

## 54 N.J.R. 449(a)

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### RULE ADOPTIONS

#### Reporter

54 N.J.R. 449(a)

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#### Agency

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LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF PHARMACY

#### Administrative Code Citation

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**Adopted Amendments: N.J.A.C. 13:39-4.21 and 4.21A**

#### Text

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**Procedures for Authorized Prescriber Ordered or Government Sponsored Immunizations Performed by Pharmacists, Pharmacy Interns, or Pharmacy Externs; Requirements for Pharmacists, Pharmacy Interns, or Pharmacy Externs to Administer Influenza Vaccine to Minors**

Proposed: May 3, 2021, at 53 N.J.R. 680(a).

Adopted: July 28, 2021, by the State Board of Pharmacy, Linda Witzal, R.Ph., President, and September 1, 2021, by the State Board of Medical Examiners, Scott E. Metzger, M.D., President.

Filed: February 10, 2022, as R.2022 d.038, **without change**.

Authority: N.J.S.A. 45:14-47 and P.L. 2018, c. 143.

Effective Date: March 7, 2022.

Expiration Date: November 3, 2024.

#### **Summary** of Public Comments and Agency Responses:

The official comment period ended July 2, 2021. The Board of Pharmacy (Board) received one comment from Elise M. Barry, MS, CFRE, Chief Executive Officer, on behalf of the New Jersey Pharmacists Association.

1. COMMENT: One commenter noted that proposed new subsection (d) would require the supervising pharmacist to confirm that the pharmacy extern meets education and training requirements. The commenter stated that the student acting in the capacity of a pharmacy extern is assigned to a practice site to acquire practical training by the school of pharmacy, so subsection (d) should be amended to require the school of pharmacy to provide documentation to the supervising pharmacist.

RESPONSE: The Board of Pharmacy does not regulate schools of pharmacy and declines to change the rule as the commenter suggested. The Board notes that the applicable schools of pharmacy may choose to provide such documentation to the supervising pharmacist.

2. COMMENT: One commenter averred that there is a discrepancy between the notice of proposal and the statute. The commenter noted that, in accordance with N.J.S.A. 45:14-63.c(2), the need for a prescription for an influenza vaccine applies to children ages seven, eight, and nine, while the Summary of the notice of proposal states that amended subsection (c) applies to patients from seven through 10 years of age. The commenter believes that the notice of proposal should align with the requirements set forth in the statute and require a prescription for children under 10 years of age.

RESPONSE: The explanatory language in the notice of proposal Summary referenced by the commenter was intended to refer to children ages seven through nine. In accordance with N.J.S.A. 45:14-63.c(2), N.J.A.C. 13:39-4.21A(c) correctly specifies that "[f]or a patient who is under 10 years of age, but is at least seven years of age, a licensed pharmacist, registered pharmacy intern, or pharmacy extern may administer the influenza vaccine only pursuant to a prescription by an authorized prescriber."

### **Federal Standards Statement**

A Federal standards analysis is not required because the adopted amendments are governed by N.J.S.A. 45:14-40 et seq., and there are no Federal laws or standards applicable to the adopted amendments.

**Full text** of the adoption follows:

#### **SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS**

13:39-4.21 Procedures for authorized prescriber ordered or government sponsored immunizations performed by pharmacists, pharmacy interns, or pharmacy externs

(a) The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

"Direct supervision" shall have the same meaning as "immediate supervision" as set forth at N.J.S.A. 45:14-41.

"Supervising pharmacist" means a licensed pharmacist authorized to administer vaccines and related emergency medications pursuant to the requirements of this section, and who is responsible for the direct supervision of a registered pharmacy intern or pharmacy extern administering immunizations to patients pursuant to this section.

(b) The provisions of this section set forth the requirements for licensed pharmacists, registered pharmacy interns, and pharmacy externs authorized to administer vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, to eligible patients who are 18

years of age and older, consistent with the requirements at N.J.S.A. 45:14-63, under the following circumstances:

[page=450] 1. Pursuant to a prescription by a New Jersey authorized prescriber for a vaccine, related emergency medications, and pharmacist, pharmacy intern, or pharmacy extern administration of the vaccine that is patient specific;

2. In immunization programs implemented pursuant to a New Jersey authorized prescriber's standing order for the vaccine, related emergency medications, and administration instructions that are not patient specific; and/or

3. (No change.)

(c) In order to administer vaccines and related emergency medications pursuant to this section, a licensed pharmacist and registered pharmacy intern shall be pre-approved by the Board to perform such functions. In order to obtain such prior Board approval, a pharmacist or pharmacy intern shall submit documentation to the Board that establishes that he or she has satisfied the following education and training requirements:

1.-2. (No change.)

3. For a licensed pharmacist, at least two hours of continuing education in immunizations, consistent with the requirements at N.J.A.C. 13:39-3A.1, in each biennial renewal period.

(d) In order to administer vaccines and related emergency medications pursuant to this section, a pharmacy extern shall satisfy the education and training requirements at (c)1 and 2 above, which shall be confirmed by the supervising pharmacist.

(e) A registered pharmacy intern or pharmacy extern who administers vaccines and related emergency medications pursuant to this section shall act under the direct supervision of the supervising pharmacist.

(f) Documentation which establishes that a licensed pharmacist, registered pharmacy intern, or pharmacy extern has satisfied the education and training requirements at (c) above shall be maintained at the pharmacy practice site. If the immunization program is to take place somewhere other than the pharmacy practice site, the documentation shall be maintained in the licensed pharmacist's, registered pharmacy intern's, or pharmacy extern's, as applicable, possession at the immunization location. Such documentation shall be made available for inspection by the Board.

