




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 Tuberculosis Tests

DATE: February 16, 2016

AUTHORIZATION(S):



SUMMARY

Issue for Decision

Should the Board of Regents adopt as an emergency action, the proposed amendment to subdivision (c) of section 64.7 of the Regulations of the Commissioner of Education to implement Chapter 464 of the Laws of 2015 relating to the execution by registered professional nurses of non-patient specific orders to administer tuberculosis tests?

Reason for Consideration

Required by State statute and review of policy (L. 2015, Ch. 464).

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 February 2016 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 on March 9, 2016. Supporting materials for the proposed rule are available upon request from the Secretary to the Board of Regents.

Background Information

Chapter 221 of the Laws of 2002 allowed registered professional nurses to administer, pursuant to non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner, purified protein derivative (PPD) tests to detect or screen for tuberculosis. However, since that time, newer tests have been developed to detect or screen for tuberculosis infections and they may be more effective than the purified protein derivative (PPD) tests. Chapter 464 of the Laws of 2015 permits registered professional nurses to administer these newer tuberculosis tests pursuant to a non-patient specific order issued by a licensed physician or a certified nurse practitioner, effective February 18, 2016. The proposed amendment implements the provisions of Chapter 464 of the Laws of 2015 and amends the provisions of subdivision (c) of section 64.7 of the Regulations of the Commissioner of Education to reflect current practices regarding the administration of tuberculosis tests.

The proposed amendment to subdivision (c) of section 64.7 of the Regulations of the Commissioner of Education defines tuberculosis tests. The proposed amendment further requires that the written non-patient specific order for the administration of tuberculosis 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 tuberculosis test(s) to be administered; (c) a protocol for administering the ordered tuberculosis test(s) or a specific reference to a separate written protocol for administering the ordered tuberculosis test(s); (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 tuberculosis test(s); or the name of the entity that employs or contracts with registered professional nurses to execute the non-patient specific order and protocol.

The proposed amendment also requires that the written protocol must, 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 tuberculosis test(s); (b) informed consent for administering the ordered tuberculosis test(s) or disclosing the tuberculosis test(s) results to a third party (if applicable) has been obtained pursuant to the criteria in the protocol; (c) any tuberculosis test results or recommendations for follow up care are disclosed in accordance with the criteria in the protocol; and (d) the administration of the ordered tuberculosis test(s) and the test results are documented in the recipient's medical record in accordance with the criteria in the protocol and that documentation relating to tuberculosis testing is maintained.

In addition to the aforementioned requirements, if the non-patient specific order authorizes the administration of a tuberculin skin test(s), the proposed amendment requires that the written protocol must: (a) require the registered professional nurse to have emergency anaphylaxis treatment agents available at the tuberculin skin testing site, except in an emergency determined by the Commissioner of Health, New York City Commissioner of the Department of Health and Mental Hygiene, a county commissioner of health, or a county public health director; (b) require that, prior to administering the tuberculin skin test(s), the potential test recipient or his or her authorized representative receives written information regarding the potential side effects and/or adverse reactions to the tuberculin skin test(s) and the appropriate course of action in the event of an adverse reaction to the test; (c) require that, prior to administering the tuberculin skin test(s), the potential test recipient or his or her authorized representative is informed of the need for a test evaluation within 48 to 72 hours after the test is administered; (d) require that the test recipient or recipient's authorized representative receives a signed certificate of tuberculin skin testing, which shall include the results with the recipient's name, date of test(s), address where the test(s) was administered, administering nurse, manufacturer and lot numbers for the tuberculin solution administered, as well as any recommendations for future tests; and (e) require that the name of the manufacturer and lot number of the tuberculin solution that was administered to the recipient are documented in his or her medical record, along with the date that the tuberculin skin test(s) was administered and the date that the test results were evaluated.

Recommendation

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

VOTED: That subdivision (c) of section 64.7 of the Regulations of the Commissioner of Education be amended, as submitted, effective February 23, 2016, 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 timely implement the requirements of Chapter 464 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 tuberculosis tests.

