*all will be in ***bold italics*** in the actual IP, but bold italics is harder to read for review purposes.

CHAPTER Ph 100 ORGANIZATIONAL RULES

Readopt with amendments Ph 101, eff. 2-5-96 (doc. #6181-A), to read as follows:

PART Ph 101 PURPOSE ~~AND SCOPE~~***; APPLICABILITY; INCORPORATED DEFINITIONS***

Ph 101.01 Purpose ~~and Scope~~. The ***purpose of the*** rules ~~of~~ ***in*** this title ***is to*** implement the statutory responsibilities***,*** ~~of the New Hampshire board of pharmacy created by~~ ***under*** RSA 318~~,~~ as amended~~,~~ and RSA 318-B~~,~~ as amended***, of the New Hampshire pharmacy board established by RSA 318:2***.

Ph 101.02 Applicability. These ~~provisions regulate~~ ***rules in title Ph shall apply to:***

(1) T~~t~~he licensing of ~~pharmacies and pharmacists,~~ ***pharmacy personnel and pharmaceutical entities;***

(2) T~~t~~he practice of pharmacy in the state of New Hampshire~~,~~***;***

(3) T~~t~~he safekeeping and distribution of ~~pharmaceuticals and~~ legend drugs~~,~~***;*** and

(4) T~~t~~he ***standards that form the bases for*** inspection of pharmacies and other licensed and unlicensed locations where legend drugs are held, stored or offered for sale.

Ph 101.03 Definitions Incorporated from Applicable Provisions in Title Plc. All terms used in these rules relative to procedures, applications, inspections, and fees that are defined in Plc 100 through Plc 400 or Plc 1000 shall have the meaning specified in title Plc.

Readopt with amendments Ph 102, eff. 2-5-96 (doc. #6181-A), and renumber as Part Ph 102, cited and to read as follows:

PART Ph 102 DEFINITIONS

~~Ph 102.01 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 102.02 Other Definitions.~~

Ph 102.01 "Administer" means "administer" as defined in RSA 318:1, I, reprinted in Appendix B.

Ph 102.02 "Advanced practice registered nurse" means "advanced practice registered nurse" as defined in RSA 318:1,I-, reprinted in Appendix B.

Ph 102.03 "Automated pharmacy system" means "automated pharmacy system as defined in RSA 318:1, XXII, reprinted in Appendix B. The term includes systems that use electronic controls to trigger the mechanical mechanisms, and does not include prepackaging or repacking devices.

Ph 102.04 "Board" means "board" as defined in RSA 318:1, III, reprinted in Appendix B.

Ph 102.05 "Central fill pharmacy" means a licensed pharmacy, in New Hampshire or any other jurisdiction of the United States, that engages in central prescription processing including filling, refilling, or both, prescriptions including the preparation, packaging, and labeling of the medication. The term excludes any non-dispensing pharmacy.

Ph 102.06 "Central prescription processing" means "central prescription processing" as defined in RSA 318:1, XXIII, reprinted in Appendix B.

Ph 102.07 "Certified pharmacy technician" means an individual who meets the qualifications specified in Ph 303.07 and has been certified by the board.

Commented [GRH1]: As far as I can tell, these ("pharmaceuticals" and "legend drugs") are NOT different things. Also, "pharmaceutical" as a thing is not defined anywhere in the statute or rules, but "prescription drug or legend drug" is defined.. "Pharmaceutical" is used frequently as an adjective (e.g., pharmaceutical services, pharmaceutical industry), but not so much to just mean "drug".

Commented [GRH2]: but not pharmaceuticals? By listing both in (3) and listing only one in (4), creates a presumption that (4) doesn't apply to "pharmaceuticals".

Commented [GH3]: Terms that will be used only in Ph 500 (practices, SOPs), will be defined in that chapter so have been removed from this chapter. Since there are now fewer than 100 definitions, I've merged the incorporated references with the others.

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. The term includes, but is not limited to, public health clinics and methadone clinics, 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.

Ph 102.09 "Compounder" means, based on context, an individual trained to compound preparations or a business entity that compounds prescriptions.

Ph 102.10 "Compounding" means "compounding as defined in RSA 318:1, III-a, reprinted in Appendix B.

