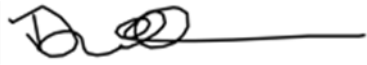




TO: The Professional Practice Committee

FROM: Douglas E. Lentivech 

SUBJECT: Proposed Amendment to Section 64.7 of the Regulations of the Commissioner of Education Relating to the Execution by Registered Professional Nurses of Non-Patient Specific Orders to Administer Immunizations

DATE: May 23, 2019

AUTHORIZATION(S):



SUMMARY

Issue for Decision

Should the Board of Regents adopt, as an emergency action, the revised proposed amendment to subdivision (a) of §64.7 of the Regulations of the Commissioner of Education relating to the execution by registered professional nurses of non-patient specific orders to administer immunizations?

Reason for Consideration

Review of policy.

Proposed Handling

The revised proposed amendment will be presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency action at the June 2019 meeting of the Board of Regents.

Procedural History

The proposed amendment was presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency action at the March 2019 meeting of the Board of Regents, effective March 12, 2109. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on March 27, 2019 for a 60-day comment period.

It is anticipated that a Notice of Emergency Adoption and Revised Rule Making will be published in the State Register on June 19, 2019 for an additional 45-day public comment period.

A copy of the revised rule and a Statement of Facts and Circumstances Which Necessitate Emergency Action are attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

The proposed amendment acted on by the Board of Regents at the March 2019 meeting, which amended subdivision (a) of section 64.7 of the Regulations of the Commissioner of Education, was intended to expand access to immunizing agents for infants, children and adults necessary to enhance the protection of the public health.

Since the publication of the proposed rule in the State Register on March 27, 2019, Department staff discovered that section 64.7(a)(1)(i)(c) used the term “vaccines” instead of the more appropriate term “immunizing agents.” The purpose of section 64.7(a)(1)(i)(c) is to allow the New State Health Department to have maximum flexibility when combatting an epidemic or outbreak. The term “immunizing agents” includes both vaccines and immunoglobulin drugs. Thus, replacing the term “vaccines” with the term “immunizing agents” will allow registered professional nurses to execute non-patient specific orders for administering vaccines and/or immunoglobulin drugs to combat an outbreak or epidemic. In addition to the 2018-2019 influenza season, New York is currently confronting severe, worsening measles outbreaks in communities in New York City and the Mid-Hudson Valley. To protect as many New Yorkers as possible from diseases such as influenza and measles, registered professional nurses need to be able to administer vaccines and, in some cases immunoglobulin drugs, pursuant to non-patient specific orders and protocols issued by physicians or nurse practitioners.

Consequently, a revision was made to the proposed rulemaking to use the more appropriate term “immunizing agents” to ensure that the intent of the proposed rulemaking to enhance the protection of the public health by expanding access to needed immunizing agents for infants, children and adults can be effectuated.

Related Regents Items

[March 2019: Proposed Amendment to Section 64.7 of the Regulations of the Commissioner of Education Relating to the Execution by Registered Professional Nurses of Non-Patient Specific Orders to Administer Immunizations](http://www.regents.nysed.gov/common/regents/files/319ppca1.pdf)
(<http://www.regents.nysed.gov/common/regents/files/319ppca1.pdf>)

Recommendation

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

VOTED: That the emergency action taken at the March 11-12, 2019 meeting of the Board of Regents, which amended subdivision (a) of section 64.7 of the Regulations of the Commissioner of Education be repealed, effective June 4, 2019, and it is further

VOTED: That subdivision (a) of section 64.7 of the Regulations of the Commissioner of Education be amended, as submitted, effective June 4, 2019, as an emergency action upon a finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare to conform the Regulations of the Commissioner of Education to current immunization standards in order to enhance the protection of the public health by expanding access to needed immunizing agents for infants, children and adults during the 2018-2019 influenza season and current measles outbreaks in New York State.

Timetable for Implementation

If adopted at the June 2019 meeting, the emergency rule will take effect on June 4, 2019.

It is anticipated that the revised proposed rule will be presented to the Board of Regents for permanent adoption at the September 9-10, 2019 Regents meeting, after publication of a Notice of Emergency Action and Revised Rule Making in the State Register and expiration of the 45-day public comment period required under the State Administrative Procedure Act. If adopted at the September 2019 meeting, the revised proposed rulemaking will become effective as a permanent rule on September 25, 2019. It is also anticipated that an additional emergency action will be necessary at the July 2019 Regents meeting to ensure that the rule remains continuously in effect until it can be adopted as a permanent rule at the September 2019 meeting.