Timetable for Implementation

If adopted at the February 2016 meeting, the emergency rule will take effect on February 23, 2016. It is anticipated that the proposed amendment will be presented to the Board of Regents for permanent adoption at the May 2016 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 and Chapter 464 of the Laws of 2015

Section 64.7 of the Regulations of the Commissioner of Education is amended, effective February 23, 2016, as follows:

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

(a) . . .

(b) . . .

[(c) Purified protein derivative (PPD) mantoux tuberculin skin tests.

(1) Pursuant to section 6909(5) of the Education Law, a registered professional nurse shall be authorized to execute the order to administer purified derivative (PPD) mantoux tuberculin skin tests, pursuant to a non-patient specific order and protocol prescribed and ordered by a licensed physician or a certified nurse practitioner, provided the order and protocol meets the requirements of paragraph (2) of this subdivision.

(2) 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 execute the order to administer the purified protein derivative (PPD) mantoux tuberculin skin test, 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 has received a purified protein derivative (PPD) mantoux tuberculin skin test and maintained as a record for the period of time prescribed in section 29.2(a)(3) of this Title.

(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 execute the order to administer purified protein derivative (PPD) mantoux tuberculin skin tests 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 execute the order to administer purified protein derivative (PPD) mantoux tuberculin skin tests outside of such employment or contract. The order shall contain but shall not be limited to the following information:

(a) identification of the purified protein derivative (PPD) mantoux tuberculin skin test;

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

(c) the name and license number of the registered professional nurse(s) authorized to execute the order to administer the purified protein derivative (PPD) mantoux tuberculin skin test; 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 execute the order to administer the prescribed purified protein derivative (PPD) mantoux tuberculin skin test;

(d) in instances in which 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 registered professional nurses to execute the order to administer purified protein derivative (PPD) mantoux tuberculin skin tests only in the course of such employment or pursuant to such contract; and

(e) the name, license number, and signature of the licensed physician or certified nurse practitioner that has issued the order.

(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 purified protein derivative (PPD) mantoux tuberculin skin testing and each recipient's record of the purified protein derivative (PPD) mantoux tuberculin skin test with manufacturer and lot number or a potential recipient's refusal to be tested 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 to syringes and needles available at the purified protein derivative (PPD) mantoux tuberculin skin testing site, except in an emergency as determined by the Commissioner of Health, a county commissioner of health, or a county public health director.

(c) When the recipient of the test is legally capable of consenting to the test, the registered professional nurse may execute the order to administer the purified protein derivative (PPD) mantoux tuberculin skin test only after the recipient is adequately informed in writing as prescribed in this clause and consents to the purified protein derivative (PPD) mantoux tuberculin skin test. In the case of minors or other recipients incapable of consenting to the test, the registered professional nurse may execute the order to administer the purified protein derivative (PPD) mantoux tuberculin skin test only after the person legally responsible for the recipient of the test is adequately informed in writing as prescribed in this clause and consents to the purified protein derivative (PPD) mantoux tuberculin skin test. Prior to the registered professional nurse executing the order to administer the test, the recipient of the test, or the person legally responsible for the recipient of the test in the case of minors or other recipients incapable of consenting to the test, shall be informed in writing about the potential side effects of and adverse reactions to the test, and the need for test evaluation within 48 to 72 hours after the test is administered.

(d) The registered professional nurse shall ensure that the recipient, or other person legally responsible for the recipient when the recipient is a minor or otherwise incapable of consenting to the test, is provided with a signed certificate of purified protein derivative (PPD) mantoux tuberculin skin testing and results, with the recipient's name, date of the test, address where the test was administered, administering nurse, manufacturer and lot number and recommendations for future tests recorded thereon. With the consent of the recipient or a person legally responsible for the recipient when the recipient is a minor or otherwise incapable of consenting, the registered professional nurse shall ensure that this information is communicated to the recipient's primary health care provider if one exists.