Ph 102.11 "Compounding area" means a space that is specifically designated for type of compounding being performed in a non-sterile compounding area, a cleanroom suite, or inside the perimeter of the segregated compounding area (SCA).

Ph 102.12 "Controlled substance" means any substance" that is subject to control under RSA 318-B.

Ph 102.13 "Dispense" means "dispense" as defined in RSA 318:1, V, reprinted in Appendix B.

Ph 102.14 "Distributor" means "distributor" as defined in RSA 318:1, V-a, reprinted in Appendix B.

Ph 102.15 "Distributor" means a pharmaceutical entity that supplies or facilitates the supply of prescription drugs or devices to someone other than the patient. The term includes manufacturers, repackagers, brokers, and jobbers. The term does not include outsourcing facilities.

Ph 102.16 "Drug preparation" as a verb means to prepare or approve a medication for dispensing when preparation is done according to manufacturer's instructions provided in the current Federal Food and Drug approved package insert.

Ph 102.17 "Drugs" means "drugs" as defined in RSA 318:1, VI, reprinted in Appendix B.

Ph 102.18 "Electronic identifier" means a unique security code or biometric identifier that specifically identifies the individual entering information into a data processing system or removing a drug from inventory.

Ph 102.19 "Electronic signature" means "electronic signature" as defined in RSA 318:1, XXIV-a, reprinted in Appendix B.

~~(b) "Evidence" means all oral or documentary material received by the board. Evidence includes, but is not limited to, testimony under oath or affirmation, documents, exhibits, and sworn statements of witnesses who are unable to appear at the proceedings.~~

~~(c) "Executive secretary" means the board's staff director, a person with delegated authority to perform administrative and clerical functions for the board.~~

Ph 102.20 "Infusion center" means a licensed facility, typically operated on an outpatient basis, where patients can receive intravenous infusions and therapeutic injections in a safe, professional, and comfortable environment.

Ph 102.21 "In-state pharmacy" means a pharmacy that has a physical presence in New Hampshire where some or all aspects of the practice of pharmacy as defined in RSA 318:1, XIV take place. The term includes any pharmacy located in New Hampshire, including but not limited to retail pharmacies, institutional pharmacies, central fill pharmacies, non-dispensing pharmacies, infusion center pharmacies, and clinic pharmacies.

Commented [GH4]: Q re: put in ch. 500?

Commented [GRH5]: RSA 318:1, XXI. defines "Wholesaler" as "a person with facilities in or outside this state who obtains drugs for distribution or delivery to persons other than consumers."

Commented [GRH6]: There doesn't seem to be a lot to distinguish "outsourcing facilities" (compounders) from "distributors" as defined here...

Commented [GH7]: need to include as a license type under in-state or institutional – talk with board

Ph 102.22 "Institution" means a facility in New Hampshire that provides inpatient health care on a short-term or long-term basis or provides outpatient health care. The term includes hospitals, nursing homes, extended care facilities, residential care facilities, and hospice houses. The term also includes infirmaries serving places whose primary purpose is not health care, such as educational institutions, correctional facilities, and military installations.

Ph 102.23 "Institutional pharmacy" means an area in an institution designated for the storage, manufacture, compounding, dispensing, or issuing of drugs to individuals in or at the institution or to other areas or departments of the institution. The term includes the placement of an automated pharmacy system at an institution that otherwise does not have a pharmacy.

Ph 102.24 "Labeling" means a term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

Ph 102.25 "Legend device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, that is restricted for distribution and use only upon the order of a licensed practitioner.

~~(d)~~***Ph 102.26*** "Licensed" means a person or place ***is*** lawfully authorized to engage in the practice of pharmacy under RSA 318~~:18 and RSA 318:37 and~~ ***The term*** includes "registered" ***and "certified"*** when used to refer to ~~pharmacists~~ ***pharmacy technicians*** ~~or~~ ***and includes "registered" when used to refer to*** pharmacies.

Ph 102.27 "Licensed advanced pharmacy technician" means an individual who meets the qualifications summarized in Ph 303.05 and has been licensed under RSA 318, who is authorized to practice per RSA 318:1, XXXIII, reprinted in Appendix B.

Commented [GH8]: The "definition" in the statute is more of a scope of practice, so I am proposing to blend the two definitions.

