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.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the pharmacy board:

(a) That the applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) That the applicant has sufficient land, buildings, and security equipment as to properly carry on the business described in the application.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section shall be subject to the provisions of RSA 318:29.

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.

318:51-d Requirements for Outsourcing Facilities.

I. Outsourcing facilities shall maintain a human drug compounding outsourcing facility registration from the United States Food and Drug Administration (FDA) and shall comply with applicable Current Good Manufacturing Practices (CGMP) requirements as defined in the Final Guidance for Industry-Human Drug Compounding Outsourcing Facilities under Section 503B of the Food, Drug, and Cosmetic Act, when compounding or manufacturing drug products for sale in New Hampshire.

II. Facilities are subject to inspection by the FDA on a risk-based schedule.

III. Outsourcing facilities shall be in compliance with applicable United States Drug Enforcement Administration (DEA) regulations.

IV. As part of the New Hampshire outsourcing facility license application process, the pharmacist-in-charge shall certify to the board that the facility is in full compliance with all applicable FDA and DEA regulations and guidelines, and state law and rules.

V. Outsourcing facilities shall be required to test all finished drug products compounded from bulk active pharmaceutical ingredients (API) to determine whether they meet final product specifications before their release for distribution. No products shall be released for use until this testing is conducted and the results confirm that the finished drug product meets specifications. Copies of the test results shall be included with each batch sent to New Hampshire customers and available for inspection by the pharmacy board.

VI. Outsourcing facilities compounding drug products from sterile, commercially available raw materials shall confirm sterility through process control validated by testing of at least 20 percent of the lots of each product shipped into New Hampshire. Results of these tests shall be provided to New Hampshire customers in receipt of the compounded preparations and available for inspection by the pharmacy board.

318:51-e Rulemaking.

The board shall adopt rules pursuant to RSA 541-A relative to:

I. The application procedure for licensing of outsourcing facilities;

II. Content of the application;

III. The standards for licensing of outsourcing facilities;

IV. The establishment of fees for licensing outsourcing facilities;

V. Standards for denial and revocation of license;

VI. Inspection requirements;

VII. Dispensing and distribution requirements of prescription drugs;

VIII. Record keeping requirements; and

IX. Requirements for outsourcing facilities.

CHAPTER Ph 2000 LICENSING OF OUTSOURCING FACILITIES IDENTIFIED AS 503B FACILTIES BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION

PART Ph 2001 PURPOSE AND SCOPE

Ph 2001 Purpose. The purpose of these provisions is to regulate the licensing of outsourcing facilities, as defined and registered by the Food and Drug Administration pursuant to section 503B of the Federal Food, Drug and Cosmetic Act, codified as 21 USC 353b.

PART Ph 2002 DEFINITIONS

Ph 2002.01 Statutory Definitions Adopted. All terms used in these rules shall have the same meaning as in RSA 318:1, RSA 318-B:1, and RSA 541-A:1.

Ph 2002.02 Other Definitions.

(a) "Outsourcing facility" means "outsourcing facility" as defined in RSA 318:1, XXX, namely, "a facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility, and complies with all of the requirements of section 503B of the Federal Food, Drug, and Cosmetic Act."

PART Ph 2003 STANDARDS OF PRACTICE FOR OUTSOURCING FACILITIES

Ph 2003.01 Standards of Practice and Requirements for Outsourcing Facilities.

(a) Outsourcing facilities shall maintain a human drug compounding outsourcing facility registration from the United States Food and Drug Administration (FDA) when compounding or manufacturing drugs for sale in New Hampshire.

(b) Outsourcing facilities shall be in compliance with applicable United States Drug Enforcement Administration (DEA) regulations.

(c) Outsourcing facilities shall be required to test all lots or batches of finished drug products compounded from bulk active pharmaceutical ingredients (API) to determine whether they meet final product specifications for sterility, endotoxin, and potency before their release for distribution. No products shall be released for use until this testing is conducted and the results confirm that the finished drug product meets specifications. Copies of the test results shall be readily available and included with each batch sent to New Hampshire customers and available for inspection by the pharmacy board.

