Adopt Ph 300 to read as follows:

CHAPTER Ph 300 LICENSING, REGISTRATION, CERTIFICATION

PART Ph 301 PURPOSE; APPLICABILITY; NOTIFICATIONS; ISSUANCE OF LICENSES; INCORPORATED DEFINITIONS

Ph 301.01 Purpose. The purpose of this chapter is to protect public health and welfare by establishing the criteria and procedures by which pharmacy personnel and pharmaceutical entities may apply to the office of professional licensure and certification (OPLC) for an initial license, registration, or certification based on criteria established by the New Hampshire pharmacy board.

Ph 301.02 Applicability.

(a) This chapter shall apply to:

(1) Any individual who is or who wishes to become any of the following:

a. A licensed pharmacist;

b. A registered pharmacy intern;

c. A licensed advanced pharmacy technician;

d. A certified pharmacy technician; or

e. A registered pharmacy technician; and

(2) Any pharmaceutical entity that is or that wishes to become licensed to conduct business under RSA 318 in New Hampshire.

(b) This chapter shall not apply to, and a pharmacy license shall not be required for, any institution that procures prescription drugs for its patients only on an individual-prescription basis for specific patients from an off-premises licensed pharmacy.

Ph 301.03 Notifications; Issuance of Licenses. The OPLC shall send all notifications to applicants and licensees and all licenses issued pursuant to this chapter in accordance with Plc 301.03.

Ph 301.04 Incorporated Definitions. All terms used in these rules relative to procedures, applications, inspections, and fees that are defined in Plc 100-400 or Plc 1000 shall have the meaning specified in title Plc.

PART Ph 302 NO IMPERSONATIONS OF APPLICANTS

Ph 302.01 Impersonation of Applicants Prohibited.

(a) As provided in RSA 318:20, I, no one shall impersonate any person applying for licensure under RSA 318.

(b) As provided in RSA 318:20, II, no third party shall sign an application, complete an application, call to check on the status of an application, or submit an application and documentation on behalf of any applicant.

(c) As provided in RSA 318:20, III, no third party shall complete an online renewal or a paper renewal, or make any changes or updates to an original application on behalf of an applicant.

PART Ph 303 QUALIFICATIONS AND REQUIREMENTS FOR INITIAL LICENSURE: PHARMACY PERSONNEL

Ph 303.01 Qualifications for Initial Licensure as a Pharmacist; Required Examinations.

(a) To qualify to apply for an initial pharmacist license, an applicant shall meet the requirements of RSA 318:18, I, reprinted in Appendix C, subject to (b) through (h), below.

(b) Subject to (d), below, the required national examination administered by the National Association of Boards of Pharmacy (NABP) shall be the National Association of Boards of Pharmacy Licensure Examination (NAPLEX).

(c) An applicant also shall pass the New Hampshire Multistate Pharmacy Jurisprudence Examination (NH MPJE) administered the NABP.

(d) The Test of English as a Foreign Language (TOEFL) required by RSA 318:18, I(a) for graduates of a foreign school or college of pharmacy other than Canadian shall be the TOEFL internet-based test (TOEFL-iBT®).

(e) Passing scores for all required examinations shall be "pass".

(f) Any candidate who fails to obtain a score of "pass" on the NAPLEX or NH MPJE shall notify the board in writing whether the applicant elects to be re-examined.

(g) Any candidate for re-examination shall register and pay for the re-take examination through the NABP online registration website accessible https://nabp.pharmacy/.

(h) Pursuant to RSA 318:18, II, which authorizes the OPLC to deny licensure as a pharmacist for grounds that include prior conviction of any felony, or of a misdemeanor resulting from a violation of a federal, state or local drug or pharmacy-related law, rule, or regulation, the OPLC shall not use the following as a basis for denying a license:

(1) Any misdemeanor conviction(s) more than 5 years prior to the application for licensure, for violation(s) of a federal, state, or local drug or pharmacy-related law, rule, or regulation; or

(2) Any felony conviction related to professional practice more than 10 years prior to the application for licensure, provided the applicant demonstrates, through explanations submitted pursuant to Ph 303.02(b)(4), that the applicant is unlikely to engage in criminal behavior if a license is issued in New Hampshire.

Ph 303.02 Information and Documentation Required for Initial Pharmacist License Application.

(a) The following information shall be submitted pursuant to Ph 306.02(b)(1)a.:

(1) Whether the applicant is or ever has been registered or licensed as any category of pharmacy personnel in New Hampshire or any other jurisdiction and, if so, an identification of the jurisdiction(s) and whether such registration or license is currently valid; and

(2) Whether the applicant has ever voluntarily surrendered any professional license in this or any other jurisdiction for any reason.

(b) The following documentation shall be submitted pursuant to Ph 306.02(b)(3)a.:

(1) A copy of the candidate's birth certificate;

(2) An official final transcript sent directly from the college to the licensing office, or if a foreign graduate, a transcript verification as provided by the Foreign Pharmacy Graduate Examination Committee (FPGEC);

(3) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each voluntary surrender reported pursuant to (a)(2); and

(4) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each criminal conviction and a complete explanation of the action(s) the applicant undertook or is undertaking to ensure that the behavior(s) which resulted in the criminal charges will not be repeated if a license is issued in New Hampshire.

