



THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

TO: The Honorable the Members of the Board of Regents
FROM: Sarah S. Benson *Sarah S. Benson*
SUBJECT: Proposed Amendment of Section 63.9 of the Regulations of the Commissioner of Education Relating to the Administration of Immunizations by Pharmacists
DATE: March 3, 2022
AUTHORIZATION(S): *Donna Bellizzi*

SUMMARY

Issue for Decision (Consent)

Should the Board of Regents amend section 63.9 of the Commissioner's Regulations relating to the administration of immunizations by pharmacists?

Reason(s) for Consideration

Required by statute (Chapter 555 of the Laws of 2021).

Proposed Handling

The proposed amendment is submitted to the Full Board for adoption as an emergency rule at the March 2022 meeting of the Board of Regents. A copy of the proposed rule (Attachment A) and a statement of facts and circumstances justifying the emergency action (Attachment B) are attached.

Procedural History

The proposed rule was presented to the Professional Practice Committee for discussion and recommendation to the Full Board for adoption as an emergency rule at the January 2022 Regents meeting, effective January 31, 2022. A Notice of Emergency Action and Proposed Rulemaking was published in the State Register on January 26, 2022 for a 60-day public comment period.

Because the January emergency action will expire on April 10, 2022, a second emergency action is necessary to ensure the emergency rule remains continuously in effect until it can be permanently adopted at the May 2022 Regents meeting. A Notice of Emergency Adoption will be published in the State Register on April 27, 2022. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

Pharmacists play an important role in New York State's vaccination efforts. New York State pharmacists have been permitted to provide immunizations for adults for influenza and pneumococcal since 2008. Studies have shown that pharmacist-provided immunizations increase overall immunization rates. Due to pharmacists' success in administering these immunizations, the Legislature has passed laws to allow pharmacists to administer additional immunizations to prevent shingles, meningitis, tetanus, diphtheria, pertussis, and COVID-19.

On November 2, 2021, the Governor signed Chapter 555 of the Laws of 2021 (Chapter 555). This law amends the Education Law to authorize certified pharmacists to administer, pursuant to a patient-specific order or a non-specific patient order issued by a licensed physician or a certified nurse practitioner, immunizations for: (1) hepatitis A; (2) hepatitis B; (3) human papillomavirus; (4) measles; (5) mumps; (6) rubella; and (7) varicella.¹ It is effective January 31, 2022.

Chapter 555 also permits certified pharmacists to administer other immunizations, to patients 18 years old or older, recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC). This is conditioned on a determination by the Commissioner of the Department of Health (DOH), in consultation with the Commissioner of Education, that an immunization: (1) may be safely administered by a licensed pharmacist within their lawful scope of practice; and (2) is needed to prevent the transmission of a reportable communicable disease that is prevalent in New York State; or (3) is a recommended immunization for such patients who: (a) meet age requirements; (b) lack documentation of such immunization; (c) lack evidence of past infection; or (d) have an additional risk factor or another indication as recommended by the ACIP of the CDC.

This law also removes the requirement that a licensed physician or certified nurse practitioner, who prescribes or issues a patient specific order or a non-patient specific order for a pharmacist to administer immunizations, must have a practice site in the county or adjoining county in which the immunizations are administered. Finally, it eliminates the sunset provisions for the authorization for certified pharmacists to administer certain immunizations, making such provisions permanent.

¹ In order to administer authorized immunizations, a licensed and registered pharmacist must be certified by the Department following the completion of a satisfactory training program.

Allowing pharmacists to administer immunizations will significantly expand access, which is essential to improving immunization rates among adults.

