



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: Douglas E. Lentivech

SUBJECT: Proposed Amendment of 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 Screen Individuals at Increased Risk of Syphilis, Gonorrhea and/or Chlamydia Infections

DATE: April 27, 2017

AUTHORIZATION(S):

SUMMARY

Issue for Decision (Consent Agenda)

Should the Board of Regents adopt as an emergency action, the proposed addition of subdivision (g) to section 64.7 of the Regulations of the Commissioner of Education to implement Chapter 502 of the Laws of 2016 relating to the execution by registered professional nurses of non-patient specific orders to screen individuals at increased risk of syphilis, gonorrhea and/or chlamydia infections?

Reason for Consideration

Required by State statute and review of policy (L. 2016, Ch. 502).

Proposed Handling

The proposed amendment will be presented to the Full Board for adoption as a second emergency action at the May 2017 meeting of the Board of Regents. A Statement of Facts and Circumstances Which Necessitate Emergency Action is attached.

Procedural History

The proposed amendment was adopted as an emergency action at the March 2017 Regents meeting, effective March 14, 2017. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on March 29, 2017 for a 45 day public comment period.

It is anticipated that the proposed amendment will be presented for permanent adoption at the June 12-13, 2017 Regents meeting. However, the March emergency rule will expire on June 10, 2017. A second emergency action is, therefore, necessary at the May 2017 Regents meeting to ensure that the rule remains continuously in effect until it can be presented for adoption and take effect as a permanent rule.

A copy of the proposed amendment is attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

According to the United States Centers for Disease Control (CDC), sexually transmitted infections (STIs) are a major public health problem throughout the United States. New York State has also seen an increase in STI rates. STIs are frequently asymptomatic and, if untreated, can lead to various complications, including, but not limited to, possible infertility and spread of the infection to other persons. The CDC recommends screening individuals at increased risk of syphilis, gonorrhea and/or chlamydia infections to identify and treat infected persons before they develop complications and to identify, test and treat their sex partners to prevent transmission and reinfection. CDC guidance identifies persons who are considered to be at increased risk for these infections and recommends that the screening include an individualized assessment of risk for syphilis, gonorrhea and/or chlamydia infections, as well as the use of the federal Food and Drug Administration's (FDA) approved tests to detect or screen for syphilis, gonorrhea and/or chlamydia infections.

Chapter 502 of the Laws of 2016, effective November 28, 2016, added a new paragraph (g) to subdivision (6) of section 6527 and a new paragraph (g) to subdivision (4) of section 6909 of the Education Law, permitting registered professional nurses to screen individuals at increased risk of syphilis, gonorrhea and/or chlamydia infections pursuant to a non-patient specific order issued by a licensed physician or a certified nurse practitioner. Chapter 502 of the Laws of 2016 addresses the public health problem of STIs by making STI screening and sexual health care a routine, and more readily available, health care service. The proposed amendment implements the provisions of Chapter 502 of the Laws of 2016 by adding a new subdivision (g) to section 64.7 of the Regulations of the Commissioner of Education that reflects current practices regarding screening of individuals at increased risk of syphilis, gonorrhea and/or chlamydia infections.

The proposed addition of subdivision (g) of section 64.7 of the Regulations of the Commissioner of Education requires that screening of individuals at increased risk of syphilis, gonorrhea and/or chlamydia shall include the administration of one or more laboratory or point of care tests approved by the FDA to detect or screen for syphilis, gonorrhea and/or chlamydia infections. The proposed amendment further requires that the written non-patient specific order for the screening to be performed 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 test(s) or assessment procedures to detect or screen for syphilis, gonorrhea and/or chlamydia infection(s) to be administered; (c) a protocol for administering the ordered screening test(s) or a specific reference to a separate written protocol for administering the ordered screening of individuals at increased risk of syphilis, gonorrhea and/or chlamydia infections; (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 screened; and (f) the name and license number of the registered professional nurse(s) authorized to execute the non-patient specific order and protocol for screening individuals at increased risk of syphilis, gonorrhea and/or chlamydia infections 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, include instructions for screening for syphilis, gonorrhea and/or chlamydia infections and 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 screening test(s); (b) informed consent for administering the ordered screening test(s) has been obtained pursuant to the criteria in the protocol from the recipient or person authorized to consent on behalf of the recipient; (c) positive results are not disclosed without a patient specific order; and (d) the administration of the ordered screening is documented in the recipient's medical record in accordance with criteria in the protocol and that documentation relating to screening is maintained.

Related Regents Items

March 2017: Proposed Amendment of 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 Screen Individuals at Increased Risk of Syphilis, Gonorrhea and/or Chlamydia Infections.

March 2017: Proposed Amendment of Sections 60.12, 63.13 and 64.5 of the Regulations of the Commissioner of Education Relating to the Execution by Licensed Pharmacists of Non-Patient Specific Orders to Dispense Drugs to Prevent Human Immunodeficiency Virus (HIV) Infections in Persons Who May Have Been Exposed to HIV.