8 NYCRR §64.7

**STATEMENT OF FACTS AND CIRCUMSTANCES
WHICH NECESSITATE EMERGENCY ACTION**

The proposed amendment is necessary to conform the Regulations of the Commissioner of Education to current immunization standards in order to enhance the protection of the public health by expanding access to immunizations for infants, children and adults, as permitted by section 6909 of the Education Law, effective for the 2018-2019 influenza season and current measles outbreaks in New York State. Section 6909 of the Education Law allows registered professional nurses to administer immunizations pursuant to non-patient specific orders issued by a licensed physician or a certified nurse practitioner in accordance with the Regulations of the Commissioner of Education. The proposed amendment will authorize more registered professional nurses to immunize infants, children and adults against additional infectious diseases, in accordance with current recommendations from the United States Centers for Disease Control and Prevention (CDC).

According to the CDC, the best way to prevent seasonal influenza is to get vaccinated every year. In 2018, seasonal influenza reached epidemic proportions in New York State and posed a serious health risk for children and those with compromised immune systems or chronic medical conditions. Additionally, there are currently two measles outbreaks in New York State communities with very low vaccination rates. Thus, it is critical to make such immunizing agents available to as many children and infants as possible to protect them from this disease. According to

the CDC, measles is a highly contagious virus. In some cases, it can cause serious health problems, especially in infants and young children. Pregnant women with measles are also at greater risk of having premature or low-birth-rate babies. Thus, the Department recommends that, in order to better address these serious health risks to New Yorkers, the Regulations of the Commissioner of Education be amended to expand access to seasonal influenza and measles vaccines for infants, children and adults effective beginning with the current influenza season and measles outbreaks. Allowing more registered professional nurses to administer seasonal influenza and measles vaccines to infants, children and adults pursuant to a non-patient specific order and protocol will protect more people from these potentially harmful and sometimes fatal diseases.

The proposed rule was adopted as an emergency action at the March 11-12, 2019 Regents meeting and became effective March 12, 2019. However, since the publication of the proposed rule in the State Register on March 27, 2019, Department staff discovered that section 64.7(a)(1)(i)(c) uses the term “vaccines”, instead of the more appropriate term “immunizing agents,” which includes both vaccines and immunoglobulin drugs. Replacing the term “vaccines” with the term “immunizing agents” will allow registered professional nurses to execute non-patient specific orders for administering vaccines and/or immunoglobulin drugs to combat an outbreak or epidemic. Thus, the proposed rule was revised by replacing the term “vaccines” with the term “immunizing agents”. Because the Board of Regents meets at fixed intervals, the earliest the proposed amendment can be presented for regular (non-emergency) adoption, after expiration of the required 60-day public comment period provided for in

the State Administrative Procedure Act (SAPA) section 202(1) and (5), would be the September 9-10, 2019 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the proposed amendment, if adopted at the September meeting, would be September 25, 2019, the date a Notice of Adoption would be published in the State Register. However, emergency adoption is necessary to maximize the potential health benefits of increasing access to the seasonal influenza and measles immunizing agents in New York State.

Therefore, a second emergency action is necessary at the June 2019 Regents meeting for preservation of the public health and general welfare in order to enable the State Education Department to immediately implement the revised proposed rule, so that registered professional nurses can immunize infants, children and adults against additional infectious diseases, including influenza and measles, pursuant to non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner, during the 2018-2019 influenza season and the current measles outbreaks in New York State.

It is anticipated that the revised proposed rule will be presented for permanent adoption at the September 9-10, 2019 Regents meeting, which is the first scheduled meeting after the expiration of the 45-day public comment period prescribed in the State Administrative Procedure Act for revised rule makings.

Attachment B

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6527, 6902 and 6909 of the Education Law

Subdivision (a) of section 64.7 of the Regulations of the Commissioner of Education is amended, as follows:

64.7 Administration of immunizations, emergency treatment of anaphylaxis, tuberculosis tests, human immunodeficiency virus (HIV) tests, opioid related overdose treatments, hepatitis C tests and screening for syphilis, gonorrhea and/or chlamydia infections pursuant to non-patient specific orders and protocols

(a) Immunizations.