Ph 303.03 Qualifications for Initial Registration as a Pharmacy Intern. An applicant for licensure as a registered pharmacy intern shall:

(a) Be at least 18 years of age;

(b) Be enrolled in or possess a pharmacy degree from an accredited college or university pharmacy program;

(c) Be of good moral character, as demonstrated by the information provided by the applicant on the application and any attachments; and

(d) Have not been:

(1) Convicted within the prior 5 years of a misdemeanor resulting from a violation of any federal, state, or local drug- or pharmacy-related law, rule, or regulation; or

(2) Convicted of a felony related to professional practice at any time, provided that the OPLC shall not deny a license based solely on a felony conviction more than 10 years prior to the application for licensure if the applicant demonstrates, through explanations submitted pursuant to Ph 303.04(b)(2), that the applicant is unlikely to engage in criminal behavior if a license is issued in New Hampshire.

Ph 303.04 Information and Documentation Required for Initial Pharmacy Intern Registration Application.

(a) The following information shall be submitted pursuant to Ph 306.02(b)(1)b.:

(1) Whether the applicant is or ever has been registered or licensed as a pharmacy intern in New Hampshire or any other state and, if so, an identification of the state(s) and whether such registration or license is currently valid; and

(2) Whether the applicant has ever voluntarily surrendered any professional license in this or any other jurisdiction for any reason.

(b) The following documentation shall be submitted pursuant to Ph 306.02(b)(3)b.:

(1) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each voluntary surrender reported pursuant to (a)(2); and

(2) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each criminal conviction and a complete explanation of the action(s) the applicant undertook or is undertaking to ensure that the behavior(s) which resulted in the criminal charges will not be repeated if a license is issued in New Hampshire.

Ph 303.05 Qualifications for Initial Licensure as an Advanced Pharmacy Technician.

(a) An applicant for licensure as an advanced pharmacy technician shall meet the following requirements:

(1) Be at least 18 years of age;

(2) Have worked not less than 2,000 hours as a certified pharmacy technician in good standing, supervised by one or more pharmacist(s) who are licensed and in good standing in the jurisdiction in which the work occurred;

(3) Hold national certification from a nationally-recognized certifying organization for pharmacy technicians, such as the Pharmacy Technician Certification Board (PTCB) or the National Healthcare Association (NHA);

(4) Have successfully completed 4 advanced technician assessment-based programs provided by a nationally-recognized pharmacy technician certification provider, 2 of which shall be on product verification and immunization administration; and

(5) Have successfully passed the pharmacy jurisprudence exam for technicians (PJET) administered by the NABP;

(6) Be of good moral character, as demonstrated by the information provided by the applicant on the application and any attachments; and

(7) Have not been:

a. Convicted within the prior 5 years of a misdemeanor resulting from a violation of any federal, state, or local drug- or pharmacy-related law, rule, or regulation; or

b. Convicted of a felony related to professional practice at any time, provided that the OPLC shall not deny a license based solely on a felony conviction more than 10 years prior to the application for licensure if the applicant demonstrates, through explanations submitted pursuant to Ph 303.06(b)(2), that the applicant is unlikely to engage in criminal behavior if a license is issued in New Hampshire.

Ph 303.06 Information and Documentation Required for Initial Advanced Pharmacy Technician License Application.

(a) The following information shall be submitted pursuant to Ph 306.02(b)(1)c.:

(1) The name, mailing address, and telephone number of the applicant's current employer; and

(2) Whether the applicant has ever voluntarily surrendered any professional license in this or any other jurisdiction.

(b) The following documentation shall be submitted pursuant to Ph 306.02(b)(3)c.:

(1) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each voluntary surrender reported pursuant to (a)(2);

(2) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each criminal conviction and a complete explanation of the action(s) the applicant undertook or is undertaking to ensure that the behavior(s) which resulted in the criminal charges will not be repeated if a license is issued in New Hampshire; and

(3) Proof of working at least 2,000 hours as a certified pharmacy technician in the form a letter of attestation from one or more supervisors or equivalent documentation.

Ph 303.07 Qualifications for Initial Certification as a Pharmacy Technician . An applicant for a certified pharmacy technician shall:

(a) Be at least 18 years of age;

(b) Have a high school diploma or equivalent;

(c) Hold national certification from a nationally-recognized certifying organization for pharmacy technicians, such as the PTCB or the NHA; and

(d) Not have been:

(1) Convicted within the past 5 years of a drug or pharmacy-related misdemeanor; or

(2) Convicted at any time of a felony related to professional practice at any time, provided that the OPLC shall not deny a license based solely on a felony conviction more than 10 years prior to the application for licensure if the applicant demonstrates, through explanations submitted pursuant to Ph 303.08(b)(2), that the applicant is unlikely to engage in criminal behavior if a license is issued in New Hampshire.

Ph 303.08 Information and Documentation Required for Initial Pharmacy Technician Certification Application.

(a) The following information shall be submitted pursuant to Ph 306.02(b)(1)d.:

(1) Identification of the certifying organization from which the applicant holds certification and the date of most recent certification;

(2) The name, mailing address, and telephone number of the applicant's current employer; and

(3) Whether the applicant has ever voluntarily surrendered any professional license in this or any other jurisdiction.

(b) The following documentation shall be submitted pursuant to Ph 306.02(b)(3)d.:

(1) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each voluntary surrender reported pursuant to (a)(3); and

(2) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each criminal conviction and a complete explanation of the action(s) the applicant undertook or is undertaking to ensure that the behavior(s) which resulted in the criminal charges will not be repeated if a license is issued in New Hampshire.

