

Readopt with amendments Ph 401.01, effective 4-18-15 (Document #10812), to read as follows:

Ph 401.01 Obtaining and Filing Renewal Applications. **Applicants for renewal of a license to practice pharmacy shall submit, by December 15th of every even-numbered year, renewal form Ph A-2. The application may be obtained from the board office. Alternatively, applicants may file the renewal application online at <https://nhlicenses.nh.gov/eGov/Login.aspx>**

~~Application form Ph A-2 for the renewal of a license to practice pharmacy in New Hampshire may be obtained from, and shall be filed at, the board office.~~

Readopt with amendments Ph 401.02, effective 6-3-15 (Document #10842), to read as follows:

Ph 401.02 Renewal Application Contents and Filing Deadline.

(a) Applications for renewal of a license to practice pharmacy in New Hampshire under RSA 318 shall be completed and filed **biennially by December 15th of each even-numbered year. on a Pharmacist Licensure Renewal Form Ph A-2 (February 2015).**

(b) With the exception of authorized immunizing pharmacists per the provisions of Ph 1300, which shall have the combined renewal fee as noted below in (~~cd~~), the application and the prescribed fee of ~~\$250+25~~ shall be filed with the board no later than **December 15th of each even-numbered year. the 15th day of December each year.** Each licensee shall **complete and obtain** ~~and~~ file his or her application for license renewal prior to this date.

(c) The **biennial** renewal fee for pharmacists who are authorized immunizing pharmacists shall be ~~\$270+35~~, which includes a fee for the immunization endorsement on their pharmacist license.

(d) Per the provisions of RSA 318:29-a, VI(b), ~~\$30+5~~ of each **biennial** pharmacist renewal fee noted in sections (b) and (c) above, shall be used to fund the impaired pharmacist program.

Readopt with amendments Ph 403.02 and 403.03, effective 4-18-15 (Document #10812), to read as follows:

Ph 403.02 Renewal Requirements.

(a) The board of pharmacy shall not issue licensure renewals unless the pharmacist indicates on the renewal application, and under penalty of unsworn falsification, that he/she has completed the minimum required hours of accredited/approved continuing pharmaceutical education courses/programs according to Ph 403.02(d). An incomplete renewal application shall **be returned to the applicant not be processed by the board.**

(b) Continuing education shall be required of all licensed, active or inactive pharmacists who apply for license renewal.

(c) Pharmacists submitting applications for their first ~~annual~~ **biennial** licensure renewal shall be exempt from the continuing education requirements.

(d) All pharmacists licensed in New Hampshire shall acquire **a total of 30 hours (3.0 CEUs) during the 24 months** ~~1.5 CEU's during the 12 months~~ immediately preceding the license renewal date of January 1st. At least **10 hours (1.0 CEUs) of the total required hours** ~~0.5 CEU's~~ shall be earned in a live setting.

(e) Continuing education credits shall not be recognized for any repeat program attended or completed. Repeat programs shall be identified as any program, live or correspondence, which carries the same ACPE, CME or any board of pharmacy program identification number.

(f) The pharmacist shall retain all certificates and/or other documented evidence of participation in an approved/accredited continuing education program/course for a period of at least 3 years. Such documentation shall be made available to the board for random audit and/or verification purposes.

(g) Not less than 10% of the registrants shall be randomly selected **by the board after October 1 of every even numbered** ~~each~~ year ~~by the board~~ for determinations of compliance with Ph 403.02.

Ph 403.03 Excess CEU's. Excess CEU's earned in one licensure period shall not be carried forward into the new licensure period. ~~for the purpose of fulfilling that year's continuing education prerequisite for licensure renewal.~~

Readopt with amendment Ph 601.01, effective 7-22-17 (Document #12335), to read as follows

Ph 601.01 License Required.

(a) No person shall act as a limited retail drug distributor, as defined in RSA 318:1,VII-a, without first obtaining a license to do so from the board according to RSA 318:51-b.

(b) No license shall be issued or renewed for a limited retail drug distributor unless the same shall be operated in a manner prescribed by RSA 318:51-b and according to Ph 600.

(c) Separate licenses shall be required for each site owned and operated by the limited retail drug distributor.

