Readopt with amendments Ph 903.01, effective 7-30-21 (Document #13244), to read as follows:

Ph 903.01 Application.

(a) No person shall conduct or operate a mail-order pharmacy located outside of this state by delivering in any manner prescription drugs or prescription devices into this state unless such pharmacy is registered in New Hampshire and a permit has been issued by the board.

(b) Application form MO-1, "Non-Resident/Mail-Order Pharmacy Application for Permit" **revised 3/2022** may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

(c) Applicants for registration as a mail-order pharmacy shall complete and submit form MO-1 or its electronic equivalent that contains the following information:

(1) Name, address, telephone number, email address, and [~~I~~]**i**nternet address, if applicable, of the pharmacy;

(2) The names, addresses and titles of all principal corporate officers, if incorporated and if unincorporated, partners or owners of the pharmacy;

[~~(3) Name, email address, and phone number of the person responsible for the processing of the application and any subsequent renewal applications;~~

~~(4) Name, email address, and phone number of the person who is responsible for the actions of the permit;~~]

[~~(5)~~]**(3)** If a corporation, a certificate of incorporation from the state in which incorporated;

[~~(6)~~]**(4)** If a limited liability company, partnership, or sole proprietorship, a tax ID number or FEIN number;

[~~(7)~~]**(5)** The name, phone number, email address, and home-state pharmacist license number of the pharmacist-in-charge of the location listed in (1) above;

[~~(8)~~]**(6)** A copy of the pharmacy's home state permit;

[~~(9)~~]**(7)** A copy of the most recent inspection report conducted by the state in which the pharmacy is located within the past 18 months;

[~~(10)~~]**(8)** An un-redacted copy of the most recent United States Food and Drug Administration inspection and 483 observation(s) and board approved inspections as defined in Ph 906.03(c) and (d)(1) from the applicant's home state;

[~~(11)~~]**(9)** A copy of the un-redacted inspection and observation response, if applicable;

[~~(12)~~]**(10)** If the pharmacy is exempt from registering with the PDMP, complete the following attestation:

"I attest, that the above-named pharmacy, for which I am the Pharmacist In Charge, is exempt from registering and reporting to the New Hampshire Prescription Drug Monitoring Program per NH RSA 318-B:33:

□ The Pharmacy does not have a Drug Enforcement Administration (DEA) Registration at all and does not do any business (dispensing, distributing, and/or shipping related to any Federally Scheduled Controlled Substances in either the pharmacy's home-state or any other U.S. State; or

□ The pharmacy only has a Drug Enforcement Administration (DEA) registration for schedule V Controlled Substances and does not do any business with Schedule II-IV Controlled Substances (dispensing, distributing, and/or shipping) in either the pharmacy's home-state or any other U.S. state – if selecting this box, you Must attach a copy of the pharmacy's current DEA registration.

By signing below I understand and affirm, that should the above-named pharmacy obtain a DEA registration for schedule II-IV and/or aspire to begin distributing/dispensing controlled substances in these schedules (either in its home-state or any other state), that I, and this pharmacy, will immediately notify the New Hampshire Board of Pharmacy and properly submit the required application as defined in Ph 904, and register with the NH Prescription Drug Monitoring Program as required by NH RSA 318-B:33"; and

[~~(13)~~]**(11)** The signature of the pharmacist-in-charge and date below the following attestation:

"I attest that I have read the NH Laws; RSA 318 and RSA 318-B and Administrative Rules for the profession that I have applied for on this renewal. I attest to reading Ph 904.01; which states in part, 'the Board must be notified within 30 days of any changes to any information from the original application'. I attest that I have answered all questions truthfully, accurately and I hereby attest that if any information on this application was submitted falsely or is misleading or a misrepresentation of the facts, I understand that such an act shall constitute cause for potential denial, revocation, or disciplinary actions of the registration that I am applying for. I understand that the pharmacy permit is issued in the name of the corporation or owner of the pharmacy and that a duly designated pharmacist in charge, as designated on this application, has accepted responsibility for the safe, effective operation of the pharmacy. My signature; ink or electronic; constitutes my acknowledgement of the responsibilities of both the pharmacist in charge and the corporation/owner/permit holder regarding the safe operation of the pharmacy."

