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Ph 100 Pharmacy Board Organizational Rules
Summary of Advance Public Comments on Draft dated 11-20-24 with Board Responses

February 12, 2025

Background

The NH Pharmacy Board is proposing to readopt Ph 100, Organizational Rules, with substantial amendments to consolidate definitions used throughout title Ph and make other changes. Approximately 20 stakeholders attended the public hearing held on December 18, 2024, and written comments were received.

Comments

Ph 103.01(a) re: board composition

Comment: *"Hannaford applauds the inclusion of a pharmacy technician to the Board, not only reflecting industry trends and expanded scope of practice but also continuing New Hampshire's leading role in recognizing the importance of technicians to the practice of pharmacy. We also understand the desire to continue to include at least one hospital pharmacist in the membership. Along these lines, given that the majority of pharmacist-patient interactions occur in the community setting, we propose that the Board also consider requiring at least one member pharmacist be a full-time community or retail pharmacist. Our proposed language is:*

> *Ph 103.01 (a) Pursuant to RSA 318:2, the New Hampshire 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. The membership comprises 5 practicing pharmacists, at least one of whom shall be a full-time hospital pharmacist,* ***at least one full-time retail/community pharmacist,*** *one pharmacy technician, and one who shall be a public member."*

Response: This rule restates the statutory requirements in RSA 318:2, so the proposed language cannot be added to the rule as suggested; a statutory amendment would be required. Further, the Board is comprised of volunteer members, so its composition depends on who is willing to serve. However, a new paragraph (c) will be proposed, as follows:

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

Ph 102.01 re: definition of "administer"

Comment: *"… over the last several years,* [we have] *received many questions regarding this definition. This may be an opportunity to clarify if this definition would include the ability for pharmacist to administer medications that are not vaccines (example long-acting antipsychotics or other long-acting injection medications). We have also received questions specifically if pharmacist can provide/ "administer" the oral typhoid vaccine. …"*

Response: The term "administer" is defined by RSA 318:1, I as "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." (Emphasis added.) Under this definition, a drug does not have to be injected to be "administered", and it seems unlikely that the definition could be made any clearer on this point. But note that the definition of "administer" may not be relevant to the question of what can be administered.

RSA 318:16-b, I authorizes pharmacy personnel to administer "influenza and [] COVID-19 vaccine[s], if available, to the general public" (emphasis added); RSA 318:16-b, II authorizes pharmacy personnel to administer "vaccines licensed by the [U. S. FDA] that are recommended by the United States Centers for Disease Control and Prevention Advisory Committee on Immunization Practices, or successor organization, to individuals 18 years of age or older". (Emphasis added)

If a drug is classified as a vaccine that meets the requirements in RSA 318:16-b, I or II, it can be administered as a shot, a substance to be ingested, or a preparation to be applied to the body. If it is not classified as a vaccine, the Board believes it can[not] be administered by pharmacy personnel under current state law.

Commented [GH1]: Board counsel review required

Commented [RT2R1]: RSA 318:1 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; … **I requested a declaratory ruling a few years ago and Board said pharmacists can administer medications beyond vaccines.** [emphasis added]

Commented [GH3R1]: **Cassandra:** If pharmacists can administer any kind of drug based on the definition of "administer", then why was specific statutory authority conferred for them to administer vaccines? Are vaccines not considered to be "medications"?

Commented [GH4R1]: Q re: needed RSA b/c interns, LAPT, *etc.*, so shouldn't impair ability of pharmacists to administer other drugs?

Commented [CB5R1]: **Under Review with Agency Counsel

Ph 102.08 re: definition of "clinic"

Comments: *"We are very concerned about this definition. Please note, it is difficult to see the definition in the absence of its usage in the new rules.*

[1.] *We recommend that veterinarians not be included in this as (as far as we know) all vet offices are dispensing. And we are not aware of any vet office that does not possess CS because they are used for surgery and euthanasia. It would put a lot of strain on OPLC inspectors if we had to inspect them every year like we do other licensees.*

[2.] *The way this is written, it seems ALL doctors' offices would fall under this category and I don't think that is the intent. Is the intent to license providers that are "dispensing" outside of the "immediate needs of the patient"?*

[3.] *Will a pharmacist present at all times? If not, consider requirement for pharmacist consultant similar to Methadone clinics or Public Health clinics currently (Ph 601.10)*

[4.] *Consider "provider dispenser" license- See Virgina Board of Pharmacy documents for example (attached)"*

Responses: The Board agrees that it is difficult to fully understand definitions without knowing how/where the defined terms will be used. The Board anticipates that adjustments to the definitions may be needed as subsequent practice standards and requirements are developed. Specific answers follow:

1. The Board has already decided to delete veterinarians from this definition.

2. A definition of "clinic" is needed so that clinics that want to have pharmacies can be licensed. A definition of "clinic pharmacy" has been added.

