

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)	Received	
Pawtucket Pharmacy, Inc.)		Docket No. PHA20110011
Pharmacy Registration No. DS789)	MAY 31 2011	
Robert J. Audet, R.Ph.)	BOARD OF	Docket No. PHA20110074
<u>Pharmacist Registration No. PH13088</u>)	PHARMACY	

CONSENT AGREEMENT

The Board of Registration in Pharmacy ("Board"), **PAWTUCKET PHARMACY, INC.** (Pharmacy Registration No. DS789), located at 65 School Street in Lowell, Massachusetts ("Registrant" or "Pharmacy"), and **ROBERT J. AUDET**, R.Ph. (Pharmacist License No. PH13088), owner and Manager of Record of Registrant ("Licensee"), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the files of the Registrant and Licensee that are maintained by the Board:

1. The parties enter into this Consent Agreement ("Agreement") to resolve disputed matters arising out of the complaints pending before the Board regarding Registrant and Licensee as Docket Nos. PHA20110011 and PHA20110074 respectively (jointly the "Complaints").
2. Registrant and Licensee acknowledge and agrees that Board Investigators inspected the Pharmacy on January 5, 2011 and observed multiple statutory and regulatory violations pertaining to the practice of pharmacy, including, but not limited to, Registrant's failure to:
 - a. maintain Pharmacy records and conduct inventories in compliance with federal and state laws and regulations, including the Board regulations (247 CMR), in violation of 247 CMR sections 6.07 (b), 7.00, 9.01(1) and 9.01(14);
 - b. have a balance tested and sealed by the state or local sealer of weights and measures annually, in violation of 247 CMR 6.01(5)(a)(4).
 - c. conduct Pharmacy operations in a clean and sanitary manner, in violation of 247 CMR 6.02(1) and 9.01(1);
 - d. provide the proper preservation and storage of prescription drug products, in violation of 247 CMR 9.01(1) and 9.01(5);
 - e. conduct Pharmacy operations in accordance with 247 CMR 6.01(5)(b), requiring a pharmacy to facilitate proper preparation and compounding of prescribed medications; and provide for an arrangement and storage of drugs that is calculated to prevent accidental misuse;
 - f. comply with United States Pharmacopoeia (USP) Compounding Standards 795, in violation of 247 CMR 9.01(3);
 - g. comply with customized patient packaging standards in violation of Board of Registration in Pharmacy Policy 98-011;

- h. report the loss of a significant amount of controlled substances 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, in violation of 247 CMR 6.02 (10);
- i. quarantine or physically separate expired/outdated drugs from dispensing inventory, in violation of 247 CMR 9.01(10);
- j. provide proper preservation and security of all drugs in the Pharmacy, 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(5); and
- k. comply with prescription transfer requirements in violation of 247 CMR 9.02; and
- l. properly reconcile DEA 222 Forms, in violation of 21 CFR 1305.09.

3. Accordingly, Registrant and Licensee acknowledge and agree:

- a. that the statutory and regulatory violations described in Paragraph 2 constitute a bases for disciplinary action by the Board, pursuant to M.G.L. c.112, §§ 42A and 61 and 247 CMR sections 9.01(1); 10.03(1)(a), 10.03(1)(b), 10.03(1)(e), 10.03 (1)(u), 10.03 (1)(v) and 10.03 (1)(w);
- b. that the Pharmacy registration is hereby placed on PROBATIONARY STATUS for the three (3) year period commencing on the Effective Date of the Agreement ("Probationary Period"). Termination of the Probationary Period shall be governed by Paragraph 5 of the Agreement;
- c. that Robert J. Audet, R.Ph. shall cease acting as Manager of Record at the Pharmacy and not seek approval to act as Manager of Record at any other pharmacy or pharmacy department for a minimum three (3) year period following the Effective Date of the Agreement;
- d. to submit a "Change of Manager" application to the Board within ten (10) days of the Effective Date of the Agreement;
- e. that the Pharmacy has ceased all prescription compounding activities as January 5, 2011 and may not resume compounding without the express approval of the Board;
- f. that the Pharmacy provide documentation to the Board verifying all outdated compounded products have been destroyed or reversed distributed;
- g. to submit a copy of the Pharmacy's updated policies and procedures regarding pharmacy security and accountability of controlled substances to the Board for review within 30 days of the Effective Date of the Agreement;
- h. to provide written confirmation to the Board, within ten (10) days of the Effective Date of the Agreement, that the current Manager of Record at the Pharmacy has completed a Board "Self-Inspection Form". The 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 biannually during the third twelve months (third year) of the Probationary Period and maintain a copy of the form on Pharmacy premises, readily retrievable at Board request, for a minimum period of three years from the Effective Date of the Agreement; and
- i. the Pharmacy 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 and federal and state statutes and regulations.

