

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
West River Pharmacy)
140 Locke Drive)
Marlborough, MA 01752)
Pharmacy Registration No. DS3572)

Docket Nos. PHA-2011-0084

JUN 19 2011

CONSENT AGREEMENT

The **Board of Registration in Pharmacy** ("Board") and **West River Pharmacy** (Pharmacy Registration No. DS3572), located at 140 Locke Drive in Marlborough, Massachusetts ("Pharmacy"), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the file of the Pharmacy that is 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 before the Board as Docket No. PHA-2011-0084 (the "Complaint").
2. The Pharmacy acknowledges and agrees that Board Investigators inspected the Pharmacy on March 31 and June 9, 2011 and observed multiple regulatory violations pertaining to the practice of pharmacy, including, but not limited to:
 - a. The Pharmacy failed to maintain Pharmacy records and conduct inventories in compliance with Board regulations, in violation of 247 CMR 6.07(1)(b), 8.05(1), 9.01(1) and 9.
 - b. The Pharmacy failed to maintain a perpetual inventory of each Schedule II controlled substance (including expired medications) received, dispensed or disposed of, with reconciliation to be performed at least once every ten days, in violation of 247 CMR 9.10 (14):
 - c. The Pharmacy failed to report the loss of a significant amount of controlled substances, in accordance with 247 CMR 6.02 (10), by failing to submit a copy of "Report of Theft or Loss of Controlled Substance" (DEA BND Form 106) to the Board within seven days of such theft or significant loss;
 - d. The Pharmacy failed to comply with current United States Pharmacopeia (USP) compounding (non-sterile – USP 795 and sterile – USP 797) standards in the practice of pharmacy, in violation of 247 CMR 9.01(3);
 - e. The Pharmacy failed to provide proper preservation and security of all drugs, including proper refrigeration and storage. No thermometer in the refrigerator was utilized to monitor proper refrigeration of such drugs, in violation of 247 CMR 9.01(1) and 9.01(5);

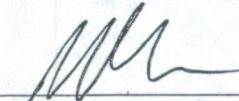
- f. Pharmacy technicians were permitted to handle Schedule II controlled substances, in violation of 247 CMR 8.05(2);
 - g. The Pharmacy failed to conduct Pharmacy operations in a clean and sanitary manner;
 - h. The Pharmacy failed to conduct operations in accordance with required supervisory ratios of pharmacist to pharmacy interns, certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees, in violation of 247 CMR 8.06(3); and
 - i. The Pharmacy failed to conduct the practice of pharmacy by appropriately licenced or registered Pharmacy personnel, in violation of 247 CMR 8.00.
3. Accordingly, the Pharmacy acknowledges and agrees:
- a. that the regulatory violations described in Paragraph 2 warrant disciplinary action by the Board, pursuant to M.G.L. c. 112, sections 42A and 61 and 247 CMR 10.03(1), subsections (a), (k), (v) and (w);
 - b. Pharmacy Registration No. DS3572 is hereby placed on **PROBATIONARY STATUS** for a minimum two (2) year period commencing on the Effective Date of the Agreement ("Probationary Period"). Termination of the Probationary Period shall be governed by Paragraph 4 of the Agreement;
 - c. to submit a "Change of Manager" application to the Board within ten (10) days of the Effective Date of the Agreement;
 - d. to provide written confirmation to the Board, within ten (10) days of the Effective Date of the Agreement, that the proposed Manager of Record at the Pharmacy has completed a Board "Self-Inspection Form." Any approved Manager of Record must complete a Self-Inspection Form (signed and dated) monthly for the first twelve months (first year) of the Probationary Period; quarterly for the second twelve months (second year) of the Probationary Period; and maintain a copy of the form on Pharmacy premises, readily retrievable at Board request, during the Probationary Period;
 - e. Within thirty (30) days of the Effective Date of the Agreement, the Pharmacy shall submit a copy of the Pharmacy's policies and procedures to the Board for review regarding: (a) pharmacy recordkeeping and accounting of controlled substances; (b) verification of destruction of expired medications in accordance with schedule; and (c) training of pharmacy personnel and step by step processes related to the compounding, preparation, record keeping (e.g. formulation record, compounding record, material safety data sheet file) and final verification (pharmacist) of non-sterile preparations;
 - f. Within thirty (30) days of the Effective Date of the Agreement, the Pharmacy shall submit to the Board a written Plan of Correction (POC) detailing corrective actions taken by the Pharmacy concerning practice areas listed in Paragraphs 2.a., 2.b. and 2.d. and Paragraph 3.e. The POC shall set forth, with respect to each practice area, the specific corrective step(s) taken and the date by which compliance was achieved. The POC shall be signed by an officer of the Pharmacy under the pains and penalties of perjury;

- g. That Pharmacy representatives, including the Manager of Record and any other Pharmacy personnel as may be requested by the Board, shall appear before the Board during the Probationary Period as may be requested to review the POC and assess implementation of the corrective actions to be taken and compliance of Pharmacy operations with relevant federal and state statutes and regulations; and
 - h. That the Pharmacy and Manager of Record shall provide specific information and documentation to the Board during the Probationary Period as may be requested to determine compliance of Pharmacy operations with the Agreement, POC and federal and state statutes and regulations.
- 4. The Pharmacy and Licensee acknowledge and agree that termination of the Probationary Period shall be granted by the Board only if the Pharmacy and Licensee have:
 - a. submitted a written request to the Board for termination of the Probationary Period; and
 - b. fully complied with all terms and conditions of the Agreement, demonstrated compliance with relevant federal and state statutes and regulations as may be specifically requested by the Board whether or not related to any inspection or site visit to the Pharmacy during the Probationary Period, and met all other requirements for licensure.
- 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 understands and agree that, at any time during the Probationary Period, upon determination by the Board of any alleged violation of any of the terms and conditions of this Agreement, or any violation of the applicable laws, rules and regulations governing the practice of pharmacy, the Board may suspend Pharmacy Registration No. DS3572 or take other action as deemed necessary and appropriate without the requirement of further proceedings pursuant to G.L. 30A.
- 8. 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.
- 9. The Pharmacy acknowledges that legal counsel was consulted in connection with the decision to enter into the Agreement or, if not, that the Pharmacy had an opportunity to do so.
- 10. The Pharmacy acknowledges by executing this Agreement, the Pharmacy is waiving the right to a formal hearing at which the Pharmacy 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 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 representative executing this Agreement states that in executing this document entitled "Consent Agreement", the Pharmacy is knowingly and voluntarily waiving all right to a formal hearing and to all of the above listed rights.

West River Pharmacy
Registration No. DS3572

By: 

Print Name: Peter DeBora

Title: CVO

Date: 12/16/11

**BOARD OF REGISTRATION
IN PHARMACY**

By: 

Stanley B. Walczyk, R.Ph.
President

Effective Date: 12/20/11

Dec. No. 2686