Ph 303.09 Qualifications for Initial Registration as a Pharmacy Technician. An applicant for a registered pharmacy technician shall:

(a) Be at least 16 years of age;

(b) Have a high school diploma or equivalent, or be working to achieve a high school diploma or equivalent; and

(c) Not have been convicted of:

(1) A drug or pharmacy-related misdemeanor within the past 5 years; or

(2) A felony related to professional practice at any time, provided that the OPLC shall not deny a license based solely on a felony conviction more than 10 years prior to the application for licensure if the applicant demonstrates, through explanations submitted pursuant to Ph 303.10(b)(2), that the applicant is unlikely to engage in criminal behavior if a license is issued in New Hampshire.

Ph 303.10 Information and Documentation Required for Initial Registered Pharmacy Technician License Application.

(a) The following information shall be submitted pursuant to Ph 306.02(b)(1)e.:

(1) The name, mailing address, and telephone number of the applicant's current employer;

(2) The name and telephone number of the applicant's supervisor; and

(3) Whether the applicant has ever voluntarily surrendered any professional license in this or any other jurisdiction.

(b) The following documentation shall be submitted pursuant to Ph 306.02(b)(3)e.:

(1) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each voluntary surrender reported pursuant to (a)(3); and

(2) If applicable, a written explanation of the date(s), jurisdiction(s), and all relevant facts and circumstances of each criminal conviction and a complete explanation of the action(s) the applicant undertook or is undertaking to ensure that the behavior(s) which resulted in the criminal charges will not be repeated if a license is issued in New Hampshire.

PART Ph 304 APPROVAL FOR ADMINISTRATION OF VACCINES

Ph 304.01 Qualifications for Administration of Vaccines. A pharmacist, pharmacy intern, licensed advanced pharmacy technician, or certified pharmacy technician who seeks to engage in the administration of vaccines shall meet the requirements of RSA 318:16-b, I - IV, reprinted in Appendix C.

Ph 304.02 Application. After meeting the statutory requirements, a pharmacist, pharmacy intern, licensed advanced pharmacy technician, or certified pharmacy technician who seeks to engage in the administration of vaccines shall file a completed "Application for Authorization to Administer Vaccines" revised [month] 2024 with the licensing bureau.

Ph 304.03 Application Processing. The licensing bureau shall process the application as provided in Ph 306 for initial applications.

Ph 304.04 Issuance; Duration of Authorization.

(a) The licensing bureau shall issue an authorization to each applicant who demonstrates compliance with the requirements in RSA 318:16-b, I - IV.

(b) The authorization shall be coterminous with the underlying license but may be renewed with the underlying license.

PART Ph 305 QUALIFICATIONS AND REQUIREMENTS FOR INITIAL LICENSURE: PHARMACEUTICAL ENTITIES

Ph 305.01 Qualifications for Initial Licensure as an In-State Pharmacy.

(a) To qualify for initial licensure as an in-state retail pharmacy, the applicant shall:

(1) Have the legal right to occupy a place of business as a pharmacy in New Hampshire, whether as a pharmacy department in a larger retail facility or as a stand-alone pharmacy, that has adequate space to meet the requirements of Ph 5## for all functions proposed to be undertaken by the applicant, as demonstrated by an initial inspection;

(2) Be eligible to obtain a DEA registration number if controlled substances will be dispensed or otherwise handled;

(3) Have no responsible officials or shareholders of 5% or more of the stock who have been convicted of any local, state, or federal drug or pharmacy law; and

(4) Have no pending indictments of any nature of any local, state, or federal drug or pharmacy law.

(b) To qualify for a license as an institutional pharmacy, the applicant shall:

(1) Be an institution as defined in Ph 402 that is licensed to operate in New Hampshire; and

(2) Otherwise meet the qualifications for an in-state pharmacy in (a)(2)-(4), above.

(c) To qualify for a license as an in-state central fill pharmacy, the applicant shall:

(1) Be located in New Hampshire;

(2) Have or expect to have a contractual arrangement with one or more retail, non-dispensing, or institutional pharmacies, or directly with an institution, to process prescriptions on behalf of that pharmacy; and

(3) Meet the qualifications for an in-state retail pharmacy in (a)(2)-(4), above.

(d) To qualify for a license as an in-state non-dispensing pharmacy, the applicant shall:

(1) Be located in New Hampshire;

(2) Be owned by, or have or expect to have a contractual arrangement with, one or more retail, central fill, or institutional pharmacies, to perform non-dispensing activities on behalf of that pharmacy; and

(3) Meet the qualifications for an in-state retail pharmacy in (a)(3)-(4), above.

Ph 305.02 Information and Documentation Required for Initial In-State Pharmacy License Application.