Proposed Amendments

Therefore, the Department proposes to amend section 63.9 of the Commissioner's regulations to implement the provisions of Chapter 555 as follows:

- Subdivision (a) of such section is amended to remove the sunset provisions for the authorization for certified pharmacists to administer certain immunizations;
- Clause (b)(1)(ii)(a) of such section is amended to remove the requirement that the licensed physician or certified nurse practitioner who prescribes or issues a patient specific order or a non-patient specific order (for a pharmacist to administer immunizations) must have a practice site in the county or adjoining county in which the immunizations are administered. It also clarifies that the physician or certified nurse practitioner who issues such orders must be licensed, registered, and maintain a practice site in New York State;
- Subparagraph (b)(2)(i) of such section is amended to add hepatitis A, hepatitis B, human papillomavirus, measles, mumps, rubella, and varicella to the list of immunizing agents that certified pharmacists can administer to patients 18 years of age or older, pursuant to a patient specific or a non-patient specific order; and
- A new subparagraph (b)(2)(iii) is added to permit certified pharmacists to administer other immunizations recommended by the ACIP for patients 18 years of age or older, pursuant to a patient specific or a non-patient specific order, if the Commissioner of DOH in consultation with the Commissioner determines that an immunization:
 - (1) may be safely administered by a licensed pharmacist within their lawful scope of practice; and
 - (2) is needed to prevent the transmission of a reportable communicable disease that is prevalent in New York State; or
 - (3) is a recommended immunization for such patients who: (a) meet age requirements; (b) lack documentation of such immunization; (c) lack evidence of past infection; or (d) have an additional risk factor or another indication as recommended by the ACIP of the CDC.

Related Regents Items

January 2022: [Proposed Amendment to Section 63.9 of the Regulations of the Commissioner of Education Relating to the Administration of Immunizations by Pharmacists](https://www.regents.nysed.gov/common/regents/files/1218brca9.pdf)

(<https://www.regents.nysed.gov/common/regents/files/1218brca9.pdf>)

Recommendation

It is recommended that the Board of Regents take the following action:

VOTED: That section 63.9 of the Regulations of the Commissioner of Education be amended, as submitted, effective April 11, 2022, as an emergency action, upon a finding by the Board of Regents that such an action is necessary for the preservation of the public health and general welfare in order to timely implement the requirements of Chapter 555 of the Laws of 2021, effective January 31, 2022, which supports access to immunization by expanding the kinds of immunizations which certified pharmacists may administer and to ensure that the emergency action taken at the January 2022 meeting remains continuously in effect.

Timetable for Implementation

If adopted at the March 2022 Regents meeting, the emergency rule will become effective April 11, 2022. It is anticipated that the proposed rule will be presented to the Board of Regents for permanent adoption at the May 2022 Regents meeting, after publication in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act. If adopted at the May 2022 meeting, the proposed rule will become effective as a permanent rule on June 1, 2022.

Attachment A

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6527, 6801, 6802, and 6909 of the Education Law and Chapter 555 of the Laws of 2021.

1. Section 63.9 of the Regulations of the Commissioner of Education is amended, as follows:

Section 63.9. Immunizations and emergency treatment of anaphylaxis pursuant to patient specific and non-patient specific orders and protocols

(a) [Applicability. This section shall apply only to the extent that the applicable provisions in Education Law sections 6527, 6801, 6802, 6828 and 6909, authorizing certified pharmacists to administer certain immunization agents and medications for the emergency treatment of anaphylaxis, have not expired or been repealed.

(b)] Immunizations.

(1) Pursuant to section 6801 of the Education Law, a pharmacist with a certificate of administration issued by the department pursuant to paragraph (3) of this subdivision shall be authorized to administer immunization agents prescribed in paragraph (2) of this subdivision to patients therein specified, provided that:

(i) the pharmacist meets the requirements for a certificate of administration prescribed in paragraph (3) of this subdivision and the order and protocol meet the requirements set forth in paragraph (5) of this subdivision; and

(ii) with respect to non-patient specific orders:

(a) the immunization is prescribed or ordered by a New York State licensed and registered physician or certified nurse practitioner, with a practice site in [the county or adjoining county in which the immunization is administered] New York State; and

(b) if the commissioner of health determines that there is an outbreak of disease, or that there is the imminent threat of an outbreak of disease, then the commissioner of health may issue a non-patient specific regimen applicable statewide.

