NH State Law - RSA 318:51-c Licensing of Outsourcing Facilities Identified as Section 503B Facilities by the United States Food and Drug Administration.

I. No person shall compound legend drugs or controlled drugs, as defined in RSA 318-B:1, VI, and no person acting as or employed by an outsourcing facility shall supply such drugs, without first having obtained a license from the board. Such license shall expire annually on June 30. An application together with a fee established by the board shall be filed annually on or before July 1.

V. (a) The outsourcing facility to which a license has been issued shall, within 30 days of any change of information supplied in the original application, notify the board.

(b) The notice required pursuant to subparagraph (a) shall contain:

(1) Current New Hampshire license number of the outsourcing facility.

(2) Name of the outsourcing facility, old and new, if applicable.

(3) Address of the outsourcing facility, old and new, if applicable.

(4) Names, addresses, and titles of new corporate officers, partners, or owners.

(c) A new license shall be required for a change of ownership of an established outsourcing facility to a successor business entity which results in a change in the controlling interest in the outsourcing facility.

VI. The outsourcing facility to which a license has been issued shall, within 30 days of any written warnings or disciplinary action from any state or federal licensing or enforcement agency, notify the board and provide a copy of the action.

Ph 2004.01 **Reporting Changes**. The person to whom a license to operate a 503B outsourcing facility has been issued in New Hampshire shall, **within 30 days** of that person's discovery of a change in any of the data contained in the application for an original or renewal permit, report that change to the board in writing by going to www.oplc.nh.gov/pharmacy then on the Right hand side, select Licensing, then select at the top of the page “Report License Changes to the Board”.

An original new permit application, “Application for Permit – Bulk Sterile & Non-Sterile Compounders (Including FDA Registered 503B Outsourcing Facilities)” shall be completed and filed in addition to the written notice when the name, location, ownership, or licensed area are changed