(d) Outsourcing facilities compounding drug products from sterile, commercially available raw materials shall be required to test all lots or batches of finished drug products to determine whether they meet final product specifications for sterility, endotoxin, and potency before their release for distribution. No products shall be released for use until this testing is conducted and the results confirm that the finished drug product meets specifications. Copies of the test results shall be readily available for each batch sent to New Hampshire customers and available for inspection.

(e) All facilities at which sterile drugs are compounded shall provide storage areas that ensure adequate lighting, ventilation, temperature, sanitation, humidity, equipment, and security conditions. All sterile compounded products shall be stored at appropriate temperatures per label requirements or in compliance with the latest edition of the official United States Pharmacopeia (USP) compendium

requirements to help ensure that the identity, strength, quality, and purity of the products are not affected. If no temperature requirements are listed, compounded products may be stored at room temperature. A separate storage section shall be provided for compounded products that are deteriorated, outdated, misbranded, or otherwise adulterated.

(f) All buildings at which sterile drugs are compounded shall be of a size, construction, and location that facilitates cleaning and maintenance. The buildings shall meet all applicable federal, state, and local standards. A facility shall not be located in a residence. All facilities shall be located in an area that is commercially zoned.

(g) Each outsourcing facility shall be equipped with an internal alarm system to detect entry after hours. The alarm system shall be of the type that transmits a signal directly to a central station protection company, to a local or state police agency that has a legal duty to respond, or to a 24-hour control station operated by the outsourcing facility.

(h) Outsourcing facilities shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting at the outside perimeter of the premises that deters unauthorized entry into the premises.

(i) Internal security policies shall be developed by the outsourcing facility to provide protection against theft by personnel.

(j) No outsourcing facility shall distribute sterile compounded drugs directly to a consumer or a patient, or operate in such a manner as to endanger the public health.

(k) Any person who compounds sterile drugs in violation of RSA 318:51-d or the provisions of Ph 2000 shall be subject to disciplinary action as provided in RSA 318:29.

Ph 2003.02 License Required.

(a) 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. No license shall be issued or renewed for an outsourcing facility unless the same shall be operated in a manner prescribed by law and according to Ph 2000. The license shall expire annually on June 30. The license shall not be transferable.

(b) Separate licenses shall be required for each compounding site owned or operated by an outsourcing facility. Provided, however, that an agent or employee of any licensed outsourcing facility shall not be required to be licensed under this section and may lawfully possess sterile compounded products if he is acting in the usual course of his business or employment.

(c) The board shall provide, on an annual basis, a license renewal form to all licensed outsourcing facilities.

(d) The prescribed fee for original and annual renewal licenses for outsourcing facilities shall be $250.00.

Ph 2003.03 Obtaining and Filing a License Application.

(a) An "Application for Pemit – Bulk Sterile & Non-Sterile Compounders (Including FDA Registered 503B Outsourcing Facilities)", form Ph OF-1, revised June 2017, for a permit to license FDA registered 503B outsourcing facilities in New Hampshire may be obtained from the board or board website;

(b) Form Ph OF-1 shall be used for:

(1) Applying for a permit to license a 503B outsourcing facility;

(2) Changing the location of a currently licensed 503B outsourcing facility; and

(3) Changing the ownership of a currently licensed 503B outsourcing facility.

(c) Form Ph OF-1 shall be filed at the board office as identified in Ph 103.03.

Ph 2003.04 Application Contents.

(a) The applicant for a license to operate an outsourcing facility in New Hampshire shall complete and file the form described in Ph 2003.03.

(b) The applicant shall indicate his or her title, and sign and date the application form under the following affirmation:

"I affirm that I am the person authorized to sign this application for licensure and affirm that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the registration herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State. I understand that as an outsource facility I am required to comply with current Good Manufacturing Practice (cGMP) standards. I have read and understand the testing requirements required for shipping compounded products into New Hampshire."

(c) The applicant shall submit the following documents with the application form:

(1) If shipping controlled drugs, a copy of the facility's current DEA registration;

(2) If licensed by the applicant's home state, a copy of the current license; and

(3) If applicable, a copy of the most recent inspection report from the applicant's home state; and

(4) If applicable, a copy of:

a. The most recent FDA inspection report;

b. The FDA issued Form 483; and

c. The applicant's response to the Form 483.