Ph 102.28 "'Licensed pharmacist' or 'pharmacist'" means "'Licensed pharmacist' or 'pharmacist'" as defined in RSA 318:1, VII, reprinted in Appendix B.

Ph 102.29 "Limited retail drug distributor" means "limited retail drug distributor" as defined in RSA 318:1, VII-a, reprinted in Appendix B.

Ph 102.30 "Mail-order pharmacy" means "mail-order pharmacy" as defined in RSA 318:1, VII-b, reprinted in Appendix B.

Ph 102.31 "Manufacturing" means "manufacturing" as defined in RSA 318:1, VIII, reprinted in Appendix B.

Ph 102.32 "Medical gas/legend device distributor" means a limited retail drug distributor that distributes only medical gases or legend devices, or both.

Ph 102.33 "Medication order" means a verbal, telephonic, written, facsimile, or electronically transmitted order provided by a prescribing practitioner for a specific drug to be administered to an individual in real time.

Commented [GH9]: Okay to add this? Or "at a designated time"?

Ph 102.34 "Methadone clinic" means a clinic that has been established for the dispensing of methadone and other medications to treat opioid addiction in accordance with federal law.

Ph 102.35 "Non-dispensing activities" means "non-dispensing activities" as defined in RSA 318:1, XXXV, reprinted in Appendix B.

Ph 102.36 "Non-dispensing pharmacy" means a licensed pharmacy, in New Hampshire or any other jurisdiction of the United States, that engages in prescription review and other related non-dispensing functions such as data entry, prospective drug review, refill authorizations, therapeutic interventions, patient counseling, claims submission, claims resolution, and claims adjudication. The term

excludes any pharmaceutical entity that fills prescriptions or otherwise stores, handles, distributes, or dispenses prescription medications or devices.

Ph 102.37 "Nurse practitioner" means an advanced practice registered nurse (APRN) licensed by the board of nursing under RSA 326-B:18.

~~(e) "Order" means the whole or any part of the final decision, whether affirmative, negative or declaratory in form, of the board in any matter other than rulemaking, but including licensing. An order has particularized effect on each party to the proceeding.~~

Ph 102.38 "Outsourcing facility" means "outsourcing facility" as defined in RSA 318:1, XXX, reprinted in Appendix B.

Ph 102.39 "Permit holder" means "permit holder" as defined in RSA 318:1, XXXVII, reprinted in Appendix B.

Ph 102.40 "Pharmaceutical entity" means a legally-formed business organization that operates, whether on a for-profit or non-profit basis and whether as a part of separate but related operations or as a stand-alone operation, as an entity that practices pharmacy. The term includes, but is not limited to:

(a) Any in-state pharmacy, including any retail pharmacy, institutional pharmacy, in-state central fill pharmacy, in-state non-dispensing pharmacy, or in-state clinic pharmacy;

(b) Any non-resident/mail-order pharmacy;

(c) Any limited retail drug distributor;

(d) Any wholesale drug distributor;

(e) Any outsourcing facility; or

(f) Any research organization.

Ph 102.41 "Pharmacy" means "pharmacy" as defined in RSA 318:1, XI, reprinted in Appendix B.

Ph 102.42 "Pharmacy benefits manager" means "pharmacy benefits manager" as defined in RSA 318:1, XI-a, reprinted in Appendix B.

Ph 102.43 "Pharmacy technician" means "pharmacy technician" as defined in RSA 318:1, XI-b, reprinted in Appendix B.

Ph 102.44 "Pharmacy intern" means "pharmacy intern" as defined in RSA 318:1, XI-aa, reprinted in Appendix B.

Ph 102.45 "Pharmacy personnel category" means any of the 5 types of licensure available for pharmacy personnel, namely pharmacists, pharmacy interns, advanced pharmacy technicians, certified pharmacy technicians, and registered pharmacy technicians.

Ph 102.46 "Practice of pharmacy" means "practice of pharmacy" as defined in RSA 318:1, XIV, reprinted in Appendix B.

Ph 102.47 "'Practitioner' or "licensed practitioner'" means "'practitioner' or "licensed practitioner'" as defined in RSA 318:1, XV, reprinted in Appendix B.

Ph 102.48 "Prescription" means "prescription" as defined in RSA 318:1, XVI, reprinted in Appendix B.

