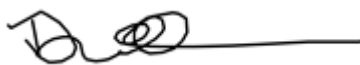






THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

TO: The Professional Practice Committee

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: June 1, 2017


AUTHORIZATION(S):


SUMMARY

Issue for Decision

Should the Board of Regents adopt 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 rule will be presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as a permanent rule at the June 2017 meeting of the Board of Regents. A copy of the proposed rule is attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

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. Because the March emergency rule will expire on June 10, 2017, a second emergency action was adopted at the May 2017 meeting, in order to ensure that the emergency rule remains continuously in effect until June 28, 2017, which is the effective date of the adoption of the permanent rule.

Additionally, following the above-referenced publication of the Notice of Emergency Adoption and Proposed Rule Making, the Department received comments from two separate commenters. An Assessment of Public Comment is attached, however, no change in the proposed amendment is recommended at this time.

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 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.

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.

June 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 28, 2017.

Timetable for Implementation

If adopted at the June 12-13, 2017 Regents meeting, the proposed rule will take effect 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

ASSESSMENT OF PUBLIC COMMENT

Since publication of a Notice of Emergency Adoption and Proposed Rule Making in the March 29, 2017 State Register, the State Education Department received the following comments:

1. COMMENT:

One commenter indicated that recent increases in cases of syphilis, gonorrhea and chlamydia infections are a major public health problem in the United States and New York City. The commenter stated that syphilis, gonorrhea and chlamydia infections may be asymptomatic and if untreated, could lead to various health complications. The commenter also stated that NYSED's proposed regulations are critical to statewide efforts to curb the incidence and prevalence of sexually transmitted infections (STIs). However, he recommends the elimination of 8 NYCRR §64.7(g)(3)(ii)(c)'s requirement that registered professional nurses (RNs) not disclose positive test results for syphilis, gonorrhea and/or chlamydia infections to the test recipient or the recipient's authorized representative without a patient specific order from a licensed physician, licensed physician assistant or certified nurse practitioner. The commenter states that he is recommending the elimination of this requirement to ensure that all New Yorkers have access to prompt STI diagnoses, which can facilitate and expedite a patient's ability to seek treatment and prevent further transmission of infection to sexual partners. The commenter further expressed concern that this requirement may delay notification of a positive result to a patient, if a licensed physician, physician assistant or certified nurse practitioner is not immediately available

to issue a patient specific order. The commenter maintains that this could impede prompt treatment counseling and prolong timely initiation of treatment.

The commenter further states that if the Department does not agree with his recommendation to eliminate this requirement, perhaps it would consider revising proposed 8 NYCRR §64.7(g)(3)(ii)(c) as follows: “positive confirmatory test results for syphilis, gonorrhea and/or chlamydia infections are not disclosed to the test recipient or the test recipient’s authorized representative by the professional registered nurse without a patient specific order from a licensed physician, licensed physician assistant or certified nurse practitioner. However, preliminary positive test results can be disclosed by the registered professional nurse to the test recipient or the recipient’s authorized representative without a patient specific order from a licensed physician, licensed physician assistant or certified nurse practitioner.” The commenter asserts that this revision would allow RNs to provide preliminary positive results and begin treatment and counseling.

DEPARTMENT RESPONSE:

The Department agrees that the increased incidence of STIs pose a major public health challenge for New York State. The Department believes that Chapter 502 of the Laws of 2016, which the proposed amendment implements, will help to curb the incidence and prevalence of gonorrhea, syphilis and/or chlamydia infections in this State. However, the Department disagrees that the commenter's recommended changes to the proposed regulations would ensure that patients have access to prompt and appropriate diagnoses and treatments for STIs. Chapter 502 of the Laws of 2016 and the proposed amendment permit RNs to execute non-patient specific order issued

