



TO: The Professional Practice Committee
Douglas E. Lentivech

FROM:

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 Opioid Related Overdose Treatment and Hepatitis C Tests

DATE:

June 8, 2015

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents adopt as an emergency action, the proposed addition of subdivisions (e) and (f) to section 64.7 of the Regulations of the Commissioner of Education to implement Part V of Chapter 57 of the Laws of 2015 and Chapter 352 of the Laws of 2014, respectively, relating to the execution by registered professional nurses of non-patient specific orders to administer opioid related overdose treatment and hepatitis C tests?

Reason for Consideration

Required by State statute (L. 2015, Part V, Ch. 57 and L. 2014, Ch. 352).

Proposed Handling

The 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 2015 meeting of the Board of Regents. A copy of the proposed rule and a Statement of Facts and Circumstances Which Necessitate Emergency Action are attached.

Procedural History

A Notice of Emergency Adoption and Proposed Rule Making will be published in the State Register no later than July 8, 2015. Supporting materials for the proposed rule are available upon request from the Secretary of the Board of Regents.

Background Information

Currently, registered professional nurses can perform, pursuant to non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner, the following procedures: (1) administration of certain immunizations; (2) emergency treatment of anaphylaxis, (3) administration of purified protein derivative (PPD) mantoux tuberculin skin tests; and (4) administration of human immunodeficiency virus (HIV) tests.

Chapter 352 of the Laws of 2014, effective December 15, 2014, added a new paragraph (e) to both subdivision 6 of section 6527 and subdivision 4 of 6909 of the Education Law, permitting registered professional nurses to execute non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner to administer hepatitis C tests. Chapter 352 was part of an extensive package of legislation to combat hepatitis C.

Part V of Chapter 57 of the Laws of 2015, effective August 11, 2015, adds a new paragraph (f) to both subdivision 6 of sections 6527 and subdivision 4 of 6909 of the Education Law, permitting registered professional nurses to execute non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner to administer urgent or emergency treatment of opioid related overdose or suspected opioid related overdose. Part V of Chapter 57 was part of an extensive package of legislation designed to combat opioid abuse.

The proposed rule, if implemented, would complement other statewide initiatives designed to address two major public health challenges in New York State: (1) reducing opiate overdose deaths; and (2) combatting hepatitis C.

In New York State, opiate overdose is a major cause of accidental death among persons who use or misuse opioids. Opioids include illegal drugs such as heroin and prescription drugs used to treat pain, such as morphine, codeine and methadone. Opioid overdose related deaths can be prevented when Naloxone is administered in a timely manner. Naloxone is a drug that has been used for over 40 years by emergency medical services (EMS) personnel to treat opioid overdose and resuscitate persons who otherwise might have died in the absence of such treatment.

To combat the continuing rise in opioid related deaths in New York State, laws were recently enacted to allow unlicensed persons to administer emergency opiate overdose treatment. In addition, Part V of Chapter 57, included amendments to sections 6527 and 6909 of the Education Law to authorize registered professional nurses to administer opioid related overdose treatment pursuant to a non-patient specific order and protocol prescribed by a licensed physician or a certified nurse practitioner. This law, when put into effect, will increase the number of registered

professional nurses who can prevent opioid related overdose deaths. In particular, registered professional nurses who work in settings such as schools, home care or mental health clinics could administer lifesaving opioid related overdose treatment when a prescriber or emergency services provider is not immediately available.

As of January 1, 2014, primary care physicians must offer a one-time hepatitis C test to all persons born between 1945 and 1964. Chapter 352 of the Laws of 2014, effective December 15, 2014, added a new paragraph (e) to both subdivision 6 of section 6527 and subdivision 4 of 6909 of the Education Law, permitting registered nurses to execute non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner to administer hepatitis C tests.

Prior to the effective date of Chapter 352, a registered nurse could offer a hepatitis C test but could not administer it without a prescription from a licensed physician or a certified nurse practitioner that was specific for that patient. Chapter 352 provides more flexibility in the administration of hepatitis C tests for a more efficient delivery of healthcare services.

According to the New York State Department of Health, an estimated 150,000 New Yorkers are unaware that they have hepatitis C. With the advent of new therapies that can stop the progression of hepatitis C or cure hepatitis C, New York State launched a campaign to increase hepatitis C testing of persons with heightened risks of being infected and link persons who test positive for hepatitis C to treatment.