Ph 102.49 "'Prescription device' or 'legend device'" means "'prescription device' or 'legend device'" as defined in RSA 318:1, XVI-a, reprinted in Appendix B.

Ph 102.50 "'Prescription drug', 'legend drug', or 'potent drug'" means "'prescription drug', 'legend drug', or 'potent drug'" as defined in RSA 318:1, XVII, reprinted in Appendix B.

Ph 102.51 "Prescriber" means a practitioner who issues a medication order or prescription.

Ph 102.52 "Product verification" means the act of validating the correct drug, strength, and form of the drug product being dispensed.

Ph 102.53 "Public health clinic" means a private, nonprofit organization that directly or indirectly, through contracts and cooperative agreements, provides primary health services and related services to residents of a defined geographic area that is medically underserved. The term includes "community health centers".

Ph 102.54 "Registered pharmacy technician" means an individual who meets the qualifications stated in Ph 303.09 and has registered in accordance with Ph 303.10.

Ph 102.55 "Remote processing" means "remote processing" as defined in RSA 318:1, XXXIV, reprinted in Appendix B.

Ph 102.56 "Research organization" means "research organization" as defined in RSA 318:1, XXXI, reprinted in Appendix B.

Ph 102.57 "Researcher" means "researcher" as defined in RSA 318:1, XXXII, reprinted in Appendix B.

Ph 102.58 "Responsible official" means any individual who, based on the applicant's legal structure, has responsibility for, or control over, the applicant. The term includes partners, officers, directors, and similarly-situated individuals.

Ph 102.59 "Retail pharmacy" means an in-state pharmacy having a physical presence in New Hampshire that is open to the public.

Ph 102.60 "Signature" means:

(a) The handwritten name of an individual affixed by the hand of that individual to a document;

(b) An electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign a document or record; or

(c) An electronic signature.

Ph 102.61 "United States Pharmacopeia (USP)" means a compendium of standards for drugs for the United States published annually by the United States Pharmacopeial Convention, a nonprofit organization.

Ph 102.62 "Wholesale drug distribution" means distribution of prescription drugs other than to the patient, including but not limited to distribution by manufacturers, repackers, own-label distributors, jobbers, and wholesale drug distributors.

Commented [GRH10]: "distribut**or**" can be defined separately; this is wholesale distribut**ion**

Ph 102.63 "Wholesaler" means "wholesaler" as defined in RSA 318:1, XXI, reprinted in Appendix B.

Readopt with amendments Ph 103.01, eff. 4-20-12 (doc. #10117), cited and to read as follows:

PART Ph 103 ~~AGENCY~~ ***PHARMACY BOARD*** ORGANIZATION

Ph 103.01 ***Board*** Composition.

(a) Pursuant to RSA 318:2, t~~T~~he New Hampshire ~~board of~~ pharmacy ***board*** is composed of 7 board members, appointed by the governor and council for a term of 5 years, limited to no more than 2 consecutive terms. ~~At least one member shall be~~ ***The membership comprises*** 5 ***practicing pharmacists, at least one of whom shall be*** a ***full-time*** hospital pharmacist, ***one pharmacy technician,*** and one ~~member~~ ***who*** shall be a public member.

(b) Members shall meet the qualifications specified in RSA 318:3.

Readopt with amendments Ph 103.02 through Ph 103.04, eff. 2-5-96 (doc. #6181-A), to read as follows:

Ph 103.02 ***Board*** Officers. Annually, in September, the ***duly-appointed*** board members shall elect, from among ~~their number~~ ***the board members***, a ~~president, a vice president, a secretary and a treasurer~~ ***chair and a vice chair***.

Ph 103.03 ***Board*** Address ***and Contact Information***.

(a) The board***'s offices*** shall ~~maintain an office~~ ***be at the offices of the office of professional licensure and certification (OPLC), currently*** at 7 Eagle Square, Concord, N.H. 03301.

(b) All correspondence with the board shall be addressed as follows:

~~State of~~ New Hampshire ***Pharmacy*** Board ~~of Pharmacy~~
c/o OPLC
7 Eagle Square
Concord, New Hampshire 03301.