May 2017: Proposed Amendment of Sections 60.12, 63.13 and 64.5 of the Regulations of the Commissioner of Education Relating to the Execution by Licensed Pharmacists of Non-Patient Specific Orders to Dispense Drugs to Prevent Human Immunodeficiency Virus (HIV) Infections in Persons Who May Have Been Exposed to HIV.

Recommendation

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

VOTED: That subdivision (g) of section 64.7 of the Regulations of the Commissioner of Education be added, as submitted, effective June 11, 2017, as an emergency rule upon a finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare to ensure that the emergency rule adopted at the March 2017 Regents meeting remains continuously in effect until the proposed rule can be presented for adoption and take effect as a permanent rule.

Timetable for Implementation

The proposed rule was adopted as an emergency rule at the March 2017 Regents meeting, effective March 14, 2017, and will expire on June 10, 2017. If adopted at the May 2017 Regents meeting, the second emergency action will become effective on June 11, 2017. It is anticipated that the proposed rule will be presented for permanent adoption at the June 2017 Regents meeting and will take effect as a permanent rule on June 28, 2017.

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 502 of the Laws of 2016

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, [and] hepatitis C tests and screening for syphilis, gonorrhea and/or chlamydia infections pursuant to non-patient specific orders and protocols.

(a) . . .

(b) . . .

(c) . . .

(d) . . .

(e) . . .

(f) . . .

(g) Screening for syphilis, gonorrhea and/or chlamydia infections.

(1) As used in this subdivision, screening means an assessment of an individual to ascertain his or her risk of having a syphilis, gonorrhea and/or chlamydia infection and may include the administration of one or more laboratory or point of care tests approved by the Federal Food and Drug Administration to detect or screen for syphilis, gonorrhea and/or chlamydia infections.

(2) A registered professional nurse may screen persons at increased risk for syphilis, gonorrhea and/or chlamydia 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 laboratory or point of care test(s) or assessment procedures to be administered;

(c) a protocol for administering the ordered screening for syphilis, gonorrhea and/or chlamydia infections or a specific reference to a separate written protocol for administering the ordered screening for syphilis, gonorrhea and/or chlamydia, 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 screened; and

(f) the name and license number of the registered professional nurse(s) authorized to execute the non-patient specific order and protocol to screen for syphilis, gonorrhea and/or chlamydia infections; 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 screening for syphilis, gonorrhea and/or chlamydia infections and 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 screening tests for syphilis, gonorrhea and/or chlamydia infections;

(b) informed consent for administering the ordered screening for syphilis, gonorrhea and/or chlamydia has been obtained from the recipient pursuant to the criteria in the protocol, or when the recipient lacks capacity to consent, from a person authorized pursuant to law to consent to health care for the recipient;

(c) positive test results for syphilis, gonorrhea and/or chlamydia infections 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 screening for syphilis, gonorrhea and/or chlamydia is documented in the recipient's medical record in accordance with criteria in the protocol and that documentation relating to the screening for syphilis, gonorrhea and/or chlamydia 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 implement Chapter 502 of the Laws of 2016, which became effective on November 28, 2016, the date it was enacted. The amendment to the Education Law made by Chapter 502 of the Laws of 2016 allows registered professional nurses to screen individuals at increased risk of syphilis, gonorrhea and/or chlamydia infections pursuant to non-patient specific orders prescribed by a licensed physician or a certified nurse practitioner.

The proposed amendment was adopted as an emergency action at the March 13, 2017 Regents meeting, effective March 14, 2017. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on March 29, 2017. 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 State Administrative Procedure Act (SAPA) section 202(1) and (5), would be the June 12-13, 2017 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the proposed amendment, if adopted at the June meeting, would be June 28, 2017, the date a Notice of Adoption would be published in the State Register. However, the March emergency rule will expire on June 10, 2017.

If the rule were to lapse, registered professional nurses would be unable to continue to screen individuals at increased risk of syphilis, gonorrhea and/or chlamydia infections pursuant to non-patient specific orders prescribed by a licensed physician or

a certified nurse practitioner which could delay treatment and potentially have the adverse impact of causing infected individuals to suffer potential complications, including but not limited to, possible infertility and/or unknowingly spreading these infections to other persons. Emergency action is therefore necessary for the preservation of the public health and general welfare to ensure that the proposed rule adopted by emergency action at the March 2017 Regents meeting remains continuously in effect until the proposed rule can be presented for adoption and take effect as a permanent rule.

It is anticipated that the proposed amendment will be presented for adoption as a permanent rule at the June 12-13, 2017 meeting of the Board of Regents, which is the first meeting scheduled after expiration of the 45-day public comment period required by the State Administrative Procedure Act. If adopted at the June 2017 meeting, the proposed amendment will become effective as a permanent rule on June 28, 2017.