



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 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) Infection in Persons Who May Have Been Exposed to HIV

**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 sections 60.12 and 63.13 and subdivision (h) of section 64.5 to the Regulations of the Commissioner of Education to implement Chapter 502 of the Laws of 2016, relating to the execution by licensed pharmacists of non-patient specific orders to dispense drugs to prevent human immunodeficiency virus (HIV) infection in persons who may have been recently exposed to HIV?

### 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), HIV infection remains a major public health problem throughout the United States. In order to prevent new HIV infections, the CDC recommends that HIV post-exposure prophylaxis drugs be made available to persons who may have been recently exposed to HIV. The CDC currently recommends that HIV post-exposure prophylaxis drugs be used after a high risk event and must be started as soon as possible to be effective, always within 72 hours after a possible HIV exposure. In the United States, persons are most commonly exposed to HIV through sexual contact or sharing of needles. In 2016, the CDC updated its guidelines for healthcare providers, which promote the use of HIV post-exposure prophylaxis drugs for persons potentially exposed to HIV. These guidelines are based on current evidence that post-exposure prophylaxis drugs can reduce a person's risk of HIV infection if taken within 72 hours of exposure as prescribed. The CDC guidelines for preventing new HIV infections are available at <https://www.cdc.gov/hiv/guidelines/preventing.html>.

Currently, in order to obtain post-exposure prophylaxis drugs, most patients must go to an emergency room. Chapter 502 of the Laws of 2016, effective November 28, 2016, added a new subdivision (7-a) to section 6527, a new subdivision (8) to section 6909 and a new subdivision (5) to section 6801 of the Education Law, permitting licensed pharmacists, pursuant to non-patient specific orders prescribed by a licensed physician or certified nurse practitioner, to dispense up to a seven day starter pack of HIV post-exposure prophylaxis medications to prevent HIV infection in a person who may have recently been exposed to HIV. By enabling licensed pharmacists to dispense a seven day starter kit of post-exposure prophylaxis drugs pursuant to a non-patient specific order, Chapter 502 of the Laws of 2016 provides an additional, cost-effective option to persons who may need immediate access to drugs to prevent HIV infection. In addition to expanding access to post-exposure HIV prophylaxis drugs, licensed

pharmacists will help strengthen consumer understanding and awareness of HIV prevention, provide referral and coordination with licensed physicians and other health care professionals for follow-up to post-exposure prophylaxis drug treatment, counsel consumers on risks, benefits, duration of treatment and the importance of treatment adherence, and urge consumers to take other appropriate HIV prevention measures.

The proposed addition of sections 60.12 and 63.13 and subdivision (h) of section 64.5 to the Regulations of the Commissioner of Education implements Chapter 502 of the Laws of 2016 by establishing the requirements for non-patient specific orders and protocols by which licensed pharmacists will be authorized to dispense a seven day starter kit of post-exposure prophylaxis drugs for the purpose of preventing HIV infection. This will improve timely access to antiretroviral drugs for persons who may have been exposed to HIV.

The proposed addition of sections 60.12 and 63.13 and subdivision (h) of section 64.5 to the Regulations of the Commissioner of Education provides that licensed pharmacists may, pursuant to non-patient specific orders and protocols prescribed by a licensed physician or certified nurse practitioner, dispense up to a seven day supply of drugs to prevent HIV infection in a person who may have been exposed to HIV. These drugs must be approved by the Federal Food and Drug Administration to prevent and/or treat HIV infection. The proposed amendment further requires that the written non-patient specific order 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 and dose of the specific drugs to be dispensed; (c) a protocol for dispensing the ordered drugs or a specific reference to a separate written protocol for dispensing the medication; (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 who may receive the dispensed drugs, provided that they are located in New York State; and (f) the name and license number of the licensed pharmacist(s) authorized to execute the non-patient specific order and protocol or the name and address of the New York State licensed pharmacy that employs or contracts with pharmacists to execute the non-patient specific order and protocol.

The proposed amendment also requires that the written protocol must, at a minimum, require the licensed pharmacist to: (a) screen each potential recipient, pursuant to criteria in the protocol, for conditions that would qualify or preclude him or her from receiving the dispensed drugs; (b) offer counseling regarding the need for follow-up care pursuant to criteria in the protocol and provide the counseling if the recipient consents; (c) offer or provide in writing, the names and addresses of hospitals or other health providers that offer follow-up care; and (d) document the pharmacy services provided, including the offer or provision of counseling and referral information.

### **Related Regents Items**

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.

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.

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.

### **Recommendation**

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

VOTED: That sections 60.12 and 63.13 and subdivision (h) of section 64.5 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 take effect 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, 6801, 6806, 6902 and 6909 of the Education Law and Chapter 502 of the Laws of 2016

1. Section 60.12 of the Regulations of the Commissioner of Education is added, to read as follows:

60.12 Orders to dispense drugs to prevent human immunodeficiency virus (HIV) infection.

(1) As used in this section, HIV post-exposure prophylaxis drugs means drugs approved by the Federal Food and Drug Administration to prevent and/or treat HIV infection.