(~~b~~***c***) The telephone number of the board shall be (603) 271-2152. ~~The fax number shall be (603) 271-2856.~~

Ph 103.04 ***Board*** Meetings.

(a) The board shall ~~meet in its office on~~ ***schedule regular meetings for*** the third Wednesday of each month ***in the OPLC offices***.

(b) Special meetings shall be held at the call of the ~~president~~ ***chair*** or ~~by any officer~~ ***vice chair***.

~~(b) A majority of the board may take action by telephone poll or written ballot provided that such action is ratified at a subsequent meeting of the board.~~

(c) The board shall act in strict compliance with the open meeting requirements of RSA 91-A:2.

Readopt with amendments Ph 104.01 and Ph 104.02, eff. 2-5-96 (doc. #6181-A), cited and to read as follows:

PART Ph 104 PUBLIC INFORMATION

Ph 104.01 ***Board*** Records. Except as exempted by law, all ***public*** records of the board may be examined by any person at the board office, during weekdays, excluding ***state*** holidays, from 8:00 a.m. to 4:00 p.m.***, by filing a request in accordance with Plc 105.***

Ph 104.02 Copies.

(a) At the time and place identified in Ph 104.01, any person examining a document may make a copy of that document by any means not injurious to the document***,*** provided that the person wishing to make the copy supplies the means of doing so in the ***OPLC's*** office~~s of the board~~. In the event a person does not have a means of copying ~~those~~ ***the*** documents, the ~~board~~ ***OPLC*** shall make copies of the documents examined upon request.

(b) The ~~prescribed~~ fee for copies of documents made ***pursuant to this section shall be as specified in Plc 1001.05.*** ~~by this board shall be a minimum of $5.00 which includes up to 20 pages then 0.25¢ for each additional page thereafter and shall be payable in advance by bank draft, money order, certified check or cash.~~

Readopt with amendments Ph 104.03, eff. 4-25-08 (doc. #9139-A), to read as follows:

Ph 104.03 Lists of Licensees/Registrants.

(a) Instead of the examination and copying permitted by Ph 104.01 and Ph 104.02, any person may request the board to provide that person with a complete mailing list of the board's licensees/registrants. ~~This request shall be accompanied by the prescribed fee for each list requested and shall be paid by check or money order.~~

(b) As provided in Plc 1001.14, no fee shall be charged for a copy of a roster or mailing list.

~~(b) The fees for the lists shall be:~~
~~(1) Pharmacist data file by e-mail 125.~~
~~(2) Pharmacist data file on CD-ROM $150.~~
~~(3) Pharmacist pre-printed mailing labels $200.~~
~~(4) Pharmacy Technician data file by e-mail $125.~~
~~(5) Pharmacy Technician data file on CD-ROM $150.~~
~~(6) Pharmacy Technician pre-printed mailing labels $200.~~
~~(7) In-State Pharmacy data file by e-mail $75.~~
~~(8) In-State Pharmacy data file on CD-ROM $100.~~
~~(9) In-State Pharmacy pre-printed mailing labels $150.~~
~~(10) Out-of-State Pharmacy data file by e-mail $75.~~
~~(11) Out-of-State Pharmacy data file on CD-ROM $100.~~
~~(12) Out-of-State Pharmacy pre-printed mailing labels $150.~~
~~(13) Drug Manufacturer/Wholesaler data file by e-mail $ 75.~~
~~(14) Drug Manufacturer/Wholesaler data file on CD-ROM $100.~~
~~(15) Drug Manufacturer/Wholesaler pre-printed mailing labels $150.~~

Commented [GRH11]: Plc 1001.14 No Fees For Certain Services. No fee shall be charged for any of the following:
...
(d) Providing a copy of a roster or mailing list.

APPENDIX A: STATE STATUTE(S) IMPLEMENTED

Rule	State Statute(s) Implemented
Ph 100	~~RSA 318:5-a, VIII,~~ RSA 541-A:16, I (a)

Commented [GH12]: repealed

APPENDIX B: STATUTORY DEFINITIONS

318:1 Definitions. – In this chapter:

I. "Administer" means an act whereby a single dose of a drug is instilled into the body of, applied to the body of, or otherwise given to a person or animal for immediate consumption or use.

