

New Hampshire Pharmacy Board

Order on Petition for Declaratory Ruling

Petition of Rep. Gary Merchant (Dec. 2, 2020)

The petitioner has asked the Board of Pharmacy (“Board”) “whether Federal [Department of Health and Human Services (“HHS”)] guidance under the [Public Readiness and Emergency Preparedness (“PREP”)] Act . . . preempts State law regarding pharmacy scope of practice related to vaccines that pharmacists, pharmacy interns, and pharmacy technicians may order or administer.” Petition of Rep. Gary Merchant (“Petition”) at 2 (Dec. 2, 2020). As explained in greater detail below, based upon an analysis of the PREP Act; the HHS Secretary’s declaration, amendments, and guidances issued thereunder; and state law, the Board concludes that there is no conflict between the HHS Secretary’s actions and the scope-of-practice statutes under the Board’s jurisdiction. Because there is no conflict, preemption doctrine does not apply. The Board’s conclusion, therefore, does not and cannot resolve the legal issues that may impede or prevent licensed pharmacists and pharmacy interns and technicians under the supervision of a licensed pharmacist (collectively “licensed pharmacy personnel”)¹ from ordering and administering vaccines.

I. Standard of Review

A declaratory ruling is “an agency ruling as to the specific applicability of any statutory provision or of any rule or order of the agency.” RSA 541-A:1; accord N.H. Admin. R. Pt. Ph §

¹ The Board uses “licensed pharmacy personnel” collectively in this declaratory ruling solely to avoid repeating the cumbersome phrase “licensed pharmacists and pharmacy interns and technicians under the supervision of a licensed pharmacist.” This declaratory ruling should not be construed as creating a new category of licensure for pharmacy personnel.

206.01(a) (allowing any person to “request a declaratory ruling from the board on matters within its jurisdiction.”). Under RSA 318:8, the Board has jurisdiction over Chapter 318 of New Hampshire Revised Statutes (the “Practice Act”). Additionally, under RSA 318:5-a, the Board has jurisdiction over its own rules (N.H. Admin. R. Ph §§ 100–2000). No provision of law grants the Board jurisdiction over any other statute or rule. Thus, the Board’s authority to issue a declaratory ruling is statutorily limited to the applicability of the Practice Act and the Board’s own rules.

II. Background

A. Legal Background

1. State Law

Under New Hampshire Law, “[a]ny person shall be regarded as practicing medicine under the meaning of this chapter who shall diagnose, treat, perform surgery, or prescribe any treatment of medicine for any disease or human ailment.” RSA 329:1. Furthermore, anyone “not being licensed [to practice medicine] or otherwise authorized according to the law of this state [who] practice[s] medicine, according to the meaning of RSA 329 . . . is engaged in unlawful practice.” RSA 329:24, I. A person who engages in unlawful practice may be subject to the criminal and civil penalties laid out in RSA 329:24, II–V.

i. The Practice Act

The Practice Act authorizes licensed pharmacy personnel, under certain conditions, to perform certain functions that, absent this authorization, would presumably constitute the practice of medicine.² For example, “a pharmacist or pharmacy intern may administer

² It would appear beyond dispute that the administration of vaccines fits the statutory definition of the practice of medicine under RSA 329. If true, it would also follow that, to administer a vaccine, a person must either be licensed to practice medicine or otherwise be authorized. A person not so licensed or authorized would appear to be engaged in unlawful practice of medicine under RSA 329:24. The Board acknowledges, however, that interpretation and

pneumococcal and varicella zoster vaccines to individuals 18 years of age or older, provided all of the criteria in [RSA 318:16-b, I–VI] have been met.” RSA 318:16-b. The referenced criteria are that the pharmacist or pharmacy intern must:

- I. Hold a current license to practice as a pharmacist or be registered as a pharmacy intern under RSA 318:15-b in New Hampshire.
- II. Possess at least \$1,000,000 of professional liability insurance coverage.
- III. In order to administer influenza, pneumococcal, and varicella zoster vaccines, have completed training specific to the administering of the respective vaccines that includes programs approved by the Accreditation Council for Pharmacy Education (ACPE) or curriculum-based programs from an ACPE-accredited college of pharmacy or state or local health department programs or programs recognized by the board.
- IV. Provide to the board evidence of compliance with paragraphs I–III.
- V. Provide notice to the primary care provider, when designated by the patient, of the administration of the pneumococcal and varicella zoster vaccines.
- VI. Maintain a record of administration of pneumococcal and varicella zoster vaccinations for each individual as required by state and federal law.

RSA 381:16-b, I–VI. Additionally, “[a] pharmacist or pharmacy intern under the direct supervision of an immunizing pharmacist may administer a COVID-19 vaccine, if available, provided that [the aforementioned] criteria . . . have been met. The pharmacist or pharmacy intern administering a COVID-19 vaccine shall notify the patient’s primary care physician.”

RSA 318:16-b.