Section 6909(5) of the Education Law directs the Commissioner of Education to promulgate regulations concerning the execution of such non-patient specific orders by registered professional nurses. The proposed rule establishes uniform requirements for registered professional nurses to meet when executing non-patient specific orders to administer opioid related overdose treatment and/or hepatitis C tests. Specifically, the proposed rule defines what information should be included in the non-patient specific order and the requirements that must be set forth in the protocol, for a registered professional nurse to follow when administering opioid related overdose treatment and/or hepatitis C tests through a non-patient specific order.

The proposed addition of paragraph (e) to section 64.7 of the Regulations of the Commissioner of Education defines opioid related overdose treatment. The proposed amendment further requires that the written non-patient specific order for the administration of opioid related overdose treatment by a registered professional nurse must contain the following information: (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, dose and route of administration of the drug to be administered to treat opioid related overdose; (c) a protocol for administering the ordered opioid related overdose treatment or a specific reference to a separate written protocol for administering the ordered opioid related overdose treatment; (d) the period of time the order is effective, including the beginning and ending dates; (e) a description of the group(s) of persons to be treated; and (f) the names and license number of the registered professional nurse(s) authorized to execute the non-patient specific order and protocol to administer the opioid related overdose treatment or the name of the entity that employs or contracts with the registered professional nurses to

execute the non-patient specific order and protocol, provided that the registered professional nurses 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.

The proposed amendment also requires that the written protocol include instructions for administering the opioid related overdose treatment and requires the registered professional nurse to ensure that: (a) each potential recipient is assessed, pursuant to the criteria in the protocol, for conditions that would qualify or preclude him or her from receiving the ordered opioid related overdose treatment; (b) consent to administer treatment is obtained pursuant to criteria in the protocol, if the potential recipient is capable of providing it; (c) the opioid related overdose treatment is documented pursuant to criteria in the protocol and includes the name and dose of the drug administered, the date, time and location of the treatment, the recipient's name and the administering registered professional nurse's name and this medical documentation relating to opioid related overdose treatment is maintained in accordance with section 29.2(a)(3) of the Rules of the Board of Regents; and (d) when opioid related overdose treatment is administered outside of a general hospital, the recipient of treatment is transferred to a hospital for follow-up care along with documentation describing the opioid related overdose treatment that was administered, in accordance with criteria in the protocol.

The proposed addition of paragraph (f) to section 64.7 of the Regulations of the Commissioner of Education defines hepatitis C tests for purposes of this amendment. The proposed amendment further requires that the written non-patient specific order for the administration of hepatitis C tests by a registered professional nurse must contain the following information: (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 hepatitis C tests to be administered; (c) a protocol for administering the ordered hepatitis C tests; (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 tested; and (f) the names and license number of the registered professional nurse(s) authorized to execute the non-patient specific order and protocol to administer the hepatitis C tests, 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 nurses 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.

The proposed amendment also requires the registered professional nurse to ensure that: (a) 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 hepatitis C tests; (b) informed consent for administering the ordered hepatitis C tests or disclosing the hepatitis C test results to a third party (if applicable) 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; (c) confirmatory, positive hepatitis C test results are not disclosed to the

test recipient or the recipient's authorized representative by the registered professional nurse without a patient specific order from a licensed physician, licensed physician assistant or certified nurse practitioner; and (d) the administration of the hepatitis C test is documented in the recipient's medical record in accordance with the criteria in the protocol and that documentation relating to the hepatitis C testing is maintained in accordance with section 29.2(a)(3) of the Rules of the Board of Regents.

Recommendation

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

VOTED: That subdivisions (e) and (f) of section 64.7 of the Regulations of the Commissioner of Education be added, as submitted, effective August 11, 2015, as an emergency action upon a finding by the Board of Regents that such action is necessary for preservation of the public health and general welfare to conform the Regulations of the Commissioner to timely implement, on its effective date, the requirements of Part V of Chapter 57 of the Laws of 2015, which authorizes registered professional nurses to execute non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner to administer opioid related overdose treatment.

Timetable for Implementation

If adopted at the June 2015 Regents meeting, the emergency rule will take effect on August 11, 2015. It is anticipated that the proposed amendment will be presented to the Board of Regents for permanent adoption at the September 2015 Regents meeting, after publication of the proposed amendment in the State Register for the 45-day public comment period required under the State Administrative Procedure Act.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6527, 6902 and 6909 of the Education Law, Part V of Chapter 57 of the Laws of 2015 and Chapter 352 of the Laws of 2014

Section 64.7 of the Regulations of the Commissioner of Education is amended, effective August 11, 2015, as follows:

64.7 Administration of [I]immunizations, emergency treatment of anaphylaxis, purified protein derivative (PPD) mantoux tuberculin skin tests, [and] human immunodeficiency virus (HIV) tests, opioid related overdose treatments and hepatitis C tests pursuant to non-patient specific orders and protocols.

