## COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY	Received	BOARD OF REGISTRATION IN PHARMACY
	MAR 05 2010	
In the Matter of Allen's Pharmacy Pharmacy Registration No. 2520	POARD OF PARMACY	Docket Nos. PHA20090210

## **CONSENT AGREEMENT**

The **Board of Registration in Pharmacy** (Board) and **Allen's Pharmacy** (Pharmacy Registration No. 2520), located at 40 Beach Street in Manchester, Massachusetts (Pharmacy or Registrant), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the files maintained by the Board:

- 1. The parties enter into this Consent Agreement (Agreement) to resolve disputed matters arising out of complaints pending against the Pharmacy as Docket No. PHA20090210 (Complaint).
- 2. The Pharmacy acknowledges the occurrence of the dispensing error alleged in the Complaint; specifically, on November 30, 2009, the Pharmacy improperly filled a prescription for a pediatric patient by dispensing Amoxicillin Suspension reconstituted with an incorrect diluent.
- 3. Board Investigators inspected the Pharmacy on December 30, 2009, and observed multiple regulatory violations pertaining to the practice of pharmacy, including, but not limited to:
  - a. The Pharmacy failed to provide proper preservation and security of all drugs in the pharmacy, including proper refrigeration and storage, specifically, the Pharmacy did not utilize a thermometer in the refrigerator to monitor proper refrigeration of such drugs, in violation of 247 CMR 9.01(5);
  - b. The Pharmacy failed to observe current United States Pharmacopoeia (USP) compounding (non-sterile USP 795) standards in the practice of pharmacy, in violation of 247 CMR 9.01(3) in:
    - (1) failing to store internal and external medications separately with appropriate labeling;
    - (2) allowing food products to be stored in the refrigerator; and
    - (3) failing to provide necessary and appropriate storage space for medications and maintain equipment necessary to conduct the practice of pharmacy accordance with USP;
  - c. Expired/outdated drugs were observed in the Pharmacy which were not quarantined and physically separated from dispensing inventory, in violation of 247 CMR 9.01(10);
  - d. The Pharmacy failed to maintain patient confidentiality at all times, in violation of 247 CMR 9.01(19); and

e. The Pharmacy failed ensure that pharmacy technicians and pharmacy technician trainees wore appropriate name tags, in violation of 247 CMR 8.03(2)(a).

## 4. Accordingly, the Pharmacy agrees:

- a. that the dispensing error and regulatory violations described in Paragraphs 2 and 3 constitutes conduct warranting disciplinary action by the Board, pursuant to M.G.L. c.112, §§ 42A and 61 and 247 CMR 9.01(1), 10.03(1)(a); 10.03(1)(b) 10.03 (1)(k), 10.03 (1)(v), and 10.03 (1)(w);
- b. that the Pharmacy is hereby **REPRIMANDED** by the Board;
- c. to submit to the Board within thirty (30) days of the Effective Date of the Agreement: (1) a copy of updated pharmacy policies and procedures regarding new standards of practice pertaining to the reconstitution of medicinal products; and (2) the names and titles of all pharmacy personnel who have completed comprehensive re-training (with signatures of re-trained individuals attesting to completion of re-training);
- d. to submit to the Board within thirty (30) days of the Effective Date of the Agreement, a detailed certification of completion of corrective action implemented by the Pharmacy (Pharmacy Manager of Record attestation);
- e. to provide written confirmation to the Board within fifteen (15) days of the Effective Date of the Agreement, that the current Pharmacy Manager of Record has completed a Board "Self-Inspection Form" (Pharmacy Manager of Record attestation). The Manager of Record must complete a Self-Inspection Form (signed and dated) and maintain a copy of the form on pharmacy premises, readily retrievable at Board request, for a minimum period of two years from the Effective Date of the Agreement; and
- f. to provide written confirmation to the Board within fifteen (15) days of the Effective Date of the Agreement, that the current Pharmacy Manager of Record has completed the Institute for Safe Medication Practices (ISMP) "Medication Safety Self-Assessment for Community/Ambulatory Pharmacy" (Pharmacy Manager of Record attestation). The Manager of Record must complete an ISMP Self-Inspection Form (signed and dated) and maintain a copy of the form on pharmacy premises, readily retrievable at Board request, for a minimum period of two years from the Effective Date of the Agreement.
- 5. This Agreement and its contents shall be incorporated into the records maintained by the Board. This Agreement and its contents are matters of public record subject to disclosure to the public and equivalent state licensing boards.
- 6. The Board agrees that in return for execution of this Agreement, the Board will not advance the prosecution of Registrant pursuant to the Complaints; any and all other rights of the Board to take action within the scope of its authority are expressly reserved.
- 7. Registrant acknowledges and agrees that the decision to enter into the Agreement and to accept the terms and conditions herein described is a final act and is not subject to reconsideration or judicial review.

- 8. Registrant acknowledges that legal counsel was consulted in connection with the decision to enter into the Agreement or, if not, that Registrant had an opportunity to do so.
- 9. Registrant acknowledges that by executing this Agreement, Registrant is waiving the right to a formal hearing at which Registrant would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to offer testify on its own behalf, to contest the allegations, to present oral argument, to appeal to court in the event of an adverse ruling, and all other rights set forth in G.L. c. 30A and 801 CMR 1.01 *et seq*. Registrant states that in executing this document entitled "Consent Agreement", Registrant understands and agrees that it is knowingly and voluntarily waiving its right and the right to a formal hearing and to all of the above-listed rights.

Allen's Pharmacy

Pharmacy Registration No. 2520

Title: / pharmacy Manager of Rocon

Date: 2/26/2010

BOARD OF REGISTRATION IN PHARMACY

Joanne M. Trifone, R.Ph.

President

Dec. No. 2266