(1) [Pursuant to section 6909(5) of the Education Law, a registered professional nurse shall be authorized to administer immunization agents prescribed in paragraph (2) of this subdivision to patients therein specified, pursuant to a non-patient specific order and protocol prescribed and ordered by a licensed physician or a certified nurse practitioner, provided the registered nurse meets the prerequisite requirements prescribed in paragraph (3) of this subdivision and the order and protocol meets the requirements of paragraph (4) of this subdivision.] As used in this subdivision:

(i) Immunizing agents means vaccines and immunoglobulin drugs approved by the federal Food and Drug Administration to provide immunity against diseases caused by the infectious agents described in clauses (a) through (d) of this subparagraph. For purposes of this subdivision, immunizing agents shall include the following:

(a) in the case of adults, vaccines against the following infectious diseases: Hepatitis A, Hepatitis B, Influenza, Pneumococcus, Diphtheria, Tetanus, Measles,

Mumps, Rubella, Varicella, Polio, Pertussis, Human Papilloma Virus, Meningococcus, and Herpes Zoster;

(b) in the case of infants and children under the age of 18, vaccines against the following infectious diseases: Diphtheria, Tetanus, Pertussis, Measles, Mumps, Rubella, Varicella, Haemophilus Influenzae Type b (Hib), Polio, Hepatitis B, Hepatitis A, Influenza, Meningococcus, Pneumococcus, Rotavirus, and Human Papilloma Virus;

(c) immunizing agents against an infectious disease that causes an epidemic or a community wide outbreak, provided that such immunizing agents are administered as part of a public health program established by the commissioner of the department of health, a county commissioner of health, or a county public health director to immunize persons against the infectious disease during the epidemic or community outbreak of the infectious disease; and

(d) additional immunizing agents approved by resolution of the Board of Regents upon recommendation by the commissioner that such additional immunization agents are safe and effective immunization agents for registered professional nurses to administer to patients, pursuant to a non-patient specific order and protocol as prescribed in this section, after consideration of the recommendations of State and/or nationwide authorities that evaluate the effectiveness and safety of immunization agents, including but not limited to the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. Such additional immunization agents, which are not specifically enumerated in this subparagraph, may be removed by resolution of the Board of Regents, upon recommendation of the commissioner that such immunization agents are not safe and effective immunization agents for registered

professional nurses to administer to patients, pursuant to a non-patient specific order and protocol as prescribed in this section, after consideration of the recommendations of State and/or nationwide authorities that evaluate the effectiveness and safety of immunization agents, including but not limited to the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

(ii) Entity means a state or local government, partnership, corporation or other legal entity that is authorized by the public health law, education law or other state statute to provide professional nursing services.

(2) [Authorized immunization agents.] A registered professional nurse may administer immunizing agent(s) pursuant to a written non-patient specific order and protocol prescribed or ordered by a licensed physician or a certified nurse practitioner, provided that the requirements of this subdivision are met.

(i) [Adult immunizations. A registered professional nurse that meets the requirements of paragraph (3) of this subdivision shall be authorized to administer the following immunization agents to patients 18 years of age or older, pursuant to a non-patient specific order and protocol prescribed and ordered by a licensed physician or a certified nurse practitioner that meets the requirements of paragraph (4) of this subdivision: Hepatitis A, Hepatitis B, Influenza, Pneumococcus, Meningococcus, Diphtheria, Tetanus, Measles, Mumps, Rubella, Varicella, Inactivated Polio, and additional immunizations agents approved by resolution of the Board of Regents upon recommendation by the commissioner that such additional immunization agents are safe and effective immunization agents for registered professional nurses to administer to patients who are 18 years of age or older, pursuant to a non-patient specific order

and protocol as prescribed in this section, after consideration of the recommendations of State and/or nationwide authorities that evaluate the effectiveness and safety of immunization agents, including but not limited to the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. Such additional immunization agents, which are not specifically enumerated in this subparagraph, may be removed by resolution of the Board of Regents, upon recommendation of the commissioner that such immunization agents are not safe and effective immunization agents for registered professional nurses to administer to patients who are 18 years of age or older, pursuant to a non-patient specific order and protocol as prescribed in this section, after consideration of the recommendations of State and/or nationwide authorities that evaluate the effectiveness and safety of immunization agents, including but not limited to the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.] The registered professional nurse shall be certified in cardio-pulmonary resuscitation or basic life support by the American Red Cross, the American Heart Association or an equivalent organization acceptable to the department which has an established record of providing programs of cardio-pulmonary resuscitation training.

