## COMMONWEALTH OF MASSACHUSETTS

BOARD OF PHARMACY

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**BOARD OF REGISTRATION** IN PHARMACY

Docket No. DS-08-001		
Docket 110. D5-08-001		

## CONSENT AGREEMENT

The Board of Registration in Pharmacy ("Board") and Medical Center Pharmacy (Pharmacy Registration No. 1451), located at 221 Boston Road in North Billerica, 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 complaint pending against the Pharmacy before the Board as Docket No. DS-08-001 (the "Complaint").
- 2. The Pharmacy acknowledges and agrees that Board Investigators inspected the Pharmacy on June 20, 2007 and observed multiple statutory and regulatory violations pertaining to the practice of pharmacy, including, but not limited to:
  - The Pharmacy failed to maintain a perpetual inventory of each Schedule II controlled substance which was received, dispensed or disposed of, with reconciliation to be performed at least once every ten days, in violation of 247 CMR 9.10 (14);
  - b. The Pharmacy failed to place a sign meeting the requirements of regulatory requirements that informs customers of their right to counseling by a pharmacist where their prescription is filled, in accordance with the requirements of 247 CMR 9.00 and G.L. c. 94C, § 21A.
  - The Pharmacy dispensed medications in non childproof containers (e.g. Medicine on Time Delivery System, Bingo Cards and weekly planners) without proper documentation, in violation of 16 CFR §1700;
  - d. The Pharmacy shall failed to maintain the necessary equipment necessary to conduct the practice of pharmacy accordance with the current United States Pharmacopoeia (USP), in violation of 247 CMR 6.01(5)(a)(5);
  - e. The Pharmacy failed to observe current USP compounding (non-sterile USP 795) standards in the practice of pharmacy, in violation of 247 CMR 9.01(3);
  - The Pharmacy failed to reconcile an inventory (biennial inventory) of controlled substances in Schedules II, III, IV and V, based upon federal biennial inventory requirements, in violation of 21 CFR §1304.11;
  - The Pharmacy failed to conform to regulatory security requirements requiring drug order deliveries that include controlled substances to be delivered directly to the pharmacy or

pharmacy department or to a secured area if the pharmacy is closed, and that the security of those controlled substances is the responsibility of the Pharmacist Manager of Record, in violation of 247 CMR 6.02 (6)(g); and

h. The Pharmacy failed to properly reconcile DEA 222 Forms, in violation of 21 CFR §1305.09.

## 3. Accordingly, the Pharmacy agrees to the following:

- a. that the statutory and regulatory violation 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 is hereby placed on PROBATIONARY STATUS for the one-year period commencing on the Effective Date of the Agreement ("Probationary Period") by the Board. Termination of the Probationary Period shall be governed by Paragraph 4 of the Agreement; and
- c. 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.
- 4. The Pharmacy acknowledges and agrees that termination of the Probationary Period shall be granted only if it 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 Pharmacy Registration No. 1451 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 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 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 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 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.

thess (sign name)

Sheldon I. Rubin, R.Ph.
Individually (Pharmacis

Individually (Pharmacist License No. 16113) regarding Paragraph 3.d. and as owner on behalf of MEDICAL CENTER PHARMACY (Mass. Pharmacy Registration No. 1451)

Date: 8/25/07

BOARD OF REGISTRATION IN PHARMACY

By: James T. De Vita, R.Ph., President

Effective Date: 38/36/54

Decision ID. No. 1606