I-a. "Advanced practice registered nurse" means a person licensed to practice as an advanced practice registered nurse in this state pursuant to RSA 326-B:18.

II. "At retail" means the dispensing of drugs or medicines pursuant to the order of a physician, dentist, veterinarian, or advanced practice registered nurse, whether or not such drugs or medicines are dispensed for a valuable consideration.

III. "Board", when not otherwise limited, means the New Hampshire pharmacy board.

III-a. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the pharmacist-patient-prescriber relationship in the course of professional practice or, for the purpose of, or as an incident, to research,

teaching, or chemical analysis, but not selling or dispensing. “Compounding” also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. “Compounding” shall not include the reconstitution of powdered formulations before dispensing or the addition of flavoring. “Compounding” shall not include the simple addition of flavoring, nor shall it include the preparation of a single dose of a nonhazardous commercially available drug or licensed biologic for administration within 2 hours of preparation to an individual patient when done in accordance with the manufacturer’s approved labeling or instructions consistent with that labeling.

V. “Dispense” means to distribute, leave with, give away, dispose of, deliver, or sell one or more doses of a drug that will be administered or taken at a later date, time, or location and shall include the transfer of more than a single dose of a medication from one container to another and the labeling or otherwise identifying a container holding more than a single dose of a drug.

V-a. “Distributor” means a person or persons who supply or facilitate the supply of prescription drugs to persons other than consumers.

VI. “Drugs”, when not otherwise limited, means all substances used as medicines or in the practice of medicine.

XVI-a. “Prescription device” or “legend device” means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is restricted for distribution and use only upon the order of a licensed practitioner.

VII. “Licensed pharmacist” or “pharmacist”, when not otherwise limited, means a person holding a license under RSA 318:18 and who is, therefore, legally authorized to practice the profession of pharmacy in this state.

VII-a. "Limited retail drug distributor" means a distributor of legend devices or medical gases delivered directly to the consumer pursuant to a practitioner's prescription order, or federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored, or dispensed to patients pursuant to the order of an authorized practitioner.

VII-b. "Mail-order pharmacy" means a pharmacy that is located in a state of the United States, other than this state, whose primary business is to dispense a prescription drug or device under a prescription drug order and to deliver the drug or device to a patient, including a patient in this state, by the United States mail, a common carrier, or a delivery service. Mail-order pharmacies include, but are not limited to, pharmacies that do business via the Internet or other electronic media.

VIII. "Manufacturing" means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by large volume extraction from substances of natural origin, or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices for resale. Manufacturing shall be governed by Good Manufacturing Practices as adopted and enforced by the federal Food and Drug Administration.

XI. "Pharmacy", when not otherwise limited, means the place registered by the office of professional licensure and certification where the profession of pharmacy is practiced and where drugs, chemicals, medicines, prescriptions, or poisons are compounded, dispensed, stored, or retailed.

XI-a. "Pharmacy benefits manager" means "pharmacy benefits manager" as defined in RSA 402-N:1, VIII.

XI-b. "Pharmacy technician" means a person, other than a pharmacist or a pharmacy intern, either registered or certified by the office of professional licensure and certification for the purpose of assisting a pharmacist in the practice of pharmacy.

XI-aa. "Pharmacy intern" means a person who is registered by the office of professional licensure and certification pursuant to RSA 318:15-b and:

(a) Is enrolled in a professional degree program of a school or college of pharmacy that has been approved by the board and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist starting no earlier than 4 months prior to the third year of study; or

(b) Is a graduate of an approved professional degree program of a school or college of pharmacy or is a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate, who is currently licensed by the office for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

(c) Is a qualified applicant awaiting examination for licensure or meeting board requirements for re-licensure; or

(d) Is participating in a residency or fellowship program.

XIV. “Practice of pharmacy” means the professional acts performed by a pharmacist and shall include the interpretation and evaluation of prescription orders; the administration, compounding, dispensing, labeling and distribution of drugs and devices; the participation in drug selection and drug-related device selection; drug evaluation; utilization or regimen review; the monitoring of drug therapy and use; medication therapy management in accordance with collaborative pharmacy practice agreements; the proper and safe storage and distribution of drugs and devices, and the proper maintenance of proper records; the responsibility of advising, when necessary or when regulated, of therapeutic values, hazards, and use of drugs and devices; the initiating, ordering, administering, and analyzing of FDA approved Emergency Use Authorization SARS-CoV-2 (COVID-19) point-of-care diagnostic kits (COVID-19 tests or test kits) to detect SARS-CoV-2 or its antibodies, so long as the pharmacist has received the adequate education and training to do so; and the offering or performing of these acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy.