(a) . . .

(b) . . .

(c) . . .

(d) . . .

(e) Opioid related overdose treatment.

(1) As used in this subdivision, opioid related overdose treatment shall include the administration of naloxone or another drug approved by the federal Food and Drug Administration to treat opioid related overdose.

(2) A registered professional nurse may administer opioid related overdose treatment for the urgent or emergency treatment of opioid related overdose or suspected opioid related overdose 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.

(3) Order and protocol.

(i) 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, dose and route of administration of the drug to be administered to treat opioid related overdose;

(c) a protocol for administering the ordered opioid related overdose treatment or a specific reference to a separate written protocol for administering the ordered opioid related overdose treatment, 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 treated; and

(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 opioid related overdose treatment; 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 nurses 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 written protocol, incorporated into the order prescribed in subparagraph (i) of this paragraph, shall, at a minimum, include instructions for administering the opioid related overdose treatment and require the registered professional nurse to ensure that:

(a) 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 opioid related overdose treatment;

(b) consent to administer treatment is obtained, pursuant to criteria in the protocol, if the potential recipient is capable of providing it;

(c) the opioid related overdose treatment is documented, pursuant to criteria in the protocol, and includes the name and dose of drug administered, the date, time and location of the treatment, the recipient's name and the administering registered professional nurse's name and this medical documentation relating to opioid related overdose treatment is maintained in accordance with paragraph 29.2(a)(3) of this Title; and,

(d) when opioid related overdose treatment is administered outside of a general hospital, the recipient of the treatment is transferred to a hospital for follow-up care along with documentation describing the opioid related overdose treatment that was administered, in accordance with criteria in the protocol.

(f) Hepatitis C tests.

(1) As used in this subdivision, hepatitis C tests mean one or more laboratory or point of care tests approved by the federal Food and Drug Administration to detect the presence of antibodies or antigens to hepatitis C or the hepatitis C virus.

(2) A registered professional nurse may administer hepatitis C tests 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.

(3) Order and protocol.

(i) 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 hepatitis C tests to be administered;

(c) a protocol for administering the ordered hepatitis C tests or a specific reference to a separate written protocol for administering the ordered hepatitis C tests, 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 tested; and

(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 hepatitis C tests; 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 nurses 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 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) 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 hepatitis C tests;

(b) informed consent for administering the ordered hepatitis C tests or disclosing the hepatitis C test results to a third party (if applicable) 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;

(c) confirmatory, positive hepatitis C test results are not disclosed to the test recipient or the recipient's authorized representative by the registered professional nurse without a patient specific order from a licensed physician, licensed physician assistant or certified nurse practitioner; and

(d) the administration of the ordered hepatitis C test(s) is documented in the recipient's medical record in accordance with criteria in the protocol and that documentation relating to the hepatitis C testing is maintained in accordance with section 29.2(a)(3) of this Title.

8 NYCRR §64.7

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE EMERGENCY ACTION

The proposed amendment is necessary to timely implement Part V of Chapter 57 of the Laws of 2015, on its effective date, August 11, 2015. The amendments to the Education Law made by Part V of Chapter 57 of the Laws of 2015 allow registered professional nurses to execute non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner to administer urgent or emergency treatment of opioid related overdose or suspected opioid related overdose, in accordance with requirements established in the Regulations of the Commissioner of Education. These amendments to the Education Law are part of a statewide initiative to address a major public health challenge in New York State - reducing opiate overdose deaths.

Since the Board of Regents meets at fixed intervals, and does not meet during the month of August, the earliest the proposed amendment can be presented for adoption on a non-emergency basis, after expiration of the required 45-day public comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the September 16-17, 2015 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the proposed rule, if adopted at the September meeting, would be October 7, 2015, the date a Notice of Adoption would be published in the State Register. However, the provisions of Part V of Chapter 57 will become effective August 11, 2015.

Therefore, emergency action is necessary at the June 2015 Regents meeting for preservation of the public health and general welfare in order to enable the State Education Department to timely implement, on its effective date, Part V of Chapter 57, so that registered professional nurses can provide potentially lifesaving procedures by

administering opioid related overdose treatment pursuant to non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner.

It is anticipated that the proposed amendment will be presented for permanent adoption at the September 16-17, 2015 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 State agency rule makings.