(g) Board approval granted to a licensed pharmacist and registered pharmacy intern pursuant to this section shall be renewed on a biennial basis. A pharmacist seeking such renewal shall submit documentation which establishes that he or she has satisfied the requirements at (c)2 and 3 above. A registered pharmacy intern seeking such renewal shall submit documentation that establishes that he or she has satisfied the requirements at (c)2 above and the number of such renewals shall be consistent with N.J.A.C. 13:39-2.7(d).

(h) An authorized prescriber's standing order shall specify the procedures that shall be followed for the reporting of adverse events. The licensed pharmacist and supervising pharmacist shall maintain and adhere to a manual of policies and procedures for dealing with acute adverse events. The supervising pharmacist shall ensure that a pharmacy intern and pharmacy extern adheres to the manual of policies and procedures for dealing with acute adverse events. The policies and procedures manual shall require, at a

minimum, that the pharmacist, pharmacy intern, or pharmacy extern, as applicable, immediately notify emergency medical personnel and obtain assistance for the patient when an adverse event requiring the administration of emergency medications occurs. The policies and procedures manual shall be reviewed annually by the licensed pharmacist and supervising pharmacist and such review shall be documented.

(i) Authorized prescribers' standing orders shall be maintained in either hard copy or electronic form as provided at (p) below, and shall be available for inspection by the Board at the pharmacy practice site and, if applicable, at the immunization location.

(j) Before administration of a vaccine, the licensed pharmacist, registered pharmacy intern, or pharmacy extern, as applicable, shall:

1.-3. (No change.)

4. Obtain a signed informed consent form, which complies with the requirements at (k) below, from the patient or the patient's representative, which shall be maintained at the pharmacy practice site. If the immunization program is to take place somewhere other than the pharmacy practice site, the signed informed consent forms shall be maintained in the licensed pharmacist's, registered pharmacy intern's, or pharmacy extern's, as applicable, possession at the immunization location, and then transferred to the pharmacy practice site. The signed informed consent forms shall be maintained in either hard copy or electronic form as provided at (p) below.

(k) The informed consent form provided by a licensed pharmacist, registered pharmacy intern, or pharmacy extern, as applicable, to a patient shall contain a check-off box which authorizes the pharmacist, pharmacy intern, or pharmacy extern, as applicable, to send copies of the patient's vaccine documentation to the patient's primary care provider, and another check-off box which prohibits the pharmacist, pharmacy intern, or pharmacy extern, as applicable, from sending copies of the patient's vaccine documentation to the patient's primary care provider. The informed consent form shall specify that a patient's failure to select one of the two check-off boxes shall result in the patient's vaccine documentation being sent to the patient's primary care provider, if identified.

(l) The licensed pharmacist, registered pharmacy intern, or pharmacy extern, as applicable, shall document all immunizations he or she performs and such documentation shall be maintained at the pharmacy practice site. If the immunization program is to take place somewhere other than the pharmacy practice site, the documentation shall be maintained in the licensed pharmacist's, registered pharmacy intern's, or pharmacy extern's, as applicable, possession at the immunization location, and then transferred to the pharmacy practice site. Such documentation shall be retained in either hard copy or electronic form, consistent with (p) below, and shall be made available for inspection by the Board. Such documentation shall include:

1.-3. (No change.)

4. The name and address of the authorized prescriber and supervising pharmacist, if applicable, and the name and address of the licensed pharmacist, registered pharmacy intern, or pharmacy extern administering the dose, and the immunization location, if different from the pharmacy practice site; and

5. (No change.)

(m) The licensed pharmacist or, as applicable, supervising pharmacist for a registered pharmacy intern or pharmacy extern shall document in detail and immediately report all clinically significant adverse events to the authorized prescriber, and to the primary care provider, if identified and if authorized on the informed consent form consistent with (k) above. The licensed pharmacist or supervising pharmacist, as applicable, shall, within 72 hours, report such events to the appropriate government reporting system.

(n) The licensed pharmacist, registered pharmacy intern, or pharmacy extern, as applicable, shall provide a copy of all patient related documentation and a copy of the signed informed consent form to each patient receiving an immunization, or to the patient's representative, to the patient's primary care provider, if provided and if authorized on the informed consent form consistent with (k) above.

(o) The supervising pharmacist or pharmacist-in-charge shall report an immunization administered to a patient by a pharmacist, pharmacy intern, or pharmacy extern to the New Jersey Immunization Information System, established pursuant to N.J.S.A. 26:4-134, as required pursuant to N.J.A.C. 8:57-3.16, for inclusion in the patient's registry.

Recodify existing (l)-(m) as (p)-(q) (No change in text.)

13:39-4.21A Requirements for pharmacists, pharmacy interns, and pharmacy externs to administer influenza vaccine to patients under 18 years of age

(a) A licensed pharmacist, registered pharmacy intern, and pharmacy extern must be authorized to administer vaccines and related emergency medications pursuant to and to comply with the requirements at N.J.A.C. 13:39-4.21.

(b) For a patient who is under 18 years of age, a licensed pharmacist, registered pharmacy intern, or pharmacy extern, as applicable, shall obtain the written consent of the patient's parent or legal guardian.

(c) For a patient who is under 10 years of age, but is at least seven years of age, a licensed pharmacist, registered pharmacy intern, or pharmacy extern may administer the influenza vaccine only pursuant to a prescription by an authorized prescriber.

[page=451] (d) A licensed pharmacist, registered pharmacy intern, or pharmacy extern shall not administer an influenza vaccine to a patient who is younger than seven years of age.

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