XVI. "Prescription" means a verbal, or written, or facsimile or electronically transmitted order for drugs, medicines and devices by a practitioner licensed in the United States, to be compounded and dispensed by licensed pharmacists in a duly registered pharmacy, and to be kept on file for a period of 4 years. A written order shall include an electronic transmission prescription received and retained in a form complying with rules adopted pursuant to RSA 318:5-a, XV. Prescriptions may also apply to the finished products dispensed or administered by the licensed pharmacist in the registered pharmacy, on order of a licensed practitioner as defined in this section.

XVI-a. "Prescription device" or "legend device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is restricted for distribution and use only upon the order of a licensed practitioner.

XVII. "Prescription drug", "legend drug," or "potent drug" means:

(a) A drug which under federal law is required, prior to being dispensed or delivered, to be labelled with any of the following statements:

(1) "Caution federal law prohibits dispensing without prescription", or

(2) "Caution federal law restricts this drug to use by or on the order of the licensed veterinarian", or

(3) "RX only", or

(b) A drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners.

XXI. "Wholesaler" means a person with facilities in or outside this state who obtains drugs for distribution or delivery to persons other than consumers.

XXII. "Automated pharmacy system" means mechanical systems that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collects, controls, and maintains all transaction information.

Commented [GRH13]: same as auto dispensing machine

XXIII. "Central prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions, such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

XXIV-a. "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

XV. "Practitioner" or "licensed practitioner" means any person who is lawfully entitled to prescribe, administer, dispense or distribute legend drugs to patients.

XXX. "Outsourcing facility" means 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.

XXXI. (a) "Research organization" means an entity, including a biotechnology company or research institute, whose primary goal is to conduct fundamental research, industrial research, or experimental development relating to drug products, disease and drug diagnostics, and/or drug manufacturing technologies.

(b) A "research organization" shall not include:

(1) A "sponsor," "sponsor-investigator," or "contract research organization" as such terms are defined in 21 C.F.R. section 312.3;

(2) An "applicant" as such term is defined in 21 C.F.R. section 314.3; a "manufacturer," "processor," "packer," or "distributor" as such terms are used in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 301 et. seq.); or

(3) A "manufacturer" or "applicant" as such terms are used in 21 C.F.R. section 601.2.

XXXII. "Researcher" means a qualified person representing a research organization licensed by the office of professional licensure and certification pursuant to RSA 318:51-f.

XXXIII. "Licensed advanced pharmacy technician" means a person licensed by the office of professional licensure and certification who:

(a) May perform all functions allowed by federal or state law and approved by the board, under the supervision of a licensed pharmacist who is physically on premises and holds an unrestricted license issued by the office.

(b) May conduct product verification, process refills, verify repackaging of drugs, and perform other pharmacist tasks not required to be completed by a licensed pharmacist.

(c) May perform duties allowed by either certified or registered pharmacy technicians.

(d) Shall not interpret or evaluate a prescription or drug order, verify a compounded drug, or counsel or advise individuals related to the clinical use of a medication.

XXXIV. "Remote processing" means accessing the pharmacy database to perform non-dispensing activities other than at a licensed pharmacy. The pharmacy shall establish controls to protect the confidentiality and integrity of patient information, as required by HIPAA, and prevent any patient information from being downloaded, duplicated, or removed from the electronic database.

XXXV. "Non-dispensing activities" are activities permitted under that individual's scope of practice that do not require the physical possession of prescription drugs. Non-dispensing activities include, but are not limited to, prescription transfers, drug utilization reviews, product verification tasks, claims adjudications, refill authorizations, entering patient and prescription information into a pharmacy's electronic database, any other task permitted under that individual's scope of practice that does not require the physical possession of prescription drugs, or other activities established by rules of the board adopted pursuant to RSA 541-A.

XXXVII. "Permit holder" means the entity that owns or operates the pharmacy licensed to operate in the state and is responsible for the facility and overall operation of the pharmacy.