(d) The board shall provide, on an ~~annual~~ **biennial** basis, a license renewal application to all licensed limited retail drug distributors. **The biennial license shall expire on June 30th of every odd-numbered year. Licensees shall file the renewal application and pay the fee in (e) below by June 15th of every odd-numbered year.**

(e) The prescribed fee for ~~annual~~ **initial** and **biennial** renewal licenses for limited retail drug distributors shall be:

- (1) For clinics under contract with the department of health and human services (DHHS), ~~\$150~~**300**;
- (2) For methadone maintenance/detoxification treatment centers, ~~\$250~~**500**; and
- (3) For medical gas suppliers, ~~\$150~~**300**.

Readopt with amendments Ph 601.06, effective 7-22-17 (Document #12335), to read as follows:

Ph 601.06 Renewal Applications.

(a) The license period shall be from July 1 thru June 30 of ~~the following year~~**every odd-numbered year.**

(b) Applications for renewal of a license to operate as a limited retail drug distributor shall consist of prescribed fee as indicated in Ph 601.01(e) and the following appropriate application form:

- (1) For medical gas suppliers, Form MM-2A, “Renewal Application for Limited Retail Drug Distributor of Medical Gases and/or Medical Devices for Sale Direct to Patient/Consumer Pursuant to a Prescription,” revised June 2017;
- (2) For clinics under contract with DHHS, Form MM-2B, “Limited Retail Drug Distributor Public Health Clinic”, revised June 2017; or
- (3) For methadone maintenance/detoxification facilities, Form MM-2C, “Limited Retail Drug Distributor Methadone Maintenance/Detoxification Facility”, revised June 2017.

(c) Medical gas supplier and methadone maintenance/detoxification renewal applicants shall submit the following additional information with their renewal applications:

- (1) For medical gas suppliers:
 - a. A copy of the current state license from the applicant’s home state licensing authority if outside New Hampshire, or an explanation as to why the renewal applicant does not have such a license; and
 - b. A copy of the most recent inspection report from the applicant’s home state licensing authority if outside New Hampshire, or an explanation as to why the renewal applicant does not have such an inspection report; and

(2) For methadone maintenance/detoxification facilities:

- a. A copy of the clinic’s current NH DHHS certified drug treatment provider certificate; and
- b. A copy of the clinic’s current DEA registration.

(d) Renewal applications shall include a dated signature and title under the following affirmations:

(1) For medical gas suppliers:

“I affirm that I am the person authorized to sign this application for licensure on behalf of the company/licensee 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.”

(2) For clinics under contract with DHHS:

“I declare under penalties of unsworn falsification under RSA 641:3 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 permit 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.”; and

(3) For methadone maintenance/detoxification facilities:

“I declare under penalties of unsworn falsification under RSA 641:3 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 permit 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. To the best of my knowledge, myself nor any of the employees listed on this application, have been arrested, investigated for, charged with, convicted of, sentenced, entered a plea of non contendere, or entered into any other legal agreements for any criminal offense in any state, territory or possession of the United States or by the federal government.”

(e) The board shall renew a license pursuant to this section if the applicant:

(1) Files a complete application that meets the requirements of these rules and RSA 318; and

(2) 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.

Readopt with amendments Ph 602.01, effective 7-22-17 (Document #12335), to read as follows:

Ph 602.01 ~~Annual~~ **Biennial** Registration Required. Pursuant to Ph 601.06, every person, or corporate entity that is not a licensed pharmacy, engaged in supplying medical gases to the consuming public, or to a patient or a patient's agent, in the state of New Hampshire, shall renew ~~annually~~ **biennially** with the board as a limited retail drug distributor **no later than June 15th of every odd-numbered year.**

Readopt with amendments Ph 1001.01, effective 10-22-16 (Document #12007), to read as follows:

Ph 1001.01 License Required.

(a) No person shall manufacture or act as a wholesale distributor of prescription drugs or prescription devices without first obtaining a license to do so from the board pursuant to this chapter. No license shall be issued or renewed for a manufacturer or wholesale drug distributor unless the same shall be operated in a manner prescribed by law and according to the rules adopted by the board of pharmacy with respect thereto.

(b) Separate licenses shall be required for each manufacturing and distribution site owned or operated by a manufacturer or wholesale distributor. Provided however, that an agent or employee of any licensed manufacturer or wholesale distributor shall not be required to be licensed under this section and may lawfully possess prescription drugs and devices if he is acting in the usual course of his business or employment.