(d) Documents required for an initial application shall include:

(1) A copy of the home state permit;

(2) A copy of a prescription label, containing the name, address, and phone number of the pharmacy, that would be used on finished prescription products mailed to NH residents;

(3) A copy of the inspection report of the facility, created in the last 18 months, from one of the entities listed in Ph 906.03(d)(1);

(4) A list of all the corporate officers, owners, title, and organization chart;

(5) A sample copy of a printed patient medication profile that shall include the following information:

a. Name and address of the patient;

b. Name, address and DEA registration number of the prescriber;

c. Name, strength, and quantity of drug dispensed;

d. Assigned prescription number;

e. Date of original filling; and

f. Date of refill(s);

(6) Pictures of the following locations at the facility:

[~~a. Outside entrance and signage;~~

~~b. The office setting;~~

~~c. The area of the facility where the refrigeration for medications is located;~~

~~d. The storage room for all medications, including the actual container storing the medication; and~~

~~e. The hot-and-cold water setup for the medications;~~]

a. At least 2 different photographs of the actual existing exterior, including the pharmacy signage, of the building in which the pharmacy will be or is currently located;

b. At least 2 different photographs of the prescription department as viewed by an approaching patron;

c. At least 4 different photographs of the prescription department as viewed from the interior, showing the prescription compounding area, refrigerator, water facilities, and pharmaceutical inventory storage area;

(7) A copy of the certificate of the alarm system is in place, or other proof the facility is alarmed;

(8) Scaled drawing of the facility and drug storage area;

(9) Copies of the following documents:

a. A copy of an inspection report, created within the last 18 months, which documents compliance with the board rules regarding sterile and non-sterile compounding in compliance with the United States Pharmacopeia Chapter 797 and Chapter 795 pursuant to RSA 318:14-a performed by:

1. Your home state's board of pharmacy;

2. The National Association of Boards of Pharmacy (NABP); or

3. New Hampshire board of pharmacy approved third party entity;

b. The below attestation, signed by the pharmacist-in-charge:

"☐ Sterile Compounded Drugs (Patient-Specific Only) * If shipping Sterile Compounded Products to NH Residents, you must attach items 1-5; additionally, by signing this application you acknowledge that the pharmacy has item #6 on hand and available upon request:

1. Any and all GAP analysis reports related to the pharmacy done within the last [~~twelve (12)~~] **12** months;

2. Any and all certification documents on compounding equipment done within the last [~~six (6)~~] **6** months;

3. An inventory listing of any [~~/~~] **and** all products shipped into the State of New Hampshire within the last [~~six (6)~~] **6** months, including product, quantity, location of shipment, and date of shipment;

4. Any Department of Health and Human Services, Food and Drug Administration Inspection Reports (Form FDA 483) issued within the last [~~twelve (12)~~] **12** months and any responses submitted to these agencies by the pharmacy;

5. Any state inspection reports issued within the last [~~eighteen (18)~~] **18** months and any responses submitted to these agencies regarding the inspection reports by the pharmacy; and

6. The pharmacy's policies and procedures on sterile compounding. (Do not attach – but must be available upon request);"

Note to the JLCAR Pursuant RSA 310-A:1-e, I. (a) the Executive Director of the OPLC has authority to assess licensing, certification, renewal fees, and any necessary administrative fees associated with licensing or certifications. RSA 310-A:1-e, I requires the OPLC to set its fees at a rate that would provide for 125% of its operating costs.

Here the rule cites to Plc 1000, and the OPLC recently adopted interim rule for Plc 1002.23, NN 2021-5, Document #13265, expiring 3/21/22, which establishes the fee of $2K for mail order pharmacies. The Committee may have questions about when the agency plans to file a regular rule. (The agency previously filed an emergency rule which necessitated filing an interim rule.)

c. A hood certification inspection report completed under dynamic conditions, not at rest, within the last 6 months;

d. A current environmental monitoring report, dated within the last 6 months, which includes:

1. Viable air and surface sampling; and

2. HEPA filter performance testing;

e. If the facility does not have a clean report, submit the following as well:

1. CAPA Report;

2. Identify the issue and explain in writing to the board;

3. A detailed report of what the corrective action plan is; and

4. A statement explaining if this is detailed in the facility's SOPs or P&P Manual; and

10) The fee as specified in Plc 1000.

(e) Failure to comply with any of the provisions of Ph 903 shall result in denial of a permit.

(f) Initial applications shall remain open and active for 60 days upon receipt of a completed application. An application is considered completed when all documentation required by the rules, application, any other supporting documentation to show proof the company is compliant with board rules, and the fee, are received by the board. If the application and all supporting documentation are not completed by the applicant within 60 days, the application will turn to an inactive status and the applicant will have to begin the process from the beginning.

(g) Any person or pharmacy whose pharmacy business model fits the definition of a mail-order pharmacy and delivers prescription drugs or prescription devices to New Hampshire residents from more than one out-of-state pharmacy shall register each such pharmacy separately.

(h) Pharmacists providing "telepharmacy services" to New Hampshire residents shall be licensed with the board unless performing these actions on behalf of a pharmacy licensed or otherwise registered by the board.

APPENDIX

Rule	**Specific State Statute the Rule Implements**
Ph 903.01	RSA 318:5-a, XII & XIII, RSA 318:37; RSA 318:38