Ph 102.24 "Permit holder" means an individual or entity to whom a license or permit has been issued under RSA 318 for the purpose of operating a pharmaceutical entity.

Source. 1921, 122:1. 1925, 84:1. PL 210:1. 1941, 140:1. RL 256:1. RSA 318:1. 1957, 72:1, 2. 1967, 82:1. 1973, 453:3. 1979, 155:1-9. 1981, 484:18, 19. 1985, 324:1. 1992, 245:1. 1993, 67:1; 78:1-3. 1994, 333:1-3. 1996, 267:20. 1997, 149:1-3. 1998, 67:2. 2000, 187:1; 188:1; 271:4. 2001, 15:1; 282:1-3. 2002, 281:1-3. 2005, 177:126, 127; 293:6. 2006, 164:1-3. 2007, 202:1-3. 2008, 217:1. 2009, 54:5. 2010, 74:1; 259:9. 2011, 63:3; 111:1. 2013, 105:3; 121:1, 2. 2014, 150:2, eff. Aug. 15, 2014. 2015, 180:2, 203:1, eff. July 1, 2015; 246:1, eff. Sept. 11, 2015. 2018, 205:1, eff. Aug. 7, 2018; 263:1, eff. June 12, 2018. 2019, 58:1, eff. July 1, 2019; 320:3, eff. Jan. 1, 2020. 2021, 76:1, eff. June 11, 2021; 121:3, eff. July 9, 2021; 189:3, eff. Jan. 1, 2022.

2022, 168:1, eff. Aug. 6, 2022; 341:3, eff. Aug. 3, 2022. 2023, 112:11, eff. July 1, 2023; 152:1, 6, eff. Sept. 26, 2023; 235:18, eff. Sept. 26, 2023. 2024, 327:126-127, eff. July 1, 2024.

FROM HB 1095 (2024. 327:126-127, eff. July 1, 2024)

327:126 Pharmacy; Definitions. Amend RSA 318:1, XI-XI-aa to read as follows:

XI. "Pharmacy," when not otherwise limited, means the place registered by the [~~board~~] ***office of professional licensure and certification*** where the profession of pharmacy is practiced and where drugs, chemicals, medicines, prescriptions, or poisons are compounded, dispensed, stored, or retailed.

XI-a. "Pharmacy benefits manager" means "pharmacy benefits manager" as defined in RSA 402-N:1, VIII.

XI-b. "Pharmacy technician" means a person, other than a pharmacist or a pharmacy intern, either registered or certified by the [~~board~~] ***office of professional licensure and certification*** for the purpose of assisting a pharmacist in the practice of pharmacy.

XI-aa. "Pharmacy intern" means a person who is registered by the [~~board~~] ***office of professional licensure and certification*** pursuant to RSA 318:15-b and:

(a) Is enrolled in a professional degree program of a school or college of pharmacy that has been approved by the board and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist starting no earlier than 4 months prior to the third year of study; or

(b) Is a graduate of an approved professional degree program of a school or college of pharmacy or is a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate, who is currently licensed by the [~~board of pharmacy~~] ***office*** for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

(c) Is a qualified applicant awaiting examination for licensure or meeting board requirements for re-licensure; or

(d) Is participating in a residency or fellowship program.

327:127 Pharmacy; Definitions. Amend RSA 318:1, XXXII-XXXIII to read as follows:

XXXII. "Researcher" means a qualified person representing a research organization licensed by the [~~board~~] ***office of professional licensure and certification*** pursuant to RSA 318:51-f.

XXXIII. "Licensed advanced pharmacy technician" means a person licensed by the [~~board~~] ***office of professional licensure and certification*** who:

(a) May perform all functions allowed by federal or state law and approved by the board, under the supervision of a licensed pharmacist who is physically on premises and holds an unrestricted license issued by the [~~board~~] ***office***.

(b) May conduct product verification, process refills, verify repackaging of drugs, and perform other pharmacist tasks not required to be completed by a licensed pharmacist.

(c) May perform duties allowed by either certified or registered pharmacy technicians.

(d) Shall not interpret or evaluate a prescription or drug order, verify a compounded drug, or counsel or advise individuals related to the clinical use of a medication.