CHAPTER Ph 100 ORGANIZATIONAL RULES

Readopt with amendment Ph 101 and Ph 102, effective 2-5-96 (Document #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:***

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

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

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

(d) 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.

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.

~~(a)~~ ***Ph 102.04 "Board" means*** ~~the New Hampshire board of pharmacy created by RSA 318.~~***"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.

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 licensed by the office.

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 that administers or dispenses, or both, prescription medications. The term includes, but is not limited to, public health clinics, health care facility-based outpatient clinics,

and standalone outpatient clinics. The term does not include drug treatment clinics, which are regulated as limited retail drug distributors.

Ph 102.09 "Clinic pharmacy" means a dispensing pharmacy integrated within a clinic, in a designated space where drugs are stored and then dispensed or sold, or both, pursuant to a valid prescription.

Ph 102.10 "Compounder" means, based on context, an individual trained to compound preparations or a business entity that compounds preparations.

Ph 102.11 "Compounding" means "compounding" as defined in RSA 318:1, III-a, reprinted in Appendix B.

Ph 102.12 "Controlled substance" means any substance that is subject to control under RSA 318-B or the federal Controlled Substances Act, title 21 of the United States Code (U.S.C.), or both.

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 "Drug Supply Chain Security Act (DSCSA)" means Pub. L. 113–54, title II, codified at 21 U.S.C. §360eee.

Ph 102.16 "Drug preparation", when used as:

(a) A verb, means to prepare or approve a medication for dispensing when preparation is done according to manufacturer's instructions provided in the current package insert approved by the federal Food and Drug Administration (FDA); and

(b) A noun, means the product created when a drug preparation process is completed.

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

Ph 102.18 "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 102.19 "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, and clinic pharmacies. The term includes an automated pharmacy system at a location that does not otherwise have a pharmacy.

Ph 102.20 "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, or both. The term includes hospitals, nursing homes, extended care facilities, residential care facilities, and hospice houses. The term also includes places whose primary purpose is not health care, such as educational institutions, correctional facilities, and military installations, if a pharmacy or an automated pharmacy system, or both, is on-site.

Ph 102.21 "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, that is operated under the oversight of a licensed pharmacist, either directly or as a consultant.

Ph 102.22 "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 102.23 "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 102.24*** "Licensed" means ~~a person~~ ***an individual*** or ~~place~~ ***entity is*** lawfully authorized to engage in the practice of pharmacy under RSA 318~~.:18 and RSA 318:37 and~~ ***The term*** includes "registered" ***or "certified"*** when used to refer to ~~pharmacists~~ ***pharmacy technicians*** ~~or~~ ***and includes "registered" when used to refer to pharmacy interns and*** pharmacies.

Ph 102.25 "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.

Ph 102.26 "'Licensed pharmacist' or 'pharmacist'" means "'licensed pharmacist' or 'pharmacist'" as defined in RSA 318:1, VII, reprinted in Appendix B.

Ph 102.27 "Limited retail drug distributor" means "limited retail drug distributor" as defined in RSA 318:1, VII-a, reprinted in Appendix B.

Ph 102.28 "Mail-order pharmacy" means "mail-order pharmacy" as defined in RSA 318:1, VII-b, reprinted in Appendix B.

Ph 102.29 "Manufacturing" means "manufacturing" as defined in RSA 318:1, VIII, reprinted in Appendix B.

Ph 102.30 "Manufacturer", for purposes of DSCSA compliance, means "manufacturer" as defined at 21 U.S.C. § 360eee(10), reprinted in Appendix C.

Ph 102.31 "Medical gas/legend device distributor" means a limited retail drug distributor that distributes only medical gases or legend devices, or both.

Ph 102.32 "Medication order" means a verbal, telephonic, written, facsimile, or electronically transmitted order provided by a prescribing practitioner for a specific drug to be administered by healthcare personnel to an individual in an institution.

Ph 102.33 "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 102.34 "Non-dispensing activities" means "non-dispensing activities" as defined in RSA 318:1, XXXV, reprinted in Appendix B.

Ph 102.35 "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 102.36 "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 102.37 "Outsourcing facility" means "outsourcing facility" as defined in RSA 318:1, XXX, reprinted in Appendix B, provided that only outsourcing facilities that are located in New Hampshire or that ship, send, or otherwise deliver prescription drugs or prescription devices into New Hampshire shall be subject to regulation under RSA 318 and the rules in title Ph.

Ph 102.38 "Permit holder" means "permit holder" as defined in RSA 318:1, XXXVII, reprinted in Appendix B.