(ii) [Child immunizations. A registered professional nurse that meets the requirements of paragraph (3) of this subdivision and who is employed or is acting as an agent for the Visiting Nurses Association or other equivalent organization as determined by the department that is legally authorized to provide nursing services, or for a State, county, municipal or other government agency, shall be authorized to administer the following immunization agents to patients under the age of 18, pursuant to a non-patient

specific order and protocol prescribed and ordered by a licensed physician or a certified nurse practitioner that meets the requirements of paragraph (4) of this subdivision: Diphtheria, Tetanus, Acellular Pertussis, Measles, Mumps, Rubella, Varicella, Haemophilus Influenzae Type b (Hib), Inactivated Polio, Hepatitis B, and additional immunizations agents approved by resolution of the Board of Regents upon recommendation by the commissioner that such additional immunization agents are safe and effective immunization agents for registered professional nurses to administer to patients who are under the age of 18 years old, pursuant to a non-patient specific order and protocol as prescribed in this section, after consideration of the recommendations of State and/or nationwide authorities that evaluate the safety and effectiveness of immunization agents, including but not limited to the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. Such additional immunization agents, which are not specifically enumerated in this subparagraph, may be removed by resolution of the Board of Regents, upon recommendation of the commissioner that such immunization agents are not safe and effective immunization agents for registered professional nurses to administer to patients who are under the age of 18 years old, pursuant to a non-patient specific order and protocol prescribed in this section, after consideration of the recommendations of State and/or nationwide authorities that evaluate the effectiveness and safety of immunization agents, including but not limited to the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.] The registered professional nurse shall ensure that anaphylactic agents, syringes and needles are available at the location where the immunizing agents are being administered.

[(iii) Epidemics. Notwithstanding the requirements of subparagraphs (i) and (ii) of this paragraph, a registered professional nurse that meets the requirements of paragraph (3) of this subdivision shall be authorized to administer to patients, pursuant to a non-patient specific order and protocol prescribed and ordered by a licensed physician or a nurse practitioner that meets the requirements of paragraph (4) of this subdivision, any immunization agents authorized under such order and protocol to be administered as part of an immunization program maintained, authorized, or under the auspices of the Commissioner of Health, a county commissioner of health, or a county public health director, when such an immunization program is instituted pursuant to an epidemic declared by such official.]

(3) [Prerequisite requirements. For a registered professional nurse authorized to administer immunization agents prescribed in paragraph (2) of this subdivision to recipients therein specified, pursuant to a non-patient specific order and protocol prescribed by a licensed physician or a certified nurse practitioner, such registered professional nurse shall be currently certified in cardio-pulmonary resuscitation by a program of the American Red Cross or the American Heart Association or an equivalent organization acceptable to the department, which has an established record of providing programs of cardio-pulmonary resuscitation training.

(4) Order and protocol.

(i) [The registered professional nurse shall either maintain or ensure the maintenance of a copy of the non-patient specific order and protocol prescribed by a licensed physician or a certified nurse practitioner which authorizes a registered professional nurse to administer immunization agents, in accordance with the

requirements of paragraph (1) of this subdivision. The order prescribed in subparagraph (ii) of this paragraph shall incorporate a protocol that meets the requirements of subparagraph (iii) of this paragraph. Such order and protocol shall be considered a record of the patient who is immunized and maintained as a record for the period of time prescribed in section 29.2(a)(3) of this Title.] The non-patient specific order shall include, at a minimum, the following:

(a) the name, license number and signature of the licensed physician or certified nurse practitioner who orders or prescribes the non-patient specific order and protocol;

(b) the name of the specific immunizing agent(s) to be administered;

(c) a protocol for administering the ordered immunizing agent(s) or a specific reference to a separate written protocol for administering the ordered immunizing agent(s), which shall meet the requirements of subparagraph (ii) of this paragraph;

(d) the period of time that the order is effective, including the beginning and ending dates;

(e) a description of the group(s) of persons to be immunized, including the age range of such persons;

(f) the name and license number of the registered professional nurse(s) authorized to execute the non-patient specific order and protocol to administer the immunizing agent(s); or the name of the entity that employs or contracts with registered professional nurses to execute the non-patient specific order and protocol, provided that the registered professional nurse(s) execute the non-patient specific order and protocol only in the course of such employment or pursuant to such contract and provided further

that the entity is legally authorized to employ or contract with registered professional nurses to provide nursing services.

(ii) [The order shall authorize one or more named registered professional nurses, or registered professional nurses who are not individually named but are identified as employed or under contract with an entity that is legally authorized to employ or contract with registered professional nurses to provide nursing services, to administer specified immunization agents for a prescribed period of time. In instances in which the registered professional nurses are not individually named in the order, but are identified as employed or under contract with an entity that is legally authorized to employ or contract with registered professional nurses to provide nursing services, such registered professional nurses shall not be authorized by such order to administer immunizations outside of such employment or contract. The order shall contain but shall not be limited to the following information:] The written protocol, incorporated into the order prescribed in subparagraph (i) of this paragraph, shall, at a minimum, require the registered professional nurse(s) to ensure that:

(a) [the specific immunization agents that the registered professional nurse(s) is permitted to administer;] each potential recipient is assessed, pursuant to criteria in the protocol, for conditions that would qualify or preclude him or her from receiving the ordered immunizing agent(s):