The Practice act also allows a pharmacist or pharmacy intern under the direct supervision of an immunizing pharmacist to “administer hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines to individuals 18 years of age or older, provided all of the criteria in [RSA 318:16-d, I–VI] have been met.” RSA 318:16-d. The referenced criteria are substantially similar to those found in RSA 318:16-b; specifically, the pharmacist or pharmacy intern must:

- I. Hold a current license to practice as a pharmacist in New Hampshire or be registered as a pharmacy intern under RSA 318:15-b in New Hampshire.
- II. Possess at least \$1,000,000 of professional liability insurance coverage.

application of RSA 329 is not within its jurisdiction and proceeds in its analysis on the assumption that its interpretation of that chapter is correct.

- III. In order to administer hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines, have completed training specific to the administering of the respective vaccines that includes programs approved by the Accreditation Council for Pharmacy Education (ACPE) or curriculum-based programs from an ACPE-accredited college of pharmacy or state or local health department programs or programs recognized by the board.
- IV. Provide to the board evidence of compliance with paragraphs I–III.
- V. Provide notice to the primary care provider, when designated by the patient, of the administration of the hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines.
- VI. Maintain a record of administration of hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccinations for each individual as required by state and federal law.

RSA 381:16-d, I–VI. No provision of New Hampshire state law permits a Pharmacy Technician to administer a vaccine of any kind.

“Any person violating the provisions of [the Practice Act], except as otherwise provided, shall be guilty of a misdemeanor if a natural person, or guilty of a felony if any other person.”

RSA 318:55, I. “In addition . . . [,] the board may impose a civil penalty not to exceed \$5,000 per violation upon any person who willfully or repeatedly violates any provision of [the Practice Act]. RSA 318:55, II.

ii. Administrative Rules

The Board of Pharmacy’s administrative rules establish certain procedures that a pharmacist must follow in order to administer vaccines, N.H. Admin. R. § 1304.01, as well as recordkeeping requirements, N.H. Admin. R. § 1304.02.

2. Federal Law

i. The PREP Act

The relevant portion of the PREP act is titled “Targeted liability protections for pandemic and epidemic products and security countermeasures.” 42 U.S.C. § 247d-6d. Under the PREP Act,

a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d (a)(1). The subsection (b) referenced above provides that

if the Secretary [of HHS] makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

42 U.S.C. § 247d-6d (b)(1).

ii. The Declaration and its Amendments

Pursuant to his authority under 42 U.S.C. § 247d-6d (b)(1), HHS Secretary Alex Azar (“Secretary”) issued a declaration on March 17, 2020. 85 C.F.R. 15198. The purpose of the declaration was to “provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ‘willful misconduct’ as defined in the PREP Act.” 85 C.F.R. 15198. In that Declaration, the Secretary determined that the spread of COVID-19 constituted a public health emergency for the purposes of the PREP Act and identified activities and covered persons that would be subject to the liability protections under the PREP Act. *Id.* at 15198–99.

The Secretary amended the Declaration four times: once on April 15, 85 C.F.R. 21012; again on June 8, 85 C.F.R. 35100; a third time on August 24, (“Third Amendment”) 85 C.F.R. 52136; and, most recently, on December 3, (“Fourth Amendment”), publication in Federal

Register pending, available at <https://www.phe.gov/Preparedness/legal/prepact/Documents/4-PREP-Act.pdf>.

The Third Amendment states that “[n]otwithstanding any State or local scope-of-practice legal requirements licensed pharmacists . . . and . . . State-licensed pharmacy interns are identified as qualified persons to order and administer [Advisory Committee on Immunization Practices (“ACIP”)]-recommended vaccines.”³ 85 C.F.R. 52139. These licensed pharmacy personnel

are qualified persons only if the following requirements are met:

- The vaccine must be FDA-authorized or FDA-approved.
- The vaccination must be ordered and administered according to ACIP’s standard immunization schedule
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient’s primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-

³ In the Fourth Amendment, the Secretary incorporated by reference an earlier Guidance that had added Registered and Certified Pharmacy Technicians to the list of qualified persons. Fourth Amendment at 15 n.19.

child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

85 C.F.R. 52140.

In addition to the four Amendments to the Declaration, HHS has also issued several guidances on this subject, including at September 3 “Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act” (“Sept. 3 Guidance”) and an October 20 “Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing” (“Oct. 20 Guidance”). These guidances largely reiterate the passages of the Third Amendment already outlined above.

3. Federal Preemption

The PREP Act includes an express preemption clause that reads:

During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.

42 U.S.C. § 247d-6d (b)(8). However, “[i]n a pre-emption case . . . , state law is displaced only ‘to the extent that it actually conflicts with federal law.’” Dalton v. Little Rock Family Planning Servs., 516 U.S. 474, 476, 116 S. Ct. 1063, 134 L. Ed. 2d 115 (1996) (per curiam) (quoting

Pacific Gas & Elec. Co. v. State Energy Res. Conservation and Dev. Comm'n, 461 U.S. 190, 204, 103 S. Ct. 1713, 75 L. Ed. 2d 752 (1983)).

