## COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY		BOARD OF REGISTRATION IN PHARMACY
In the Matters of	- ) )	
Pelham Community Pharmacy	j ,	Docket Nos. PHA-2011-0212
196 Bear Hill Road	• )	PHA-2010-0195
Waltham, MA 01880	)	
Pharmacy Reg. No. DS89647	)	

## CONSENT AGREEMENT

The Board of Registration in Pharmacy ("Board") and Pelham Community Pharmacy (Pharmacy Registration No. DS89647) located at 196 Bear Hill Road in Waltham, Massachusetts ("Pharmacy" or "Registrant"), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the file of the Pharmacy as maintained by the Board:

- 1. The Board and the Pharmacy enter into this Consent Agreement ("Agreement") to resolve complaints against the Pharmacy pending before the Board- Docket Nos. PHA-2011-0212 and PHA-2010-0195 ("Complaints").
- 2. The Pharmacy acknowledges and agrees that Board Investigators inspected the Pharmacy on July 6, 2011 and October 7, 2011 and observed regulatory violations pertaining to the practice of pharmacy on each date (as more specifically described in the Complaint Docket Nos. PHA-2011-0212 and PHA-2010-0195) including, but not limited to:
  - a. The Pharmacy failed to maintain a perpetual inventory of a Schedule II controlled substance (morphine powder) reconciled at least once every ten days and did not include expired medications received, dispensed or disposed of, on the required inventory;
  - b. The Pharmacy failed to report the loss of a significant amount of controlled substances by failing to submit a copy of the "Report of Theft or Loss of Controlled Substance" filed with the U.S. Drug Enforcement Administration (DEA BND Form 106) with the Board within seven days of such loss;
  - c. The Pharmacy failed to observe U.S. Pharmacopeia ("USP") Compounding Standard 795 (non-sterile) in the practice of pharmacy; specifically, in the design, arrangement and use of products in the compounding area to prevent cross-contamination (observations included trazedone 50 mg tablets on top of vial without lot number, manufacturer name or expirations date; single use oral syringes intended for use on various flavoring agents and compounds; no beyond use or open dates on various medications, including insulin, triamcinolone acetonide 1% cream and Eucerin cream;

- d. The Pharmacy failed to provide proper preservation and security of drugs in the Pharmacy, including failure to ensure proper refrigeration and storage of such drugs;
- e. The Pharmacy failed to quarantine and physically separate expired/outdated drugs from the Pharmacy dispensing inventory;
- f. The Pharmacy permitted pharmacy technicians to handle Schedule II controlled substances;
- g. The Pharmacy failed to insure that pharmacy technicians and individuals performing pharmacy technician functions were trained or performing services in accordance with written training program guidelines developed and implemented by the Pharmacy for pharmacy technicians and pharmacy technician trainees;
- h. The Pharmacy failed to insure that certain Pharmacy employees (two) performing pharmacy technician functions were registered by the Board as pharmacy technicians; and
- i. The Pharmacy failed to remedy or correct certain violations cited in a deficiency statement by the date specified in the plan of correction submitted by the Pharmacy.
- 3. The Pharmacy acknowledges the occurrence of the dispensing error alleged in the Complaint Docket No. PHA-2010-0195; specifically, that on or about September 15, 2010, the Pharmacy dispensed a prescription for Morphine Sulfate 20mg/ml for a geriatric patient with incorrect drug milligram information on the prescription label.
- 4. For the purpose and with the intent of resolving the Complaints, the Pharmacy (through its owner and legal representative) and the Board acknowledge and agree to the following:
  - a. The regulatory violations and dispensing error described in Paragraphs 2 and 3 constitute conduct warranting disciplinary action by the Board, pursuant to M.G.L. c. 112, sections 42A and 61; 247 CMR 10.03(1), subsections (a), (b), (d), (m), (k), (v) and (w); and 247 CMR 6.02(10) and 6.13; and
  - b. The Pharmacy and the Board agree that the Board shall impose a sanction of **REPRIMAND** on the Pharmacy's registration (DS 89647) for the acts and omissions identified in Paragraphs 2 and 3.
- 5. The Agreement and its contents shall be incorporated into the records maintained by the Board. The Agreement is a public record subject to disclosure to the public and equivalent state licensing boards.
- 6. The Board agrees that in return for execution of the Agreement, the Board will not advance the prosecution of the Pharmacy 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. The Pharmacy 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. The Pharmacy acknowledges that legal counsel was consulted in connection with the decision to enter into the Agreement.
- 9. The Pharmacy acknowledges that by executing this Agreement, the Pharmacy is waiving the right to a formal hearing at which it would possess the rights to confront and cross-examine witnesses, to call witnesses, to present evidence, to offer testimony on its own behalf, to contest the allegations, to present oral argument, to appeal to a 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. The Pharmacy states that in executing this document entitled "Consent Agreement", it is knowingly and voluntarily waiving all rights to a formal hearing and all of the above listed rights.
- 10. The provisions of this Agreement shall apply to and bind the Pharmacy, its affiliates, officers, directors, employees, agents, successors and assigns.

PELHAM COMMUNITY **PHARMACY** 

Registration No. DS89647

By:

Bhiren H. Patel. R.Ph., Owner

**BOARD OF REGISTRATION IN PHARMACY** 

By:

Fensky, R.Ph., President,

. Sencabaugh, R.Ph. Executive Director

Agreement Effective Date: