COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of	)	Docket Nos. DS-0729-006
North Shore Pharmacy Services	)	DS-08-012
360 Audubon Road	)	DS-08-014
Wakefield, MA 01880	)	DS-08-019
Pharmacy Registration No. 3458	)	DS-08-042
	)	DS-08-043
	)	DS-08-093
	)	20080818DS010
	)	PHA-2010-0204
	)	PHA-2011-0028

CONSENT AGREEMENT

The **Board of Registration in Pharmacy** ("Board") and **North Shore Pharmacy Services** (Pharmacy Registration No. 3458), located at 360 Audubon Road in Wakefield, 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 Nos. DS-0729-006, DS-08-012, DS-08-014, DS-08-019, DS-08-042, DS-08-043, DS-08-093, 20080818DS010, PHA-2010-0204, and PHA-2011-0028 (the "Complaints").

2. The Pharmacy acknowledges and agrees that Board Investigators and Quality Assurance Coordinator inspected the Pharmacy on May 24, 2007, August 11, 2007 and December 2, 2010, and observed multiple alleged regulatory violations pertaining to the practice of pharmacy, including, but not limited to:

   a. The Pharmacy was allegedly in violation of 247 CMR 9.10 (14) (DS-08-019);
   b. The Pharmacy was allegedly in violation of 247 CMR 6.02 (10) (DS-0729-006);
   c. The Pharmacy was allegedly in violation of 247 CMR 8.06 (3)(a) (DS-08-019);
   d. The Pharmacy was allegedly in violation of 247 CMR 9.01(3) (DS-08-019);
   e. The Pharmacy was allegedly in violation of 21 CFR § 1304.11 (DS-08-019);
   f. The Pharmacy was allegedly in violation of 247 CMR 9.01(10) (DS-08-019);
   g. The Pharmacy was allegedly in violation of 247 CMR 8.05(2) (DS-08-019);
   h. The Pharmacy was allegedly in violation of 247 CMR 8.06(1)(2) (DS-08-019);
   i. The Pharmacy was allegedly in violation of 247 CMR 6.02(9) (DS-08-093);
   j. The Pharmacy was allegedly in violation of 247 CMR 8.03(3) (DS-08-019);

k. The Pharmacy was allegedly in violation of 247 CMR 9.01(1) and 9.01(5). (PHA-2010-0204); and

l. The Pharmacy was allegedly in violation of 247 CMR 15.03(3) and 15.04. (PHA-2010-0204).

3. The Pharmacy acknowledges the occurrence of the dispensing errors alleged in the Complaints and other deficient practices related to the dispensing of certain medications; as described in:

a. Docket No. DS-08-012;
b. Docket No. DS-08-014;
c. Docket Nos. PH-08-042 and PH-08-043;
d. Docket No. 20080818DS010;
e. PHA-2010-0204; and
f. PHA-2011-0028.

4. For the purpose and with the intent of resolving the Complaints, the Pharmacy, and any successor entity owning or operating the Pharmacy, acknowledges and agrees that the Pharmacy and Pharmacy operations as of the Effective Date of the Agreement, shall be subject to the following terms and conditions:

a. The regulatory violations and dispensing errors described in Paragraphs 2 and 3 constitute conduct warranting disciplinary action by the Board, pursuant to M.G.L. c.112, §§ 42A and 61 and 247 CMR 10.03 (1)(a), 10.03 (1)(k), 10.03 (1)(v) and 10.03 (1)(w);

b. Pharmacy Registration No. 3458 is hereby placed on **PROBATIONARY STATUS** for a minimum twenty-four (24) month 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. Within sixty (60) 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 Pharmacy concerning practice areas listed in Paragraph 2. The POC shall set forth, with respect to each violation, 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;

d. The Pharmacy shall submit to the Board a copy of the Pharmacy Regulatory Compliance Plan utilized by the Pharmacy for the purpose of evaluating and ensuring continuing compliance of below listed Pharmacy operation areas with relevant federal and state statutes and regulations ("Plan");

e. The Plan shall include, at a minimum, a comprehensive assessment of Pharmacy compliance with federal and state statutes and regulations in the below listed

Pharmacy operation areas, implementation of measures necessary to correct noncompliance and the development and implementation of:

(1) Pharmacy policies, procedures, training programs and guidance documents related to Pharmacy operations and identification of areas appropriate for revision to enhance patient safety;

(2) Pharmacy compounding practices for evaluation of compliance with USP Standard 795 for Compounding Non Sterile Preparations and USP Standard 797 for Sterile Pharmaceutical Compounding as required by 247 CMR 6.01(5)(c) and 247 CMR 9.01(3);

(3) Clearly delineated organizational responsibilities and accountability of Pharmacy staff and management, any other service providers, and contractors for regulatory compliance, required reporting to regulatory agencies and corrective actions implemented in their area(s) of responsibility;

(4) Compliance training in relevant federal and state statutes and regulations for Pharmacy staff and management, including initiation training for new management and pharmacy staff;

(5) A system and schedules for conducting regular inspections and annual self-audits of Pharmacy operations for the purposes of ensuring patient safety and maintaining Pharmacy compliance with relevant federal and state statutes and regulations;

(6) A system for tracking Pharmacy compliance with relevant federal and state statutes and regulations;

(7) A system for establishing "Return to Compliance" plans for noncompliance identified during inspections and self audits;

(8) Pharmacy practices for scheduling personnel to determine compliance of pharmacist to support personnel ratios at each Pharmacy for compliance with 247 CMR 8.06. The evaluation must include such factors as daily dispensing volume, pharmacist breaks, high volume periods, and appropriate staff delegation in analysis and make any recommendations regarding pharmacist scheduling and procedures to insure staffing and practice complies with all relevant statutes and regulations;