by a licensed physician (physician) or a certified nurse practitioner (nurse practitioner) to screen individuals at increased risk of syphilis, gonorrhea and/or chlamydia infections. These screenings typically include laboratory and point of care testing to screen for or aid in the diagnosis of these diseases. This law and the proposed amendment do not authorize RNs to determine medical diagnoses or determine presumed medical diagnoses. Moreover, New York Law does not authorized RNs to "dispense" or otherwise supply prescription drugs to a patient that has not been ordered or prescribed for the patient by a physician or other authorized prescriber. A physician, nurse practitioner, physician assistant or midwife must determine a medical diagnosis for each patient and prescribe antibiotics or other treatments for him or her. For this reason and others, the proposed amendment requires RNs to disclose to the patient his or her positive test results pursuant a patient specific order from a health care professional that is authorized to diagnose and treat sexually transmitted infections. The Department does not believe this is an unduly burdensome requirement. RNs who provide these STIs screening services should at a minimum, work in collaboration with health care professionals authorized to diagnose and treat sexually transmitted infections. These health professionals must be available to provide timely, appropriate care to patients in need of a medical diagnosis. Patients suffering from these diseases deserve the same quality of medical care that is available to patients diagnosed and treated in clinics, private practices or local health departments for other common communicable diseases, such as genital herpes, UTIs, chancroid, pubic lice, yeast infections and scabies.

The Department further notes that point of care tests currently used to detect gonorrhea, syphilis and/or chlamydia are not "preliminary" tests that would lead to

earlier communications with a patient regarding test results. For example, many health care providers use nucleic acid amplification tests (NAATs), which detect chlamydia DNA or gonorrhea DNA. Many health care providers use two tests in rapid succession; a Non-Treponema Serologic Test, which, if positive, may be followed immediately with a Treponemal Serologic Test to detect syphilis infection.

The proposed amendment is consistent with New York Law and for this reason, as well as all the aforementioned reasons, the Department respectfully declines to eliminate 8 NYCRR §64.7(g)(3)(ii)(c)'s patient specific order requirement for RNs to disclose positive results to test recipients or their authorized representatives. For the same reasons, the Department also declines to revise 8 NYCRR §64.7(g)(3)(ii)(c) to permit RNs to disclose "preliminary" positive test results to patients, who they have screened for syphilis, gonorrhea and/or chlamydia infections pursuant non-patient specific orders.

2. COMMENT:

One commenter stated that she did not see the rationale for needing a patient specific order for an RN to disclose positive test results for syphilis, gonorrhea or chlamydia infections to a patient. The commenter stated that these are all curable bacterial STDs and in public health STD clinics, RNs are trained to give these test results on a daily basis. Further, the commenter noted that many times, in public clinics and clinician offices, RNs provide positive test results over the phone. The commenter also stated that waiting for a clinician to write a patient-specific order to give a positive test result can result in delays in getting curative treatment, which can lengthen the time a patient is communicable and, further, that delays in treatment are not desirable from a

public health standpoint and contribute to increases in rates of syphilis, gonorrhea and chlamydia; all of which are increasing dramatically in the State. The commenter asks that this stipulation be removed from the proposed regulation.

DEPARTMENT RESPONSE:

In most cases, New York State Law requires an RN to execute medical regimens that are ordered for a specific patient by a physician, nurse practitioner or other qualified health care practitioner who has examined the patient. In addition, an RN cannot execute medical protocols that allow the RN to make medical diagnoses or perform medical services that are outside the scope of practice of the RN.

The commenter appears to describe situations in which a physician, nurse practitioner, physician assistant or midwife has medically evaluated a patient, provided medical counseling regarding the patient's health status and laboratory tests (and presumably reviewed test results) before they are disclosed to a patient.

In contrast, Chapter 502 of the Laws of 2016, which allows RNs to execute non-patient specific orders (issued by a physician or nurse practitioner) to medically screen those at-risk for syphilis, chlamydia and/or gonorrhea infections, does not require any physician or other medical provider to examine or have a treatment relationship with the recipient of the ordered screenings. This law and the proposed amendment do not authorize RNs to determine medical diagnoses or determine presumed medical diagnoses. A physician, nurse practitioner, physician assistant or midwife must determine a medical diagnosis for each patient and prescribe antibiotics or other treatments for him or her. The proposed amendment is consistent with New York Law and for this reason, as well as the reasons mentioned above, the proposed amendment

requires RNs to disclose to patients positive test results pursuant a patient specific order from a health care professional who is authorized to diagnose and treat sexually transmitted infections. The Department does not believe this is an unduly burdensome requirement. RNs who provide these STI screening services should at a minimum, work in collaboration with health care professionals authorized to diagnose and treat sexually transmitted infections. These health professionals must be available to provide timely, appropriate care to patients in need of a medical diagnosis. Patients suffering from these diseases deserve the same quality of medical care that is available to patients diagnosed and treated in clinics, private practices or local health departments for other common communicable diseases, such as genital herpes, UTIs, chancroid, pubic lice, yeast infections and scabies.