Ph 102.39 "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 in-state retail pharmacy, in-state institutional pharmacy, in-state central fill pharmacy, in-state non-dispensing pharmacy, or in-state clinic pharmacy;

(b) Any mail-order pharmacy;

(c) Any limited retail drug distributor;

(d) Any pharmaceutical provider;

(e) Any outsourcing facility; or

(f) Any research organization.

Ph 102.40 "Pharmaceutical provider" means any entity required to be licensed by:

(a) RSA 318:51-a, namely manufacturers including repackagers, wholesalers, distributors, or reverse distributors; or

(b) RSA 318:51-g, namely virtual manufacturers, virtual wholesale distributors, jobbers or brokers including sales or marketing offices, any third-party logistics companies, and any other agent involved in the handling or distribution of prescription drugs, medical gases, or prescription medical devices or equipment in the supply chain that affects the pedigree of the products.

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 manager" means the individual designated by the permit holder to manage the day-to-day operations of the pharmaceutical entity being licensed.

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

Ph 102.45 "Pharmacy intern" means "pharmacy intern" as defined in RSA 318:1, XI-aa, reprinted in Appendix B.

Ph 102.46 "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 102.47 "Practice of pharmacy" means "practice of pharmacy" as defined in RSA 318:1, XIV, reprinted in Appendix B.

Ph 102.48 "'Practitioner' or 'licensed practitioner'" means "'practitioner' or 'licensed practitioner'" as defined in RSA 318:1, XV, reprinted in Appendix B.

Ph 102.49 "Prescription" means "prescription" as defined in RSA 318:1, XVI, reprinted in Appendix B.

Ph 102.50 "'Prescription device' or 'legend device'" means "'prescription device' or 'legend device'" as defined in RSA 318:1, XVI-a, reprinted in Appendix B.

Ph 102.51 "'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 102.52 "Prescriber" means a practitioner who issues a medication order or prescription.

Ph 102.53 "Product verification" means the act of validating the correct drug, strength, and form of the drug product being dispensed.

Ph 102.54 "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 102.55 "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 102.56 "Remote processing" means "remote processing" as defined in RSA 318:1, XXXIV, reprinted in Appendix B.

Ph 102.57 "Repackager" for purposes of DSCSA compliance, means "repackager" as defined in 21 U.S.C. §360eee(16), reprinted in Appendix C.

Ph 102.58 "Research organization" means "research organization" as defined in RSA 318:1, XXXI, reprinted in Appendix B.

Ph 102.59 "Researcher" means "researcher" as defined in RSA 318:1, XXXII, reprinted in Appendix B.

Ph 102.60 "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 102.61 "Retail pharmacy" means an in-state pharmacy having a physical presence in New Hampshire that is open to the public.

Ph 102.62 "Reverse distributor" means "reverse distributor" as defined in RSA 318:1, XXIX, reprinted in Appendix B.

Ph 102.63 "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 102.64 "Third-party logistics provider", for purposes of DSCSA compliance, means "third-party logistics provider" as defined in 21 U.S.C. §360eee(22), reprinted in Appendix C. The term is equivalent to "third-party logistics provider" as defined in RSA 318:51-g, III(g), reprinted in Appendix B.

Ph 102.65 "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 102.66 "Virtual manufacturer" means "virtual manufacturer" as defined in RSA 318:51-g, III(e), reprinted in Appendix B.

Ph 102.67 "Virtual wholesale distributor" means "virtual wholesale distributor" as defined in RSA 318:51-g, III(f), reprinted in Appendix B.

Ph 102.68 "Wholesale distributor", for purposes of DSCSA compliance, means "wholesale distributor" as defined at 21 U.S.C. § 360eee(29), reprinted in Appendix C.

Ph 102.69 "Wholesale distribution", for purposes of DSCSA compliance, means "wholesale distribution" as defined at 21 U.S.C. § 353(e)(4), reprinted in Appendix C.

Ph 102.70 "Wholesaler" means "wholesaler" as defined in RSA 318:1, XXI, reprinted in Appendix B.

Readopt with amendment Ph 103.01, effective 4-20-12 (Document #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.

(c) To the extent possible, at least one of the practicing pharmacists shall be a community or retail pharmacist.

Readopt with amendment Ph 103.02 through Ph 103.04, effective 2-5-96 (Document #6181-A), to read as follows:

Ph 103.02 ***Board*** Officers***; Responsibility for Review of Proposed Continuing Pharmacy Education Programs***.

(a) 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***.