4. Additionally, Licensee acknowledges and agrees:
 - a. that the Pharmacy practices and regulatory violations described in Paragraph 2 constitute conduct warranting disciplinary action by the Board, pursuant to M.G.L. c.112, §§ 42A and 61 and 247 CMR sections 9.01(1), 10.03(1)(a); 10.03(1)(b); 10.03(1)(e), 10.03 (1)(u), 10.03 (1)(v) and 10.03(1)(w);
 - b. that the Licensee's Pharmacist license is hereby placed on PROBATIONARY STATUS for a minimum three (3) year period commencing on the Effective Date of the Agreement ("Probationary Period"). Termination of the Probationary Period regarding shall be governed by Paragraph 5 of the Agreement; and
 - c. Within six (6) months of the Effective Date of the Agreement, Licensee shall complete five (5) continuing education (CE) hours of PHARMACY LAW and submit the ORIGINAL CE certificates of completion to the Board along with a copy of the Agreement by that date. The Licensee may not use these CEs for CE license renewal requirements for the years 2011 and 2012.
 5. Registrant and Licensee hereby acknowledge and agree that a petition for termination of the Probationary Period shall be reviewed by the Board in accordance with the following requirements:
 - a. Licensee shall submit a written request to the Board requesting termination of the Probationary Period; and
 - b. Registrant and Licensee must demonstrate full compliance with all terms and conditions of the Agreement and all other requirements for licensure.
 6. 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.
 7. The Board agrees that in return for execution of the Agreement, the Board will not advance the prosecution of the Registrant and Licensee pursuant to the Complaints; any and all other rights of the Board to take action within the scope of its authority are expressly reserved.
 8. The Registrant and Licensee understands and agrees that, at any time during the Probationary Period, upon a determination by the Board of any 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 seek to immediately suspend the respective registration and license of the Registrant and Licensee without the requirement of further proceedings pursuant to G.L. c. 30A for a period of time deemed necessary by the Board.
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9. The Registrant and Licensee acknowledge and agree that should the Registrant or Licensee be found to have violated any of the statutes and/or regulations governing the practice of pharmacy for conduct occurring during the Probationary Period, the Board may consider the practices and regulatory violations described in Paragraph 2 and more fully described in the

Complaints in determining an appropriate sanction for the subsequent offense.

10. The Registrant and Licensee acknowledge and agree 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.
11. The Registrant and Licensee acknowledge that legal counsel was consulted in connection with the decision to enter into the Agreement or, if not, that the Registrant and Licensee had an opportunity to do so.
12. The Registrant and Licensee acknowledge by executing this Agreement, the Registrant and Licensee are waiving the right to a formal hearing at which the Registrant and Licensee would possess the rights 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.* The Registrant and Licensee in executing this Agreement state that in executing this document entitled "Consent Agreement", the Registrant and Licensee are knowingly and voluntarily waiving all right to a formal hearing and to all of the above listed rights.

Pawtucket Pharmacy, Inc.

Pharmacy Registration No. 789

By: Robert J. Audet

Title: President

Robert J. Audet, R.Ph.

Pharmacist Registration No. 13088

Robert J. Audet

Date: 5-29-11

**BOARD OF REGISTRATION
IN PHARMACY**

By: Stanley B. Walczyk

Stanley B. Walczyk, R.Ph.
President

Effective Date: 4/1/11

Decision ID. No. 2575 & 2576