(a) In addition to the information required by Plc 304.03, an applicant for any in-state pharmacy license shall provide the following information:

(1) The location where the pharmacy is proposed to be located, including street name and number, municipality, and county;

(2) Whether licensing is sought for the entire store area or the pharmacy department only;

(3) The anticipated total number of hours per week and the anticipated opening and closing time each day that the pharmacy will be open and available to provide professional services, provided that the applicant shall not be required to adhere to the anticipated hours stated;

(4) The name, business address, and occupation of each responsible official;

(5) If the applicant is a partnership, the percentage of ownership held by each partner including limited partners, and if any partner is a corporation, the information required for corporations for that partner;

(6) If the applicant or a partner is a corporation or a limited liability corporation, the following:

a. The corporation's full legal name as shown on the document(s) that created the entity, and each name under which the corporation does business in New Hampshire;

b. The corporation's principal place of business;

c. The name, address, and telephone number of the corporation's agent of record in New Hampshire for service of process;

d. A list of each type or class of voting stock and the number of shares authorized and outstanding for each class;

e. The name, address, corporate title, occupation, and percentage of stock held for each corporate officer and corporate director;

f. The name, address, occupation, and percentage of stock held for each holder of 5% or more of each class of voting stock and, if a listed shareholder is a corporation or a partnership, the information required by (5), above, or this subparagraph, as applicable;

g. The full legal name and state or country of formation of each parent, sister, and subsidiary company;

(7) The name and New Hampshire license number of each pharmacist and each pharmacy technician to be employed at the pharmacy, if known;

(8) The name and title of each individual who has or will have security access to the pharmacy, if known;

(9) Answers to the questions in Plc 304.04(e) for each individual and entity identified in (4) through (8), above.

(b) In addition to the documentation required by Plc 304.04, an applicant for any in-state pharmacy license shall provide a drawing to scale of the pharmacy that identifies:

(1) For all pharmacies, the dimensions and specific use(s) of each area of the pharmacy, including without limitation the portion devoted to the preparation of prescriptions if applicable; and

(2) For other than non-dispensing pharmacies, if the pharmacy is within a larger retail facility, the type of physical barrier that will separate the pharmacy from the rest of the store when the pharmacy is not open to the public.

Ph 305.03 Qualifications for Initial Licensure as a Non-Resident/Mail-Order Pharmacy. To qualify for licensure as a non-resident/mail order pharmacy, the applicant shall maintain a license in good standing from the regulatory authority in the jurisdiction in which the applicant is located, as required by RSA 318, 37, II(b)(1).

Ph 305.04 Information and Documentation Required for Initial Non-Resident/Mail-Order Pharmacy License Application.

(a) In addition to the information required by Plc 304.03, an applicant for licensure as a non-resident/mail-order pharmacy shall provide the following

(1) The pharmacy's name, physical address, mailing address if different, telephone number, and website address if any, together with the internet address the pharmacy will use when serving NH residents;

(2) The name, address, and title of each responsible official;

(3) If a corporation, a certificate of incorporation from the state in which incorporated; and

(4) The name, phone number, and email address of the responsible official in charge of the location listed in (1), above, and if the individual is a licensed pharmacist, the home-state pharmacist license number.

(b) In addition to the documentation required by Plc 304.04, an applicant for a non-resident/mail-order pharmacy license shall provide the following:

(1) A copy of the pharmacy's home state permit;

(2) Either of the following:

a. A copy of current NABP digital pharmacy accreditation; or

b. All of the following:

i. 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;

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

iii. 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; and

iv. Scaled drawings and square footage of the pharmacy and drug storage area;

(3) A copy of the applicant's current DEA registration certificate if the pharmacy will be shipping controlled drugs;

(4) A copy of the most recent inspection report of the facility, created in the last 18 months, from one of the following:

a. The board of pharmacy in the pharmacy's home state;

b. The NABP; or

c. A third party entity ~~approved by the board of pharmacy in the pharmacy's home state~~ authorized by a state or federal regulatory agency to conduct pharmacy compliance inspections;

Commented [HG1]: Need this qualifier?

(5) A list of all the corporate officers, owners, and others having control over the applicant, by full name and title, and an organization chart that shows the relationship of the persons named to the applicant's operations; and

(6) A copy of the certificate of the alarm system that is in place, or other proof the facility is alarmed.

Ph 305.05 Qualifications for Initial Licensure as a Limited Retail Drug Distributor.

(a) To qualify for licensure as a limited retail drug distributor, the applicant shall, as required by RSA 318:51-b, II:

(1) Be of good moral character or, for an applicant that is a legal entity, have managing officers who are of good moral character;

(2) Have sufficient space and security equipment to properly carry on the business described in the application; and

(3) If other than a medical gas/legend device distributor , have a written contract with a pharmacist licensed in NH to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.

(b) As provided in RSA 318:51-b, III, no license shall be granted to:

(1) Any person who has, within 5 years of the application date, been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in RSA 318 or RSA 318-B; or

(2) Any person who is a drug-dependent person.

(c) If the applicant owns and operates more than one site, the applicant shall apply for a separate license for each site.

Ph 305.06 Information and Documentation Required for Initial Limited Retail Drug Distributor License Application.

(a) In addition to the information required by Plc 304.03, an applicant for a limited retail drug distributor license shall provide the following information:

(1) Whether the applicant proposes to operate as a drug use treatment facility or a medical gas/legend device distributor;

(2) If the applicant proposes to sell medical gases/legend devices directly to consumers in New Hampshire, the following:

a. The location of the facility from which distribution occurs, by street address, municipality, state, and zip code;

b. If the facility is located in a jurisdiction other than New Hampshire, whether the location is licensed by the board of pharmacy or another licensing agency in that jurisdiction;

c. If the facility is not licensed in the jurisdiction in which it is located, an explanation of why no license has been obtained including a citation to applicable law if no license is required; and

d. Whether the applicant intends to ship oxygen or other medical gases, diabetic testing supplies, or other legend devices and if “other”, what will be shipped;

(3) If the applicant proposes to hold, store, or dispense controlled substances as a drug use treatment facility, the following:

a. A brief description of the security system, including whether it is based on sound or motion and where the signal is received;

b. A list of all persons with access to the controlled substances; and

c. The name and license number of the NH-licensed pharmacist with whom the applicant has contracted to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.