(b) [the period of time that the order is effective, including the beginning and ending dates;] the potential recipient, or when the potential recipient lacks capacity to consent, a person authorized pursuant to law to consent to health care for the potential recipient, receives federally required vaccine information, such as vaccine information

statements, if applicable, and instructions on addressing adverse reactions to the vaccine;

(c) [the name and license number of the registered professional nurse(s) authorized to administer the immunization agent(s) pursuant to the order; or the name of the entity that is legally authorized to employ or contract with registered professional nurses to provide nursing services with whom registered professional nurses who are not individually named are employed or under contract to administer the prescribed immunization agent(s) pursuant to the order;] informed consent for administering the ordered immunizing agent(s) has been obtained, pursuant to the criteria in the protocol, from the recipient, or when the recipient lacks capacity to consent, a person authorized pursuant to law to consent to health care for the recipient;

(d) [in instances in which the registered professional nurses are not individually named in the order, but are identified as employed or under contract with an entity that is legally authorized to employ or contract with registered professional nurses to provide nursing services, the order shall contain a statement limiting the registered professional nurses to administering immunizations only in the course of such employment or pursuant to such contract; and] the administration of the ordered immunizing agent(s) is documented, including the recipient's name, date of administration, address of administration, administering nurse, immunization agent(s), manufacturer(s), lot number(s), in accordance with criteria in the protocol and that documentation relating to the immunizing agent(s) is maintained in accordance with section 29.2(a)(3) of this Title;

(e) [the name, license number, and signature of the licensed physician or nurse practitioner who has issued the order.] the recipient, or when the recipient lacks

capacity to consent, a person authorized pursuant to law to consent to health care for the recipient, receives a certificate of immunization with the recipient's name, date of administration, address of administration, administering nurse, immunization agent(s), manufacturer(s), and lot number(s). With the consent of the recipient or a person authorized to consent for the recipient, the registered professional nurse shall communicate this information to the recipient's primary health care provider;

(f) adverse outcomes resulting from the administered immunizing agent(s) shall be reported to the United States Department of Health and Human Services, as may be required by federal law; and

(g) immunizing agents administered to recipients are reported to the department of health or the New York City Department of Health and Mental Hygiene, as may be required by law.

[(iii) The protocol, incorporated into the order prescribed in subparagraph (ii) of this paragraph, shall require the registered professional nurse to meet the following requirements:

(a) The registered professional nurse shall ensure that each potential recipient is assessed for untoward conditions that would preclude immunization(s) and each recipient's record of immunization with manufacturer and lot number or a potential recipient's refusal to be immunized shall be documented in accordance with section 29.2(a)(3) of this Title.

(b) The registered professional nurse shall be responsible for having emergency anaphylaxis treatment agents, related syringes and needles available at the immunization site.

(c) The registered professional nurse shall inform each recipient of potential side effects and adverse reactions, orally and in writing, prior to immunization. The registered professional nurse shall provide written instructions to the recipient regarding the appropriate course of action in the event of untoward or adverse reactions, which statements are required to be developed by a competent entity knowledgeable about the untoward or adverse reactions of the immunization agent which shall be administered, such as the Centers for Disease Control of the U.S. Department of Health and Human Services, which issues vaccine information statements. The registered professional nurse shall not administer immunizations unless the recipient is adequately informed as prescribed in this clause and the recipient consents to the immunization; except for minors or other recipients incapable of consenting to the administration of an immunization, in which case a person legally responsible for the recipient shall have given prior written consent to the immunization after having been informed in writing as prescribed in this clause before it may be administered; or shall be in attendance during the immunization, informed as prescribed in this clause, and have consented to the immunization before it may be administered.

(d) The registered professional nurse shall provide to each recipient or other person legally responsible when the recipient is a minor or otherwise incapable of consenting to immunization, a signed certificate of immunization with the recipient's name, date of immunization, address of administration, administering nurse, immunization agent, manufacturer and lot number and recommendations for future immunizations recorded thereon. With the consent of the recipient or a person legally responsible when the recipient is a minor or otherwise incapable of consenting, the

registered professional nurse shall communicate this information to the recipient's primary health care provider, if one exists.

(e) Each registered professional nurse shall report any adverse outcomes as may be required by Federal law on the vaccine adverse event reporting system form of the Centers for Disease Control of the U.S. Department of Health and Human Services, or on the successor form.

(f) Each registered professional nurse shall ensure that a record of all persons immunized including the recipient's name, date, address of administration, administering nurse, immunization agent, manufacturer, lot number and recommendations for future immunizations is recorded and maintained in accordance with section 29.2(a)(3) of this Title.]