(d) The applicant shall submit scale drawings of the facility, detailing usage of all space.

(e) The applicant shall supplement the application with any certificates, affidavits, plans, documents, or other information sufficient to show full compliance with all of the requirements for licensure.

(f) If the applicant is a corporation, or if the outsourcing facility will be operated under a corporate name, the applicant shall submit a certificate from the secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the State of New Hampshire under the corporate name.

(g) The application shall be filed with the prescribed fee of $250.00.

Ph 2003.05 Additional Requirements. In addition to the requirements imposed by Ph 2003.04, an applicant for an outsourcing facility license shall demonstrate that he or she is of good moral character or, if the applicant is an association or corporation, that the managing officers are of good moral character, as evidenced by the absence, within the last 5 years, of conviction of any felony, or of a misdemeanor resulting from a violation of any drug related law of the United States or of any state.

Ph 2003.06 Issuance, Denial and Revocation of License.

(a) If an applicant files an application, complete in all respects and demonstrates fulfillment of all requirements of these rules and RSA 318, the board shall issue a license which shall authorize the operation of an outsourcing facility in the location, and only under the name specified in the license.

(b) After consideration of the application, the board shall notify the applicant in writing of all deficiencies in the application which, in the absence of correction, shall result in the denial of the application. The applicant shall, within 20 days of the date of the notice of deficiency, deliver to the board either documents evidencing the correction of those deficiencies, or a written request for an appeal before the board. In the absence of a timely filing of either documentation or a request for an appeal, the application shall, without further action or notice by the board, be denied effective as of the expiration of 20 days after the date of the notification of deficiency.

(c) The revocation of an outsourcing facility license shall permanently withdraw the authority to supply compounded sterile products in New Hampshire unless a subsequent license is issued pursuant to (d) below.

(d) A subsequent license may be obtained only by:

(1) Complying with all the requirements of RSA 318 and these rules regarding the original licensing of outsourcing facilities;

(2) Paying all penalties assessed in connection with the cause for revocation; and

(3) By demonstrating that the cause for revocation does not exist at the time of the subsequent application.

PART Ph 2004 NOTIFICATION REQUIREMENTS

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. An original new permit application, "Application for Pemit – Bulk Sterile & Non-Sterile Compounders (Including FDA Registered 503B Outsourcing Facilities)", form Ph OF-1, revised June 2017, shall be completed and filed in addition to the written notice when the name, location, ownership, or licensed area are changed.

Ph 2004.02 Notice of Disciplinary Action. An outsourcing facility licensed under these rules 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 to the board office, identified in Ph 103.03.

PART Ph 2005 RENEWAL LICENSES

Ph 2005.01 Renewal Permits Required. The person to whom a license to operate a 503B outsourcing facility has been issued shall renew that license by June 30th of each year.

Ph 2005.02 Renewal Application Where Obtained and Filed.

(a) Applications for the renewal of a license to operate a 503B outsourcing facility, "Renewal – Bulk Sterile & Non-Sterile Compounders (Including FDA Registered 503B Outsourcing Facilities)", form Ph OF-2, revised June 2017, may be obtained from the board's website at www.oplc.nh.gov/pharmacy, and shall be filed at, the board office.

(b) The applicant shall indicate his or her title, and sign and date the application form under the following affirmation:

"I affirm that I am the person authorized to sign this application for licensure and affirm that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the registration herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State. I understand that as an outsource facility I am required to comply with current Good Manufacturing Practice (cGMP) standards. I have read and understand the testing requirements required for shipping compounded products into New Hampshire."

(c) The applicant shall submit the following documents with the application form:

(1) If shipping controlled drugs, a copy of the facility's current DEA registration;

(2) If licensed by the applicant's home state, a copy of the current license;

(3) I f applicable, a copy of the most recent inspection report from the applicant's home state; and

(4) If applicable, a copy of:

a. The most recent FDA inspection report;

b. The FDA issued Form 483; and

c. The applicant's response to the Form 483.

Ph 2005.03 Renewal Application Contents and When Filed.