(b) In addition to the documentation required by Plc 304.04, an applicant for a limited retail drug distributor license shall provide the following:

(1) If the applicant is a distributor of medical gases/legend devices, the following:

a. A drawing of the facility to scale and with square footage shown;

b. If the facility is not in New Hampshire but is licensed by the board of pharmacy or another agency in the jurisdiction where it is located, a copy of the license;

c. A copy of the facility's most recent inspection report completed by the state licensing board or agency where the facility is domiciled, if it is located outside New Hampshire;

d. Any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements of Ph 5##; and

(2) If the applicant is a drug use treatment facility, the following:

a. A copy of the facility's current "NH DHHS Certified Drug Treatment Provider" certificate;

b. A copy of the facility's current DEA registration; and

c. Affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements for operation of a drug abuse treatment facility specified in He-A 304.

Ph 305.07 Qualifications for Initial Licensure as a Manufacturer, Repackager, ~~Broker,~~ or Wholesale Drug Distributor. ~~[Ph 1000? ("Manufacturers, Wholesalers, and Distributors")~~

Commented [HG2]: Keep? Delete?

(a) To qualify for initial licensure as a manufacturer, repackager, broker, or wholesale drug distributor, the applicant shall:

(~~a~~1) As required by RSA 318:51-a, II:

~~(1)~~a. Be of good moral character or, if a legal entity, have managing officers who are of good moral character; and

~~(2)~~b. Have sufficient space and security equipment as to properly carry on the business described in the application, namely that the applicant has sufficient space, security equipment, and operational procedures to ensure compliance with the federal Drug Supply Chain Security Act (DSCSA) standards for the storage, handling, and distribution of prescription drugs, including the use of electronic systems to capture, store, and maintain transaction information, transaction history, and transaction statements as required under DSCSA.

~~(3) Have a written contract with a pharmacist licensed in the state to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.~~

(2~~b~~) As provided in RSA 318:51-a, III, no license shall be granted to:

~~(1)~~a. Any person who has, within 5 years of the application date, been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in RSA 318 or RSA 318-B; or

~~(2)~~b. To any ~~person identified as a~~ drug-dependent person.

Commented [HG3]: Suggested by EL - but statute just says "any drug-dependent person", and including "identified as" will prompt the question "identified by whom/what organization?"

(b) No license shall be granted to any applicant that fails to demonstrate compliance with DSCSA requirements, including but not limited to the ability to verify and validate the licensure of trading partners and ensure the integrity of the drug supply chain.

Ph 305.08 Information and Documentation Required for Initial Wholesalers and Manufacturers License Application.

(a) In addition to the information required by Plc 304.03, an applicant for a wholesale drug distributor license shall provide the following information:

(1) The physical location of the facility where the manufacturing or distribution, or both, occurs, or if a broker only, the business mailing address;

(2) Whether the applicant is a manufacturer, virtual manufacturer, wholesaler/distributor, broker/reseller, relabeler/repackager, virtual distributor, third-party logistics provider that physically stores prescription products in its own facilities prior to shipping, a reverse distributor, or another type of operation;

(3) Whether the applicant will be selling or shipping, or both, any of the following as wholesale:

a. Controlled substances;

b. Human prescription drugs;

c. Veterinary prescription drugs;

d. Prescription devices;

e. Medical gases; or

f. Some other type of product(s), identified in the application;

(4) If the applicant will be shipping controlled drugs, the DEA registration number;

(5~~6~~) If the applicant is a manufacturer, whether the company is currently licensed by the US FDA~~.~~; and

(6~~5~~) If located in another jurisdiction:

a. The number of the home state controlled substance license, if applicable; and

b. Whether the facility is licensed by that jurisdiction's board of pharmacy or other licensing authority~~; and~~.

~~c. Proof of compliance with DSCSA requirements, including electronic systems to verify trading partners and provide transaction information, transaction history, and transaction statements.~~

(b) In addition to the documentation required by Plc 304.04, an applicant for a wholesale drug distributor license shall provide the following:

(1) Evidence of compliance with the requirements of the DSCSA, including:

a. Systems for maintaining transaction information, transaction history, and transaction statements data; and

b. Procedures for investigation and verification of suspect products;

(2) A copy of the applicant's policies and procedures for ensuring the security and integrity of the drug supply chain, including measures to prevent counterfeit or adulterated drugs; and

(3) If acting as a third-party logistics provider or reverse distributor, documentation demonstrating compliance with DSCSA reporting and record-keeping obligations.

Commented [HG4]: ??

Commented [HG5]: Suggested by EL - but it does not belong in the paragraph asking for information, and it is already covered in the next paragraph asking for documentation.

Commented [HG6]: 318:51-g, III
(d) "Third-party logistics provider" is a person that contracts with a wholesale distributor or a manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug, gas, device, or equipment.

Ph 305.09 Qualifications for Initial Licensure as an Outsourcing Facility. To qualify for initial licensure as an outsourcing facility, the applicant shall:

(a) As required by RSA 318:51-c, II:

(1) Be of good moral character or, if a legal entity, have managing officers who are of good moral character; and

(2) Have sufficient land, buildings, and security equipment as to properly carry on the business described in the application; and

(b) As provided in RSA 318:51-c, III, no license shall be granted to:

(1) Any person who has, within 5 years of the application date, been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in RSA 318 or RSA 318-B; or

(2) Any person who is a drug-dependent person.

