

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of _____)
Medical Pharmacy)
Pharmacy Registration No. 1709)

Docket No. PHA20090223

Received

SEP 01 2010

BOARD OF
PHARMACY

CONSENT AGREEMENT

The Board of Registration in Pharmacy (Board) and **Medical Pharmacy** (Registration No. 1709), located at 769 Washington Street in Stoughton, Massachusetts (Pharmacy), 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 complaint pending against the Pharmacy as Docket No. PHA20090223 (Complaint).
2. On December 22, 2009, a Board Investigator inspected the Pharmacy and observed multiple violations of Board regulations pertaining to the practice of pharmacy (247 CMR), including, but not limited to, the failure of the Pharmacy to:
 - a. maintain records and conduct inventories in compliance with federal and state laws and Board regulations (247 CMR), in violation of 247 CMR sections 6.07(b), 9.01(1) and 9.01(14);
 - b. conduct Pharmacy operations in a clean and sanitary manner, in violation of 247 CMR 6.02(1) and 9.01(1);
 - c. provide the proper preservation and storage of prescription drug products, in violation of 247 CMR 9.01(1) and 9.01(5);
 - d. conduct Pharmacy operations in a manner that facilitates proper preparation and compounding of prescribed medications; and provide for an arrangement and storage of drugs that is calculated to prevent accidental misuse, in violation of 247 CMR 6.01(5)(b);
 - e. comply with United States Pharmacopoeia ("USP") Compounding Standards 795, in violation of 247 CMR 9.01(3);
 - f. provide for adequate procedures for insuring all medications are accurately labeled and that for any medications for dispensing, the medications include an accurate beyond use date and lot number; in violation of 247 CMR 9.01(3)(10); and
 - g. maintain a written copy of a Continuous Quality Improvement (CQI) Program, maintain a record of all Quality Related Events for a minimum of two year period and provide documentation of a CQI program with ongoing education at least annually, in violation of 247 CMR 15.00.

3. Accordingly, the Pharmacy acknowledges and agrees to the following:
 - a. that the regulatory violations described in Paragraph 2 constitute professional misconduct warranting disciplinary action by the Board, pursuant to M.G.L. c.112, §§ 42A and 61 and 247 CMR 9.01(1);
 - b. that the Pharmacy registration is hereby placed on PROBATIONARY STATUS for a minimum one 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 provide written confirmation to the Board, within 120 days of the Effective Date of the Agreement, that all Pharmacy personnel engaged in the practice of compounding pharmaceutical preparations have completed Board-approved training in accordance with USP 795 Compounding Standards; and
 - d. that monthly during the twelve month period following the Effective Date of the Agreement, Registrant shall complete, and provide written verification of completion to the Board by the last day of each month, a Board "Self-Inspection Form." Registrant must maintain a copy (signed and dated) of each monthly Self-Inspection Form at the Pharmacy, readily retrievable at Board request, for the twelve month period a minimum two year period following the Effective Date of the Agreement.
4. The Pharmacy acknowledges and agrees that termination of the Probationary Period shall be granted by the Board only if the Pharmacy has:
 - 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 and meets 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 Complaint; 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 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, or otherwise discipline, Pharmacy Registration No. 1709 without the requirement of further proceedings pursuant to G.L. c. 30A for a period of time deemed necessary by the Board.

8. The Pharmacy acknowledges and agrees that should the Pharmacy be found to have violated any of the statutes or regulations governing the practice of pharmacy for conduct occurring during the Probationary Period, the Board may consider the practices described in Paragraph 2 and more fully described in the Complaint in determining an appropriate sanction for the subsequent offense.
9. 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 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 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.

MEDICAL PHARMACY

By: George A. Marra
George A. Marra, R.Ph.
Owner and Manager of Record

Effective Date: 8-31-2010

BOARD OF REGISTRATION
IN PHARMACY

By: Joanne M. Trifone
Joanne M. Trifone, R.Ph.
President

Date: 8/26/10

Decision ID. No. 2271