

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

R

BOARD OF REGISTRATION
IN PHARMACY

SEP 04 2008

In the Matter of)	BOARD OF	
Arrow Prescription Center)	PHARMACY	Docket Nos. DS-08-062
Pharmacy Registration No. 2292)		PH-08-049
Sylweriusz Sajewicz, R.Ph.)		
Pharmacist Registration No 16633)		

CONSENT AGREEMENT

The Board of Registration in Pharmacy ("Board") and **Arrow Prescription Center** (Pharmacy Registration No. 2292), located at 427 North Elm Street in Westfield, Massachusetts ("Pharmacy"), and **Sylweriusz Sajewicz, R.Ph.** (Pharmacist Registration No 16633), by and on behalf of the Pharmacy as owner and Manager of Record (MOR) of the Pharmacy ("Pharmacist") 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 rising out of complaint pending before the Board as Docket Nos. DS-08-062 and PH-08-049 (the "Complaints").
2. The Pharmacist acknowledges and agrees that Board Investigators inspected the Pharmacy on February 19, 2008 and observed multiple statutory and regulatory violations pertaining to the practice of pharmacy, including, but not limited to:
 - a. 247 CMR 9.01(14) - Perpetual Inventory of Schedule II medications was not available for inspection.
The Pharmacy failed to maintain a perpetual inventory of each Schedule II controlled substance received, dispensed or disposed of, with reconciliations performed at least once every ten days;
 - b. 247 CMR 6.07(1)(i) - Biennial inventory was not available for inspection.
The Pharmacy failed to reconcile an inventory of controlled substances in Schedules II, III, IV and V, based upon federal biennial inventory requirements, in violation of 21 CFR §1304.11;
 - c. 247 CMR 6.01(5)(b) - Haphazard arrangement of controlled substance inventory
There shall be within every pharmacy or pharmacy department a prescription area of not less than 300 square feet to accommodate the appropriate pharmaceutical equipment, apparatus, and supplies, and to facilitate the proper preparation and compounding of

prescribed medications. This area shall provide for an arrangement and storage of drugs that is calculated to prevent their accidental misuse;

- d. 247 CMR 9.05 - Prescription files were not maintained in accordance with 247 CMR 9.05 as follows:
 - (1) Prescriptions for controlled substances in Schedule II were not segregated from all other records and maintained in a separate file identified as such;
 - (2) Prescriptions for controlled substances in Schedules III, IV, and V were not maintained in a separate file identified as such; and
 - (3) Prescriptions for controlled substances in Schedule VI, prescriptions for non-controlled substances, were not segregated from all other records and maintained together in a separate file identified as such;
- e. 247 CMR 6.01(5)(a)(5), 6.01(5)(b) and 9.01(3) - Internal and external medications were not stored separately.

The Pharmacy shall failed to provide necessary and appropriate storage space for medications and maintain equipment necessary to conduct the practice of pharmacy accordance with the current United States Pharmacopoeia (USP);
- f. 247 CMR 6.01(5)(a)7 and 6.02(1) – Pharmacy sink was not functioning. Cleaning products were intermingled with internal and external compounding supplies. Compounding area was a multipurpose area containing food and cleaning supplies;
- g. 247 CMR 9.01(3) – Pharmacy did not observe current United States Pharmacopoeia (USP) compounding standards (USP 795 – non-sterile compounding);
- h. 247 CMR 9.01(10) - Expired/outdated drugs were observed in the Pharmacy;
- i. 247 CMR 15.00 - Pharmacy had not established a Continuous Quality Improvement Program;
- j. 247 CMR 8.02 - Non-registered personnel (cashier) was observed to be performing technician functions; and.
- k. 247 CMR 9.01(5) – Inadequate refrigerator convection
Refrigerated storage was inadequate for the amount of product stored.

3. Accordingly, the Pharmacist, individually and on behalf of the Pharmacy, agrees to the following:

- a. that the regulatory violations described in Paragraph 2 herein constitute a basis for disciplinary action by the Board, pursuant to M.G.L. c.112, §§ 42A and 61 and 247 CMR 9.01(1);
- b. that the respective licenses of the Pharmacy and the Pharmacist are hereby placed on PROBATIONARY STATUS for the three-year period commencing on the Effective Date of the Agreement (“Probationary Period”). Termination of the Probationary Periods shall be governed by Paragraph 4 herein; and
- c. to submit a copy of the Pharmacy’s updated policies and procedures regarding pharmacy security and accountability of controlled substances for Board review within 30 days of the Effective Date of the Agreement.

4. The Pharmacist, individually and on behalf of the Pharmacy, hereby acknowledges and agrees that termination of the Probationary Periods shall be granted by the Board in accordance with the following requirements:

- a. the Pharmacist has submitted a written request to the Board for termination of the Probationary Period; and
 - b. the Pharmacist and Pharmacy have fully complied with all terms and conditions of the Agreement and meet 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 or the Pharmacist 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 Pharmacist, individually and on behalf of the Pharmacy, 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 Pharmacy Registration No. 2292 without the requirement of further proceedings pursuant to G.L. c. 30A for a period of time deemed necessary by the Board.
8. The Pharmacist, individually and on behalf of the Pharmacy, acknowledges and agrees that should the Pharmacy 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 described in Paragraph 2 herein and more fully described in the Complaint in determining an appropriate sanction for the subsequent offense.
9. The Pharmacist, individually and on behalf of 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.
10. The Pharmacist, individually and on behalf of 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.
11. The Pharmacist, individually and on behalf of the Pharmacy, acknowledges that by executing this Agreement, the Pharmacist individually and on behalf of the Pharmacy, is waiving the right to a formal hearing at which the Pharmacist and 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 Pharmacist, individually and on behalf of the Pharmacy, states that in executing this document entitled "Consent Agreement", the Pharmacist, individually and on behalf of the

Pharmacy, is knowingly and voluntarily waiving all rights to a formal hearing and to all of the above listed rights.

Linda A. Pyzik
Witness (sign name)

LINDA A. Pyzik
Witness (print name)

Sylwester Sajewicz
Sylwester Sajewicz, R.Ph.
Individually (Pharmacist License No. 16633)
and as owner and MOR of
ARROW PRESCRIPTION CENTER
(Mass. Pharmacy Registration No. 2292)

Date: 8-29-08

BOARD OF REGISTRATION
IN PHARMACY

By: Sophia Pasedis
Sophia Pasedis, Pharm.D., R.Ph.
President

Effective Date: 9/4/08

Decision ID. Nos. 1715 (DS)
1716 (PH)