Ph 305.10 Information and Documentation Required for Initial Outsourcing Facility License Application.

(a) In addition to the information required by Plc 304.03, an applicant for an outsourcing facility license shall provide the following information:

(1) Whether the applicant does or will ship or otherwise handle controlled drugs; and

(2) If the applicant is not located in New Hampshire, w~~W~~hether the applicant is licensed by the applicant's home state;

(b) In addition to the documentation required by Plc 304.04, an applicant for an outsourcing facility license shall provide the following:

(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) 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;

(5) Scale drawings of the facility, detailing usage of all space; and

(6) Any certificates, affidavits, plans, documents, or other information sufficient to show full compliance with all of the requirements for licensure.

Ph 305.11 Qualifications for Initial Licensure as a Research Organization.

(a) To qualify for licensure as a research organization, the applicant shall, as required by RSA 318:51-f, II:

(1) Have managing officers who are of good moral character; and

Commented [HG7]: Pharmacy Bd. page says "Sterile/Non-Sterile Bulk Compounder, Outsourcing Facility, FDA 503B" Are those different names for the same thing? Or are they all under the "Outsourcing Facility" umbrella?

Commented [HG8R7]: Outsourcing as defined by 503B = broadest term; includes non-patient-specific compounding

Commented [HG9R7]: 21 USC s. 353B sterile compounding

Commented [HG10R7]: look at definitions; ref 21 USC?

(2) Have sufficient space and security equipment to carry on the research operations described in the application in accordance with applicable state and federal laws and standards for the type of research being done.

(b) As provided in RSA 318:51-f, V, no license shall be granted to any research organization if any of its managing officers or researchers:

(1) Have, within 5 years of application, been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in RSA 318 or RSA 318-B; or

(2) Is a drug-dependent person.

Ph 305.12 Information and Documentation Required for Initial Research Organization License Application.

(a) In addition to the information required by Plc 304.03, an applicant for a research organization license shall provide the following information:

(1) The specific drug(s) or class(es) of drugs that will be investigated;

(2) The type of research to be done, such as:

a. Fundamental research;

b. Industrial research; or

c. Experimental development relating to:

1. Drug products, disease, and drug diagnostics;

2. Drug manufacturing technologies; or

3. Any combination of 1. and 2., above;

(b) In addition to the documentation required by Plc 304.04, an applicant for a research organization license shall provide the following:

(1) ...

Ph 305.13 Qualifications for Initial Licensure as a Clinic Pharmacy. To qualify for licensure as a clinic pharmacy, the applicant shall:

(a) Be authorized by the N.H. secretary of state to conduct business in New Hampshire; and

(b) Own or have a contract to provide pharmacy services to the clinic the pharmacy will serve.

Ph 305.14 Information and Documentation Required for Initial Clinic Pharmacy License Application.

(a) In addition to the information required by Plc 304.03, an applicant for a clinic pharmacy license shall provide the following information:

(1) If the applicant is not also the clinic owner, the name and … of the owner of the clinic;

(2) The type of pharmacy services expected to be provided to the clinic;

(3) … WHAT ELSE?

(b) In addition to the documentation required by Plc 304.04, an applicant for a clinic pharmacy license shall provide the following:

Commented [HG11]: What documentation is needed?

Commented [HG12]: Ph 102.08 "Clinic" means a facility, building, or part of a building devoted to the diagnosis and care of patients on an outpatient basis where drugs are administered. The term includes, but is not limited to, public health clinics and infusion centers, and includes veterinary clinics that possess controlled substances, and includes clinics that are part of a larger health care facility and clinics that are not part of a larger health care facility. The term does not include drug treatment clinics, which are regulated as limited retail drug distributors.

Ph 102.## "Clinic pharmacy" means a pharmacy that exclusively serves a clinic in New Hampshire and is not licensed as an institutional pharmacy.

Commented [HG13]: Any other qualifications?

Commented [HG14]: More discussion needed

Commented [HG15]: If the applicant doesn't own the clinic, what do we need to know about it?

(1) …WHAT?

PART Ph 306 PROCESSING OF INITIAL APPLICATIONS

Ph 306.01 Timing of Application Filing.

(a) An applicant for licensure as a pharmacist, pharmacy intern, or advanced pharmacy technician shall submit a complete application as specified in Ph 306.02 prior to undertaking any work for which licensure is required, provided that no applicant in these personnel categories shall undertake any work for which licensure is required prior to being licensed under RSA 318 and Ph 300.

(b) An applicant for certification as a pharmacy technician shall apply for certification within 15 days after the start date of employment as a certified pharmacy technician.

(c) An applicant for registration as a pharmacy technician shall file an application for registration within 15 days after the start date of employment as a pharmacy technician.

(d) An applicant for licensure in any pharmaceutical entity category shall submit all items required by the applicable sections of Ph 305 prior to undertaking any work for which licensure is required, provided that no applicant shall undertake any work for which licensure is required prior to being licensed under RSA 318 and Ph 300.

Ph 306.02 Applying for Initial Licensure: Pharmacy Personnel.

(a) Any individual who meets the applicable qualifications in Ph 303 and wishes to become licensed in a pharmacy personnel category in New Hampshire shall submit an application for licensure as specified in this section and in accordance with the timing requirements in Ph 306.01.