(a) Applications for renewal of a license to operate a 503B outsourcing facility shall consist of a completed application form as described in Ph 2005.02 and the prescribed fee of $250.

(b) Renewal applications as required pursuant to Ph 2005.01 shall be submitted to the board office identified in Ph 103.03 no later than the 15th day of June of each year.

Ph 2005.04 Renewal Application Deficiencies. The board shall notify the applicant in writing as to whom the application for renewal is deficient. The applicant may, within 10 days after the date of the notice of deficiency, correct the deficiency or file with the board a written request for an appeal.

Ph 2005.05 Issuance and Denial of Renewal License.

(a) If an applicant shall timely file an application, complete in all respects, that demonstrates the fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal permit.

(b) An application which continues to fail to meet the requirements of these rules and RSA 318 shall, after the notice and opportunity for a hearing, be denied.

PART Ph 2006 POLICIES, PROCEDURES AND RECORDKEEPING

Ph 2006.01 Written Policies and Procedures.

(a) Written policies and procedures shall be developed by management personnel to assure that the outsourcing facility prepares for, protects against, and handles crises situations that affect the security or operation of the facility. Such crises shall include fires, floods, or other natural disasters, and situations of local, state or national emergency.

(b) Written policies and procedures described in (a) above shall also provide for:

(1) The management and correction of all errors or inaccuracies in inventories;

(2) The assurance that any outdated stock, or any stock with an expiration date that, in the outsourcing facility's view, does not allow sufficient time for repacking or resale, shall be prepared for return to the outsourcing facility or otherwise destroyed; and

(3) The control over the shipping and receiving of all stock within the operation.

(c) A copy of the policies and procedures, or sections thereof, shall be made available to the board upon request.

Ph 2006.02 Responsibility for Operation. An outsourcing facility shall maintain a list of principals and persons in charge including officers, directors, or primary stockholders and their qualifications.

Ph 2006.03 Returned Goods. An outsourcing facility shall maintain a procedure for the handling and disposal of returned goods.

Ph 2006.04 Handling Recalls.

(a) An outsourcing facility shall maintain a written policy for handling recalls and withdrawals for products.

(b) Policies required by (a) above shall cover all recalls and withdrawals of compounded sterile products due to:

(1) A voluntary action on the part of the compounder;

(2) The direction of the Food and Drug Administration, or any other federal, state or local governmental agency; and

(3) Replacement of existing merchandise with an improved product or new design.

Ph 2006.05 Recordkeeping.

(a) The requirements of Ph 2006.05 shall be in addition to all record keeping and reporting requirements contained in all federal regulations and state rules.

(b) Inventories and other records of transactions regarding the receipt and disposition of sterile compounded products shall be maintained and made available for inspection by the board's inspectors for a period of 2 years.

(c) Records may be kept at a central location rather than at each outsourcing facility, but records shall be made available for inspection within 72 hours of request by the board's inspectors.

Ph 2006.06 Inspections.

(a) Outsourcing facilities shall be subject to inspections by the FDA on a risk-based schedule.

(b) Information that is considered to contain trade secrets or which might be proprietary in nature shall be protected from public disclosure.

PART Ph 2007 DISPENSING AND DISTRIBUTION REQUIREMENTS

Ph 2007.01 Dispensing and Distribution Requirements. Compounded sterile drugs shall be dispensed in accordance with Ph 704.

PART Ph 2008 LEGAL REQUIREMENTS

Ph 2008.01 Compliance with State and Federal Law.

(a) All outsourcing facilities licensed under this chapter shall comply with all applicable state and federal laws, rules, and regulations.

(b) All outsourcing facilities licensed and doing business in New Hampshire, shall, before shipping or distributing any compounded sterile drugs, verify that the recipient is properly licensed to receive and possess such drugs.

(c) All outsourcing facilities licensed and doing business in New Hampshire shall not provide unsolicited compounded sterile drug samples to licensed practitioners.

(d) Except as provided in (c) above, a duly authorized agent of an outsourcing facility licensed and doing business in New Hampshire, may possess and distribute compounded sterile drugs to individuals who may lawfully possess such drugs as may be necessary to further the licensed activity of the outsourcing facility.