(e) Each registered professional nurse shall ensure that a record of all persons so testing including the recipient's name, date of the test, address where the test was administered, administering nurse, test results, manufacturer, lot number and recommendations for future tests is recorded and maintained in accordance with section 29.2(a)(3) of this Title.]

(c) Tuberculosis tests.

(1) As used in this subdivision, tuberculosis tests means one or more laboratory or point of care tests approved by the federal Food and Drug Administration to detect or screen for tuberculosis infections, including, but not limited to, tuberculin skin tests (purified protein derivative [PPD] tests).

(2) A registered professional nurse may administer tuberculosis 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 tuberculosis tests to be administered;

(c) a protocol for administering the ordered tuberculosis tests or a specific reference to a separate written protocol for administering the ordered tuberculosis 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 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 tuberculosis 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 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 that is legally authorized to employ or contract with registered professional 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 tuberculosis tests;

(b) informed consent for administering the ordered tuberculosis tests or disclosing the tuberculosis tests 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) any tuberculosis test results are disclosed and any recommendations for follow up care are made in accordance with the criteria in the protocol; and

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

(e) additional requirements for tuberculin skin tests. If the non-patient specific order authorizes a tuberculin skin tests, the written protocol shall, in addition to the foregoing:

(1) require the registered professional nurse to have emergency anaphylaxis treatment agents available at the tuberculin skin testing site, except in an emergency determined by the Commissioner of Health, New York City Commissioner of the Department of Health and Mental Hygiene, a county commissioner of health, or a county public health director;

(2) require that, prior to administering the tuberculin skin tests, the potential test recipient or a person authorized pursuant to law to consent to health care for the recipient receives written information regarding the potential side effects and/or adverse reactions to the tuberculin skin tests and the appropriate course of action in the event of an adverse reaction to the test;

(3) require that, prior to administering the tuberculin skin tests, the potential test recipient or his or her authorized representative is informed of the need for a test evaluation within 48 to 72 hours after the test is administered;

(4) require that the test recipient or recipient's authorized representative receives a signed certificate of tuberculin skin testing, which shall include the results with the recipient's name, date of tests, address where the tests was administered, administering nurse, manufacturer and lot numbers for the tuberculin solution administered, as well as any recommendations for future tests; and

(5) require that the name of the manufacturer and lot number of the tuberculin solution that was administered to the recipient are documented in his or her medical record, along with the date that the tuberculin skin tests was administered and the date that the test results were evaluated.

(d) . . .

(e) . . .

(f) . . .

8 NYCRR §64.7

STATEMENT OF FACTS AND CIRCUMSTANCES

WHICH NECESSITATE EMERGENCY ACTION

The proposed amendment is necessary to implement Chapter 464 of the Laws of 2015, which is effective February 18, 2016. The amendment to the Education Law made by Chapter 464 of the Laws of 2015 allows registered professional nurses to administer other tests to detect or screen for tuberculosis infections, pursuant to non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner, in addition to purified protein derivative (PPD) tests that registered professional nurses currently administer pursuant to such orders. These other and newer tests may be more effective than the purified protein derivative (PPD) tests in detecting or screening for tuberculosis infections.

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 45-day public comment period provided for in the State Administrative Procedure Act (SAPA) section 202(1) and (5), would be the May 16-17, 2016 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the proposed amendment, if adopted at the May meeting, would be June 1, 2016, the date a Notice of Adoption would be published in the State Register. However, the provisions of Chapter 464 of the Laws of 2015 are effective February 18, 2016.

Therefore, emergency action is necessary at the February 2016 Regents meeting for preservation of the public health and general welfare in order to enable the State Education Department to immediately implement Chapter 464 of the Laws of 2015, so that registered professional nurses can administer potentially more effective tuberculosis tests to detect and screen for tuberculosis infections 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 May 16-17, 2016 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.