~~Ph 306.07 Facilitated Licensing for Active Duty Military and Military Spouses.~~(b) Each applicant for licensure who is on active military duty or who is a military spouse shall apply for licensure as provided in Plc 304.02.

(~~b~~c) Each applicant for initial licensure shall submit to the licensing bureau a "Universal Application for Initial License" dated April 2024 and the "Pharmacy Personnel Supplement to Universal Application for Initial License" dated [month] 2025 that provides:

(1) The information required by Plc 304.03 and the information required by:

a. For pharmacists, Ph 303.02(a);

b. For registered pharmacy interns, Ph 303.04(a);

c. For licensed advanced pharmacy technicians, Ph 303.06(a);

d. For certified pharmacy technicians, Ph 303.08(a); and

e. For registered pharmacy technicians, Ph 303.10(a);

(2) The signature and attestation required by Plc 304.05;

(3) The additional information and documentation required by Plc 304.04 and required by:

a. For pharmacists, Ph 303.02(b);

b. For registered pharmacy interns, Ph 303.04(b);

c. For licensed advanced pharmacy technicians, Ph 303.06(b);

d. For certified pharmacy technicians, Ph 303.08(b); or

e. For registered pharmacy technicians, Ph 303.10(b); and

(4) The application processing and licensing fee specified in Plc 1002.38.

Ph 306.03 Applying for Initial Licensure: Pharmaceutical Entities.

(a) Any entity that meets the applicable qualifications in Ph 305 and wishes to become licensed or registered in New Hampshire shall submit an application for licensure as specified in this section and in accordance with the timing requirements in Ph 306.01.

(b) Each applicant for initial licensure shall submit to the licensing bureau a "Universal Application for Initial License" dated April 2024, and a "Pharmaceutical Entity Supplement to Universal Application for Initial License" dated [month] 2025, that provides

(1) The information required by Plc 304.03 and the information required by:

a. For an in-state pharmacy, Ph 305.02(a);

b. For a non-resident/mail-order pharmacy, Ph 305.04(a);

c. For limited retail drug distributors, Ph 305.06(a);

d. For wholesale drug distributors, Ph 305.08(a);

e. For outsourcing facilities, Ph 305.10(a); or

f. For research organizations, Ph 305.12(a);

(2) The signature and attestation required by Plc 304.05;

(3) The additional information and documentation required by Plc 304.04 and required by:

a. For an in-state pharmacy, Ph 305.02(b);

b. For a non-resident/mail-order pharmacy, Ph 305.04(b);

c. For limited retail drug distributors, Ph 305.06(b);

d. For a wholesale drug distributor, Ph 305.08(b);

e. For outsourcing facilities, Ph 305.10(b); or

f. For research organizations, Ph 305.12(b); and

(4) The application processing and licensing fee specified in Plc 1002.38.

Ph 306.04 Processing of Applications for Initial Licensure of Pharmacy Personnel; Decisions.

(a) Within 30 days of receipt of an application submitted pursuant to Ph 306.02 or Ph 306.03, the licensing bureau shall process the application as provided in Plc 304.06.

(b) The application shall be subject to the abandonment provisions of Plc 304.06(h) and the withdrawal provisions of Plc 304.07.

(c) After determining that an application is complete, the licensing bureau shall review the application and notify the applicant of its decision in accordance with Plc 304.08 and Plc 304.09.

(d) The licensing bureau shall issue a license to any applicant who:

(1) Meets the applicable qualifications identified in Ph 303, or Ph 304.01, ~~or Ph 305,~~ as applicable ~~to the license applied for~~;

(2) Has demonstrated good character based on the answers the background and character questions in Plc 304.03(e); and

(3) Has submitted an application that meets all requirements of Ph 306.02 ~~or Ph 306.03, as applicable~~.

Ph 306.05 Processing of Applications for Initial Licensure of Pharmaceutical Entities; Decisions.

(a) Within 30 days of receipt of an application submitted pursuant to Ph 306.03, the licensing bureau shall process the application as provided in Plc 304.06.

(b) The application shall be subject to the abandonment provisions of Plc 304.06(h) and the withdrawal provisions of Plc 304.07.

(c) After determining that an application for an in-state pharmacy is complete, the licensing bureau shall refer the application for a site inspection to be conducted, to determine whether the premises are secure and suitable for the activities to be conducted as described in the application and required by applicable provisions of Ph 500.

(d) Upon being notified that the site inspection has been completed satisfactorily, or after determining that an application for another type of pharmaceutical entity is complete, the licensing bureau shall review the application and notify the applicant of its decision in accordance with Plc 304.08 and Plc 304.09.

(e) For any in-state pharmacy, the licensing bureau shall issue a temporary license to any applicant who:

(1) Meets the applicable qualifications identified in Ph 305;

(2) Has satisfactorily completed an initial inspection;

(3) Has demonstrated good character based on the answers the background and character questions in Plc 304.03(e); and

(4) Has submitted an application that meets all requirements of Ph 306.03, as applicable.

(f) Within 60 days of the issuance of the temporary permit, the pharmacy shall be inspected for full compliance with all aspects of the operations to be conducted, provided that if the inspection is satisfactory, the licensing bureau shall issue a full license.

(g) For all other pharmaceutical entities, the licensing bureau shall issue a license to any applicant who:

(1) Meets the applicable qualifications identified in Ph 305;

(2) Has demonstrated good character based on the answers the background and character questions in Plc 304.03(e); and

(3) Has submitted an application that meets all requirements of Ph 306.03, as applicable.