(9) Pharmacy procedures for insuring all outdated medications are separated from active inventory and, within 60 days of the expiration date, removed from the Pharmacy on a regular schedule pursuant to and agreement with a licensed reverse distributor;

(10) Pharmacy procedures for insuring adequate and secure storage of Schedule II medications at the Pharmacy, in compliance with federal and state pharmacy statutes and regulations;

(11) Pharmacy policies and actual performance of pharmacy functions by appropriately licensed or registered Pharmacy personnel, in compliance with relevant federal and state statutes and regulations;

(12) Pharmacy procedures to conduct regular meetings (at least quarterly) of Pharmacy personnel to be held at the Pharmacy for the purpose of reviewing all medication error incidents and all related information, including root cause analysis findings, best practice recommendations, and risk for error warnings regarding sound-alike/look-alike/high medications and steps to be taken to prevent recurrence;

(13) Pharmacy development and presentation of an in-service training at the Pharmacy to all pharmacists, pharmacy interns and pharmacy technicians, with appropriate and timely written assessment of comprehension and compliance, with records of such training and assessment maintained during the Probationary Period, on the following topics:

(i) Pharmacy practice and proper delegation of pharmacy duties and responsibilities to support personnel in compliance with the Supervisory Ratio requirements of 247 CMR 8.06(3);

(ii) Current high risk for error medications, including sound alike/look-alike, similarly packaged, and newly issued medications, and the practices and procedures implemented by the Pharmacy to reduce the likelihood of error involving these medications;

(iii) All pharmacists, pharmacy interns, pharmacy technicians commencing employment with the Pharmacy at any date after the date that the in-service training required hereunder has been provided at the Pharmacy must complete the in-service training on these topics (with follow-up written assessment where required by statute or regulation) not later than 30 days after commencing employment; and

(iv) The Pharmacy must maintain record of completion of in-service training on these topics, as well as follow-up assessment results for all pharmacists, pharmacy interns, pharmacy technicians during the Probationary Period.

f. Within forty-five (45) days of the Effective Date of the Agreement, and subject to the approval of the Board, the Pharmacy shall retain the assistance of an independent consultant (which is mutually acceptable to the Pharmacy and the Board) with expertise in patient safety and medication error prevention, and Massachusetts and federal statutes and regulations pertaining to the practice of pharmacy ("Independent Consultant");

g. Within one hundred twenty (120) days of the Effective Date of the Agreement, the Pharmacy, with the aid of its Independent Consultant, shall complete an assessment of regulatory compliance, patient safety and medication error prevention policies and procedures, Pharmacy management and the POC referenced in paragraph 4(c);

h. Within one hundred fifty (150) days of the Effective Date of the Agreement, the Pharmacy and the Independent Consultant, shall issue a report ("Report"), which summarizes the results of the compliance assessment, lists all measures necessary to correct identified violations (including those referenced in the POC), includes recommendations to improve existing management responsibility and accountability systems and regulatory compliance systems, and patient safety and medication error prevention policies and procedures, and establishes a schedule for implementing recommended measures and improvements;

i. Within one hundred eighty (180) days of the Effective Date of the Agreement, the Pharmacy shall submit the Report to the Board. The Board will review the Report to determine if the areas identified have been addressed and if the schedule for implementing corrective measures referenced in paragraph 4(h) is appropriate;

j. Within thirty (30) days of receipt of any Board comments, the Pharmacy shall amend the report by responding to the Board's comments and submit an amended Report to the Board;

k. Within six (6) months of submitting the Report or amended Report to the Board (whichever is later), the Pharmacy shall submit to the Board a certification of completion of corrective measures taken ("Certification of Completion"). The Certification shall be signed by an officer of the Pharmacy and signed under the pains and penalties of perjury;

l. That duly authorized executive-level Pharmacy representatives, including representatives from Pharmacy Operations, Legal and Regulatory Affairs Departments, and the Independent Consultant, as may be requested by the Board, shall appear before the Board on a date to be determined by the Board to review the Plan and assess implementation of the corrective actions to be taken and compliance of Pharmacy operations with relevant federal and state statutes and regulations; and

m. That bi-annually during the Probationary Period, commencing as of the Effective Date of the Agreement, or more frequently as the Board determines to be necessary and appropriate, Pharmacy representatives, and the Independent Consultant, as requested by the Board, shall appear before the Board to review and assess Pharmacy operations and compliance with the Agreement, the Plan, and relevant federal and state statutes and regulations. 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, the Plan, and federal and state statutes and regulations.

5. 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, demonstrated compliance with relevant federal and state statues 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 meets 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 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.

8. The Pharmacy understands and agrees 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, after providing an opportunity for the Pharmacy to respond to the determination of violation in accordance with G.L. c. 30A, the Board may seek to suspend Pharmacy Registration No. 3458 or take other action as deemed necessary and appropriate after providing an opportunity for the Pharmacy to respond to the determination of violation, for a period of time deemed necessary by the Board.

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.

12. The provisions of this Agreement shall apply to and bind the Pharmacy, its affiliates, officers, directors, employees, agents, successors and assigns.

NORTH SHORE
PHARMACY SERVICES
Registration No. 3458

By: _____

Print Name: Regis T. Robbins

Title: Secretary

BOARD OF REGISTRATION
IN PHARMACY

By: _____
Stanley B. Walczyk, R.Ph.
President

Date: 6/3/11

Effective Date: 6/3/11