(c) **All licenses for manufacturers and wholesale distributors of prescription drugs and medical devices containing a prescription drug shall expire biennially on June 30th of every even-numbered year. The renewal application may be obtained from the board office. Alternatively, applicants may file the renewal application online at <https://nhlicenses.nh.gov/eGov/Login.aspx>** ~~Licensed manufacturers and wholesale distributors of prescription drugs and devices shall annually complete and submit a board provided Renewal Application, revised 09/16.~~

(d) The prescribed fee for original and ~~annual~~**biennial** renewal licenses for manufacturers and wholesale distributors of prescription drugs and devices shall be ~~\$500250~~.

(e) No in-state license shall be issued until such time as the applicant has satisfactorily completed a site inspection performed by the board confirming the facility:

(1) Is of suitable size, construction and location to allow proper storage, handling and security of drugs;

(2) Is located in a commercially zoned area;

(3) Has adequate outside lighting to allow for proper security;

(4) Has notified the local police department that legend drugs are being stored at the facility; and

(5) Has a functioning alarm system in place.

Readopt with amendments Ph 1002.12, effective 10-22-16 (Document #12007), to read as follows:

Ph 1002.12 Reporting Changes.

(a) It shall be the responsibility of the manufacturer/wholesaler to immediately notify the board of any changes of information submitted in the application for licensure.

(b) Failure to provide the board with notification of changes in the application contents, within 30 days of such changes, shall subject the licensee, after notice and opportunity to be heard pursuant to Ph 200, to a fine of \$150.00.

(c) The deadline for renewal applications shall be midnight June 30th **of every even-numbered year**.. Any application received after that date shall be subject to a \$25.00 reinstatement fee. Licenses shall not be issued until the late fee is satisfied. **Licenseses shipping to or doing business in New Hampshire with an expired license are subject to discipline by the board pursuant to RSA 318:55.**

(d) If the ownership at the customer service level has changed, the name of the business has changed or more than 50% of the stock ownership has changed hands then a new application shall be required.

(e) If a manufacturer, wholesaler or distributor has any license or permit revoked, suspended or voluntarily surrendered the facility shall notify the board within 7 days and include a copy of the corresponding documentation.

Readopt with amendments Ph 2003.02, effective 7-22-17 (Document #12336), to read as follows:

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 **biennially annually** on June 30 **of each odd-numbered year**. 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) **Renewal applications shall be filed no later than June 15th of every odd-numbered year and may be obtained from the board office. Alternatively, renewal applications may be filed online at <https://nhlicenses.nh.gov/eGov/Login.aspx>. 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~~**\$500.00**.

Readopt with amendments Ph 2003.04, effective 7-22-17 (Document #12336), to read as follows:

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~~**\$500.00**.

Readopt with amendments Ph 2005.01, effective 7-22-17 (Document #12336), to read as follows:

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~~**-15th** of ~~every~~**every odd-numbered** year.

Readopt with amendments Ph 2005.02, effective 7-22-17 (Document #12336), to read as follows:

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. **Alternatively, renewal applications may be filed online at <https://nhlicenses.nh.gov/eGov/Login.aspx>**

(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.

Readopt with amendments Ph 2005.03, effective 7-22-17 (Document #12336), to read as follows:

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 **renewal** application form as described in Ph 2005.02 and the prescribed fee of ~~\$250~~**500.00**.

(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~~**every odd-numbered** year.

Appendix

Rule	Statute
Ph 401.01	RSA 318:5-a, I,III, V, VII, and VII-a
Ph 401.02 (a) and (b)	RSA 318:25
Ph 401.02(c) and (d)	RSA 318:5-a, VII and RSA 318:16-b, IV
Ph 403.02	RSA 318:29, I,II, IV, and V; RSA 318:5-a,VII-a
Ph 403.03	RSA 318:25, III
Ph 601.01	RSA 318:5-a, I,II, III, IV-a, V, VI, and VII; RSA 318:51-b
Ph 601.06	RSA 318:5-a, I, II, III, IV-a, V, VI, and VII; RSA 318:51-b
Ph 602.01	RSA 318:51-b
Ph 1001.01	RSA 318:51-a, I
Ph 1002.12	RSA 318:51-a, I
Ph 2003.02	RSA 318:51-c; RSA 318:51-d; RSA 318:51-e
Ph 2003.04	RSA 318:51-c; RSA 318:51-d; RSA 318:51-e
Ph 2005.01	RSA 318:51-c, I; RSA 318:51-e, I-IV, and IX
Ph 2005.02	RSA 318:51-c, I; RSA 318:51-e, I-IV, and IX
Ph 2005.03	RSA 318:51-c, I; RSA 318:51-e, I-IV, and IX