, and permit the Board to initiate formal adjudicatory action under G.L. c. 30A and 801 CMR 1.00 et seq.
- 13. CVS and Registrants acknowledge and agree that should the Board find that Registrant has violated any of the statutes or regulations governing the practice of pharmacy in the Commonwealth of Massachusetts, the Board may consider the conduct of Registrant as described in paragraphs 2 through 6 and more fully described in the Complaints in determining the appropriate sanction for the subsequent offense.
- 14. The Agreement and its contents shall be incorporated into records maintained by the Board. The Agreement is a public record subject to disclosure without limitation to the public and equivalent state licensing boards.

- 15. CVS and Registrants acknowledge that legal counsel was consulted in connection with the decision to enter into this Consent Agreement.
- 16. CVS and Registrants acknowledge that the decision to enter into this Agreement and to accept the terms and conditions herein described is a final act not subject to reconsideration or judicial review.
- 17. CVS and Registrants acknowledge and agree, by executing this Agreement, it is waiving any and all rights to a formal hearing at which it would have the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its own behalf, to contest the allegations, to present oral argument, to appeal to the courts, and all other rights as set forth in G. L. c. 30A and 801 CMR 1.01 et seq. CVS and Registrants understand that in executing this document entitled "Consent Agreement," it is knowingly and voluntarily waiving its right to a formal hearing and to all of the rights listed above.

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Witness		R

Registrant Nos. 2687, 2786, 2880 & 3422

By: Manual

Title: VP, PHARMACH PROFESSIONAL SERVICES

CVS Pharmacy, Inc.

By: Down

Title: VP, PHARMACY PROFESSIONAL
SERVICES

BOARD OF REGISTRATION

IN PHARMACY

By:

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

President

Date:

Effective Date:
Decision Nos.

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