(b) At the meeting at which officers are elected, or at the first meeting after the effective date of this section if annual elections have already been held, the newly-elected chair shall designate 2 board members to have primary responsibility for:

(1) Reviewing proposed continuing pharmacy education programs or courses that are received by the board; and

(2) Presenting their assessment of whether the proposed program or course meets the criteria for approval in Ph 403.15(a) to the board.

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), located as noted in Plc 103.03*** ~~at 7 Eagle Square, Concord, N.H. 03301~~.

(b) All correspondence with the board shall be addressed as ~~follows:~~ ***provided in Plc 103.03(d).***

~~State of New Hampshire Board of Pharmacy~~
~~7 Eagle Square~~
~~Concord, New Hampshire 03301.~~

(~~b~~***c***) The telephone number of the board shall be ~~(603) 271-2152~~ ***the number listed in Plc 103.03(e)***. ~~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 conduct meetings in strict compliance with the open meeting requirements of RSA 91-A:2.

Readopt with amendment Ph 104.01 and Ph 104.02, effective 2-5-96 (Document #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 amendment Ph 104.03, effective 4-25-08 (Document #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.~~

APPENDIX A: STATE STATUTE(S) IMPLEMENTED

Rule	State Statute(s) Implemented
Ph 101	RSA 541-A:16, I(a); RSA 318
Ph 102	RSA 318:1
Ph 103	RSA 318:2; RSA 541-A:16, I(a)
Ph 104	RSA 91-A:4; RSA 541-A:16, I(a)

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.

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.

XXIX. "Reverse distributor" means a person or persons who facilitate the removal, disposal, or destruction of prescription drugs to persons other than consumers.

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.

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.

RSA 318:51-g Licensure of Drug or Device Distribution Agents. –

III. For purposes of this section:

(a) A drug or device distribution agent shall include virtual manufacturers, virtual wholesaler distributors, jobbers or brokers (including sales/marketing offices), and third-party logistics companies, and any other agent involved in the handling or distribution of prescription drugs, medical gases, or prescription medical devices or equipment in the supply chain that affects the pedigree of the products.

(b) "Broker or jobber" is any party that mediates between a buyer and a seller for the sale or shipment of prescription drugs, gases, equipment, or devices.

(c) "Pedigree" is a document or an electronic file containing information that records each distribution of any given prescription drug, medical gas, or prescription medical device or equipment.

(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.

(e) "Virtual manufacturer" is anyone that owns the NDA or ANDA for a prescription drug, gas, device, or equipment that contracts with others for the actual manufacturing.

(f) "Virtual wholesale distributor" is anyone engaged in wholesale distribution of prescription drugs, gases, devices, or equipment.

Source. 2019, 264:14, eff. Sept. 17, 2019. 2023, 79:317, eff. Sept. 1, 2023.

APPENDIX C: DSCSA DEFINITIONS

21 U.S.C. §360eee:

(10) Manufacturer The term "manufacturer" means, with respect to a product—

(A) a person that holds an application approved under section 355 of this title or a license issued under section 262 of title 42 for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

(B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or

(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

(13) Product The term "product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 360eee–1 of this title, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 2021 of title 42, imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 360ddd of this title), homeopathic drugs marketed in accordance with applicable guidance under this chapter, or a drug compounded in compliance with section 353a or 353b of this title.

(16) Repackager The term "repackager" means a person who owns or operates an establishment that repacks and relabels a product or package for—

(A) further sale; or

(B) distribution without a further transaction.

(22) Third-party logistics provider The term "third-party logistics provider" means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(29) Wholesale distributor The term "wholesale distributor" means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 353(e)(4) of this title).

§353(e)(4) For the purposes of this subsection and subsection (d), the term **"wholesale distribution"** means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

(A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(B) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act [42 U.S.C. 247d], except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(H) the distribution of a drug by the manufacturer of such drug;

(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 360eee–1(e) of this title;

(L) salable drug returns when conducted by a dispenser;

(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a "medical convenience kit") if—

(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 360(b)(2) of this title;

(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 801 et seq.];

(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(iv) in the case of a medical convenience kit that includes a product, the product is—

(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

(II) a product intended to maintain the equilibrium of water and minerals in the body;

(III) a product intended for irrigation or reconstitution;

(IV) an anesthetic;

(V) an anticoagulant;

(VI) a vasopressor; or

(VII) a sympathomimetic;

(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(Q) the distribution of medical gas, as defined in section 360ddd of this title;

(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 360eee(16)(B) of this title and registered under section 360 of this title for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.