(2) Authorized immunization agents. A certified pharmacist who meets the requirements of this section shall be authorized to [administer to]:

(i) administer to patients 18 years of age or older, immunizing agents to prevent influenza, pneumococcal, acute herpes zoster, hepatitis A, hepatitis B, human papillomavirus, measles, mumps, rubella, varicella, COVID-19, meningococcal, tetanus, diphtheria, [COVID-19,] or pertussis disease, pursuant to a patient specific order or a non-patient specific order; [and]

(ii) administer to patients between the ages of two and [eighteen] 18 years of age, immunizing agents to prevent influenza, pursuant to a patient specific order or a non-patient specific order[.]; and

(iii) administer other immunizations recommended by the advisory committee on immunization practices of the centers for disease control and prevention for patients 18 years of age or older, pursuant to a patient specific or a non-patient specific order, if the commissioner of health in consultation with the commissioner determines that an immunization:

(a) may be safely administered by a licensed pharmacist within their lawful scope of practice; and

(b) is needed to prevent the transmission of a reportable communicable disease that is prevalent in New York State; or

(c) is a recommended immunization for such patients who:

(1) meet age requirements;

(2) lack documentation of such immunization;

(3) lack evidence of past infection; or

(4) have an additional risk factor or another indication as recommended by the advisory committee on immunization practices of the centers for disease control and prevention.

[(c)] (b) Anaphylaxis treatment agents.

(1) ...

(2) ...

(3) ...

Attachment B

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE EMERGENCY ACTION

The proposed rule is necessary to implement Chapter 555 of the Laws of 2021 (Chapter 555), which was effective January 31, 2022. This amendment conforms the Commissioner's regulation to Chapter 555, which amends the Education Law, inter alia, to authorize certified pharmacists to administer, pursuant to a patient-specific order or a non-specific patient order issued by a licensed physician or a certified nurse practitioner, immunizations for: (1) hepatitis A; (2) hepatitis B; (3) human papillomavirus; (4) measles; (5) mumps; (6) rubella; (7) varicella.

Chapter 555 also permits certified pharmacists to administer other immunizations, to patients 18 years old or older, recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), if the Commissioner of the Department of Health (DOH) in consultation with the Commissioner determine that an immunization: (1) may be safely administered by a licensed pharmacist within their lawful scope of practice; and (2) is needed to prevent the transmission of a reportable communicable disease that is prevalent in New York State; or (3) is a recommended immunization for such patients who: (a) meet age requirements; (b) lack documentation of such immunization; (c) lack evidence of past infection; or (d) have an additional risk factor or another indication as recommended by the advisory committee on immunization practices of the CDC.

Additionally, Chapter 555 removes the requirement that a licensed physician or certified nurse practitioner, who prescribes or issues a patient specific order or a non-

patient specific order for a pharmacist to administer immunizations, must have a practice site in the county or adjoining county in which the immunizations are administered.

Finally, Chapter 555 removes the sunset provisions for the authorization for certified pharmacists to administer certain immunizations.

The proposed amendment was presented to the Professional Practice Committee for discussion and recommendation to the Full Board for adoption as an emergency rule at the January 2022 meeting of the Board of Regents, effective January 31, 2021. Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for adoption, after expiration of the required 60-day public comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the May 16-17, 2022 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date for the proposed rule, if adopted at the May meeting, would be June 1, 2022, the date the Notice of Adoption would be published in the State Register. However, Chapter 555 became effective January 31, 2022. This necessitated an emergency rule to be adopted at the January 2022 meeting of the Board of Regents.

However, the emergency rule will expire on April 10, 2022. Therefore, a second emergency action is necessary at the March 2022 meeting for the preservation of the public health and general welfare in order to enable the State Education Department to timely implement the requirements of Chapter 555, which expands the immunizations that certified pharmacists are authorized to administer and the public's access to them and to ensure that the emergency action taken at the January 2022 meeting remains continuously in effect until the rule can be permanently adopted.

It is anticipated that the proposed rule will be presented for adoption as a permanent rule at the May 16-17, 2022 Regents meeting, which is the first scheduled meeting after the expiration of the 60-day public comment period prescribed in SAPA for State agency rule makings.