B. Procedural Background

On December 2, 2020, Rep. Gary Merchant submitted this petition for a declaratory ruling. Specifically, Rep. Merchant asked the Board “whether Federal HHS guidance under the PREP Act . . . preempts State law regarding pharmacy scope of practice related to vaccines that pharmacists, pharmacy interns, and pharmacy technicians may order or administer.” Petition at 2.

Under N.H. R. Admin Ph 206.02 (a), the Board must respond to the petitioner in writing stating its declaratory ruling on “the issues or questions raised in the petition” “[w]ithin 90 days of the receipt of the petition for a declaratory ruling”

III. Analysis

The Petition seeks a declaratory ruling on whether the Secretary’s Declaration and guidances under the PREP Act preempt state law. The PREP Act’s preemption clause only applies to any provision of State law that is “is different from, or is in conflict with, any requirement applicable under this section” 42 U.S.C. § 247d-6d (b)(8)(a) (emphasis added).

As explained in further detail below, the Secretary’s Declarations and guidances do not preempt any provision of state law over which the Board of Pharmacy has jurisdiction because the portions of the Declaration and guidances purporting to authorize licensed pharmacy personnel to administer vaccines are, by the plain language of the PREP Act, recommendations.

Requirements and Recommendations under a PREP Act Declaration

A declaration by the Secretary serves two functions. First, the declaration “recommend[s], under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures.” 42

U.S.C. § 247d-6d (b)(1). Second, the declaration “state[s] that subsection (a) is in effect with respect to the activities so recommended.” *Id.* The referenced subsection (a) (quoted in full above) grants to covered persons liability from claims for loss related to covered countermeasures that are subject to a declaration. 42 U.S.C. § 247d-6d (a)(1). By the plain language of the statute, the Secretary’s declaration specifying the administration of a covered countermeasure is a recommendation. Section 247d-6d (b)(1) refers to the declaration as a “recommendation” not once but twice. (“ . . . the Secretary may make a declaration . . . recommending . . .” and “. . . stating that subsection (a) is in effect with respect to the activities so recommended.”). By contrast, the civil immunity that may stem from such a recommendation is phrased as a requirement. 42 U.S.C. § 247d-6d (a)(1) (“a covered person shall be immune” (emphasis added)).

The Third Amendment “identif[ies] as qualified persons covered under the PREP Act . . . state-licensed [pharmacy personnel] to order and administer . . . any vaccine that [ACIP] recommends to persons ages three through 18” 85 C.F.R. § 52137. Based upon the understanding of the PREP Act laid out above, this would appear to have two functions. First, it recommends that licensed pharmacy personnel be permitted to administer ACIP-recommended vaccines to children.⁴ Second, under the conditions laid out in the Declaration, it grants those licensed pharmacy personnel liability from civil claims for loss. Only these immunity provisions are mandatory—rather than recommendations—under the PREP Act.

⁴ The language of the Third Amendment is somewhat unclear and might lead a casual reader to conclude that the Secretary’s Declaration grants licensed pharmacy personnel legal permission to order and administer vaccines. The Fourth Amendment, however, corrects this lack of clarity by explaining, of the Third Declaration, that “[o]n August 19, the Secretary amended the Declaration to add additional categories of Qualified Persons and to amend the category of disease, health condition, or threat for which he recommends the administration or use of Covered Countermeasures.” Fourth Amendment at 3 (emphasis added).

Although the Third Amendment uses the term “authorize” in one instance, it is in the context of adding licensed pharmacy personnel to the definition of “covered persons.” 85 C.F.R. § 52137. This “authorization” cannot be read in context as granting licensed pharmacy personnel legal permission to order and administer vaccines that they would ordinarily not be permitted to. Nor does the PREP Act give the Secretary authority to grant such an authorization through a PREP Act declaration.⁵ The use of the term “authorization” in the Oct. 20 Guidance is, similarly, limited to the context of adding licensed pharmacy personnel to the definition of “covered persons” and, therefore, subjecting them to the liability protections of the PREP Act. Oct. 20 Guidance at 2–3.

A mere recommendation is not a legal requirement and, therefore, cannot conflict with state law. The grant of immunity is a mandatory provision and, therefore, could potentially conflict with some provision of state law. The Board, however, does not have jurisdiction over any such provision. The Practice Act does not deal with civil “claims for loss.” Nor do any of the Board’s administrative rules. Whether the Declaration preempts state tort law is, therefore, not for the Board to decide.

IV. Conclusion

For the foregoing reasons, the Board concludes that there is no conflict between the HHS Secretary’s Declaration and the scope-of-practice statutes under the Board’s jurisdiction. Preemption doctrine, therefore, does not apply.

Approved by vote of the Board of Pharmacy on December 16, 2020.

⁵ The Congressional Research Service has explained the immunity provisions of the PREP Act and the effect of a Declaration by the Secretary at length. See CONG. RESEARCH SERV., THE PREP ACT AND COVID-19: LIMITING LIABILITY FOR MEDICAL COUNTERMEASURES (2020) (available at <https://crsreports.congress.gov/product/pdf/LSB/LSB10443>).

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Authorized Representative of the

New Hampshire Board of Pharmacy

CC: Rep. Gary Merchant