3. In order to be considered a "pharmacy", a pharmacist must be present or under contract to be available for consultation. This does not affect the ability of physicians and other health care practitioners to provide medications to patients.

4. The Virginia law is interesting, but cannot be incorporated into the Board's rulemaking efforts. If the "provider-dispenser" model is deemed important to implement in New Hampshire, the matter must be taken up by the Legislature.

Ph 102.09 re: definition of "compounder"

Comment: *"Recommend to strike* [the word "prescriptions" from the end of the sentence]. *… it could be OTC, however it would still require prescription but does it make it confusing?"*

Response: The word "prescriptions" was intended to be "preparations", and this change has been made.

Ph 102.13 re: definition of "distributor"

Comment: *"Needs to align with DSCSA"*

Response: RSA 318:1, V(a) defines "distributor" very generally. The DSCSA defines "wholesale distributor", a different term, at 21 USC § 360eee(29)[1]. To the extent anyone perceives a need to adjust the NH statutory definition, legislation would be required. However, a definition of the "Drug Supply Chain Security Act (DSCSA)" has been added, and terms that are or may be needed to determine compliance with the DSCSA also have been added.

Ph 102.29 re: definition of "manufacturing"

Comment: "Align with DSCSA"

Response: The term defined in RSA 318:1, VIII is "manufactur**ing**",[2] and the definition does not appear to conflict with the federal definition of "manufactur**er**".[3] However, the federal definition of "manufacturer" has been added for purposes of DSCSA compliance.

Ph 102.31 re: definition of "medication order"

Comment: "See Ph 2300 definition: Remove "at a designated time"- medication order could be "as needed" which is not at a designated time"

Response: The intent is to distinguish a "medication order" from a "prescription". At the most basic level, a medication order is for a prescription drug to be administered by healthcare facility personnel in an institution. The definition has been revised accordingly.

Ph 102.36 re: definition of "outsourcing facility"

Comment: "Align with DSCSA"

Response: The definition in RSA 318:1, XXX is " '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." The definition of "outsourcing facility" for purposes of the DSCSA is as follows:

"(4)(A) The term 'outsourcing facility' means a facility at one geographic location or address that--

(i) is engaged in the compounding of sterile drugs;

(ii) has elected to register as an outsourcing facility; and

(iii) complies with all of the requirements of this section.

(B) An outsourcing facility is not required to be a licensed pharmacy.

(C) An outsourcing facility may or may not obtain prescriptions for identified individual patients."

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[1] 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).

[2] "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."

[3] Per 21 USC § 360eee(10), "[t]he 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).

To the extent anyone perceives a need to adjust the NH statutory definition, legislation would be required.

Ph 102.38 re: definition of "pharmaceutical entity"

Comment: *"Reconsider Terminology* [in (a) re: in-state pharmacies] -- *ties back to definition of clinic"*

Response: It is not clear what this comment intended to convey. However, "clinic pharmacy" has been added as a separately-defined term, as noted above.

Ph 102.41 re: definition of "pharmacy technician"

Comment: *"Statute* [RSA 318:1, XI-b] *says registered or certified...doesn't reference LAPT. Add reference to LAPT statute 318:15-c so it would include LAPT too."*

Response: The Board cannot change a statutory definition by adopting a rule. In any event, LAPTs are already specifically authorized to perform duties that can be performed by certified or registered pharmacy technicians by RSA 318:1, XXXIII(c) (allows LAPTs to "perform duties allowed by either certified or registered pharmacy technicians.").

Ph 102.47 re: definition of "'prescription device' or 'legend device'"

Comment: *"Already have definition of "legend device" above. Recommend: Remove "legend device" definition (above) and keep prescription device with reference to statute"*

Response: The term "legend device" is used independently of "prescription device" in RSA 318, but someone looking for a definition of "legend device" would not find it easily because the term in the statute is within the combined term "'prescription device' or 'legend device'". The definition of "legend device" by itself in the rules is the same as the statutory definition with one grammatical correction. The Board believes it is important to retain the separate definition for the benefit of the users of the rules.

Ph 102.62 re: definition of "wholesale drug distribution"

Comment: *"Align with DSCSA"*

Response: See response at Ph 102.13, above. A definition of "wholesale distributor" for purposes of DSCSA is being added. To the extent anyone perceives a need to adjust the NH statutory definition, legislation would be required.

Ph 102.63 re: definition of "wholesaler"

Comment: *"Align with DSCSA"*

Response: 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." DSCSA defines "wholesale distributor" differently, but it is a different term. As noted above, a definition of "wholesale distributor" for purposes of DSCSA is being added. To the extent anyone perceives a need to adjust the NH statutory definition, legislation would be required.