(2) A licensed physician may issue a written non-patient specific order and protocol for a licensed pharmacist to dispense up to a seven day supply of HIV post-exposure prophylaxis drugs to prevent HIV infection in persons who have potentially been exposed to HIV, provided that the requirements of this section 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 who issues the non-patient specific order and protocol;

(b) the name and dose of the specific drug(s) to be dispensed;

(c) a protocol for dispensing the drug(s) or a specific reference to a separate written protocol for dispensing the drug(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 who may receive the dispensed drugs, provided that the group(s) of persons are located in New York State; and

(f) the name and license number of each licensed pharmacist authorized to execute the non-patient specific order and protocol or the name and address of the New York State licensed pharmacy that employs or contracts with the licensed pharmacist(s) to execute the non-patient specific order and protocol.

(ii) The written protocol, incorporated into the order prescribed in subparagraph (i) of this paragraph, shall, at a minimum, require the licensed pharmacist to:

(a) screen each potential recipient, pursuant to criteria in the protocol, for conditions that would qualify or preclude the potential recipient from receiving the dispensed drugs;

(b) offer counseling regarding the need for follow-up care pursuant to criteria in the protocol and provide the counseling if the recipient consents;

(c) offer or provide in writing, the names and addresses of hospitals or other health providers that offer follow-up care, which shall be identified in the protocol;

and

(d) document the pharmacy services provided, including the offer or provision of counseling and referral information described in this subparagraph, and maintain the documentation in accordance with section 29.2(a)(3), section 63.6(b)(7) and section 63.6(b)(8) of this Title.

(4) A licensed physician may issue a written patient specific order or prescription to a licensed pharmacist to dispense HIV post-exposure prophylaxis drugs pursuant to applicable law.

2. Section 63.13 of the Regulations of the Commissioner of Education is added, to read as follows:

63.13 Non-patient specific orders and protocols.

Orders to dispense drugs to prevent human immunodeficiency virus (HIV) infection. A licensed pharmacist may, pursuant to a non-patient specific order and protocol issued by a licensed physician in accordance with section 60.12 of this Title or by a certified nurse practitioner in accordance with subdivision (h) of section 64.5 of this Title, dispense up to a seven day supply of HIV post-exposure prophylaxis drugs for the purpose of preventing HIV infection in persons who have potentially been exposed to HIV.

3. Subdivision (h) of section 64.5 of the Regulations of the Commissioner of Education is added, to read as follows:

(h) Orders to dispense drugs to prevent human immunodeficiency virus (HIV) infection.

(1) As used in this subdivision, HIV post-exposure prophylaxis drugs means drugs approved by the Federal Food and Drug Administration to prevent and/or treat HIV infection.

(2) A certified nurse practitioner may issue a written non-patient specific order and protocol for a licensed pharmacist to dispense up to a seven day supply of HIV post-exposure prophylaxis drugs to prevent HIV infection in persons who have

potentially been exposed to HIV, 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 certified nurse practitioner who issues the non-patient specific order and protocol;

(b) the name and dose of the specific drug(s) to be dispensed;

(c) a protocol for dispensing the drugs(s) or a specific reference to a separate written protocol for dispensing the drug(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 who may receive the dispensed drugs, provided that the group(s) of persons are located in New York State; and

(f) the name and license number of each licensed pharmacist authorized to execute the non-patient specific order and protocol or the name and address of the New York State licensed pharmacy that employs or contracts with the licensed pharmacist(s) to execute the non-patient specific order and protocol.

(ii) The written protocol, incorporated into the order prescribed in subparagraph (i) of this paragraph, shall, at a minimum, require the licensed pharmacist to:

(a) screen each potential recipient, pursuant to criteria in the protocol, for conditions that would qualify or preclude the potential recipient from receiving the dispensed drugs;



(b) offer counseling regarding the need for follow-up care pursuant to criteria in the protocol and provide the counseling if the recipient consents;

(c) offer or provide in writing, the names and addresses of hospitals or other health providers that offer follow-up care, which shall be identified in the protocol;  
and

(d) document the pharmacy services provided, including the offer or provision of counseling and referral information described in this subparagraph, and maintain the documentation in accordance with section 29.2(a)(3), section 63.6(b)(7) and section 63.6(b)(8) of this Title.

(4) A certified nurse practitioner may issue a written patient specific order or prescription to a licensed pharmacist to dispense HIV post-exposure prophylaxis drugs pursuant to applicable law.

## **8 NYCRR §§60.12, 63.13 and 64.5**

### 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 licensed pharmacists to execute non-patient specific orders to dispense HIV post-exposure prophylaxis drugs prescribed by a licensed physician or a certified nurse practitioner for the purpose of preventing HIV infection.

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 this rule were to lapse, licensed pharmacists would be unable to continue to execute non-patient specific orders to dispense HIV post-exposure prophylaxis drugs prescribed by a licensed physician or a certified nurse practitioner for the purpose of

preventing HIV infection which could have an adverse impact on persons who have potentially been exposed to HIV. 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 amendment 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.