Ph 306.06 Challenging a Denial of Initial Licensure. An applicant who wishes to challenge the denial of an application for initial licensure shall do so as provided in Plc 304.10.

Ph 306.07 Initial Licensure: Issuance and Duration.

(a) The OPLC shall issue initial licenses in accordance with Plc 304.11.

(b) Initial licenses shall be valid as provided in Plc 304.12.

APPENDIX A: STATE STATUTES IMPLEMENTED

[table]

APPENDIX B: DOCUMENTS INCORPORATED BY REFERENCE

[table]

APPENDIX C: STATUTORY PROVISIONS

RSA 318:16-b Pharmacist Administration of Vaccines. – A pharmacist, pharmacy intern, licensed advanced pharmacy technician, or certified pharmacy technician, under the supervision of an on-site immunizing pharmacist may administer influenza and a COVID-19 vaccine, if available, to the general public. A pharmacist, pharmacy intern, or licensed advanced pharmacy technician, under the supervision of an on-site immunizing pharmacist may administer haemophilus influenza, hepatitis A, hepatitis B, hepatitis A and B, human papillomavirus, meningococcal, pneumococcal, tetanus and diphtheria, varicella, zoster, MMR (measles, mumps, and rubella), and Tdap (tetanus, diphtheria and pertussis) vaccines, which have been approved by the Food and Drug Administration, to individuals 18 years of age or older as ordered by an immunizing pharmacist. The pharmacist, pharmacy intern, licensed advanced pharmacy technician, or certified pharmacy technician shall:

I. Hold a current license to practice as a pharmacist, be registered as a pharmacy intern under RSA 318:15-b in New Hampshire, or be licensed as a licensed advanced pharmacy technician under RSA 318:15-c, or be a certified pharmacy technician and registered with the board pursuant to RSA 318:15-a.

II. Possess at least $1,000,000 of professional liability insurance coverage.

III. In order to administer vaccines, have completed training specific to administration of the respective vaccines that includes programs approved by the Accreditation Council for Pharmacy Education (ACPE) or curriculum-based programs from an ACPE-accredited college of pharmacy or state or local health department programs or programs recognized by the board. This training shall include hands-on injection technique and the recognition and treatment of emergency reactions to vaccinations.

IV. Have a current certificate in basic cardiopulmonary resuscitation.

V. Provide to the board evidence of compliance with paragraphs I- IV.

VI. Provide notice to the primary care provider, when designated by the patient, of the administration of any vaccine.

VII. Record the vaccination in the state vaccine registry in accordance with RSA 141-C:20-f and/or when required by state and federal law and maintain a record of the vaccination as required by state and federal law.

VIII. Submit reports of any adverse reactions following vaccination to the Centers for Disease Control (CDC) Vaccine Adverse Event Reporting System (VAERS).

IX. Review the vaccine registry or other vaccination records before administering the vaccination.

Source. 2008, 283:1. 2011, 213:1, eff. Aug. 26, 2011. 2017, 51:1, eff. July 11, 2017. 2020, 39:58, eff. July 29, 2020. 2021, 192:1, eff. Nov. 8, 2021. 2022, 274:1, eff. Sept. 22, 2022.

RSA 318:18 Pharmacists. –

I. (a) An applicant for examination and licensure as a pharmacist shall have graduated with the basic, professional pharmacy baccalaureate degree or pharmacy doctor degree from a school of pharmacy, college of pharmacy, or pharmacy department of a university approved by the board including programs accredited by the American Council on Pharmaceutical Education or the Canadian Council for Accreditation of Pharmacy

Programs or, if a graduate of a foreign school or college of pharmacy other than Canadian, the applicant shall be fully certified by the Foreign Pharmacy Graduate Equivalency Committee (FPGEC) which shall include passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) and Test of English as a Foreign Language (TOEFL), with scores approved by the board of pharmacy as set forth in the rules.

(b) In addition to the above, all applicants for examination and licensure as a pharmacist shall:

(1) Not be less than 18 years of age;

(2) Be of good professional character and temperate habits; and

(3) File proof satisfactory to the office of professional licensure and certification, substantiated by proper affidavits, of a minimum of one year (1,500 hours) internship activity in a community or institutional pharmacy in the United States or Canada or an equivalent program which has been approved by the board of pharmacy; and shall pass the national examination administered by the National Association of Boards of Pharmacy (NABP) to establish his or her fitness to practice the profession of pharmacy. The internship required in this section shall be service and experience in a community or institutional pharmacy under the supervision of a licensed pharmacist and shall be predominantly related to the selling of drugs and medical supplies; interpreting, compounding, preparing and dispensing of prescriptions; preparing of pharmaceutical products; keeping records and making reports required under federal and state statutes; and otherwise practicing pharmacy under the immediate supervision and direction of a licensed pharmacist.

II. The office of professional licensure and certification may deny licensure as a pharmacist for grounds which include, but which shall not be limited to, prior conviction of a felony; or of a misdemeanor resulting from a violation of a federal, state or local drug or pharmacy-related law, rule, or regulation.

Source. 1921, 122:11. 1925, 84:2. PL 210:18. RL 256:18. 1949, 280:3. RSA 318:18. 1969, 276:1. 1973, 72:68. 1979, 155:16. 1981, 484:7, 20. 1985, 324:5. 1988, 106:2. 1997, 149:4. 2001, 282:4. 2010, 259:3, eff. July 6, 2010. 2023, 79:309, 310, eff. Sept. 1, 2023.