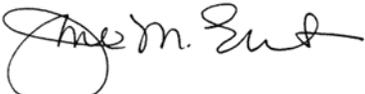




TO: The Honorable the Members of the Board of Regents

FROM: Jhone M. Ebert 

SUBJECT: Proposed Amendments to Section 136.6 of the
Commissioner's Regulations Relating to School Health
Services

DATE: June 1, 2017

AUTHORIZATION(S):  

SUMMARY

Issue for Decision (Consent Agenda)

Should the Board of Regents adopt as a second emergency action, amendments to Section 136 of the Commissioner's Regulations relating to epinephrine auto-injectors?

Reason(s) for Consideration

Required by statute (Chapter 373 of the Laws of 2016)

Proposed Handling

At its March 2017 meeting, the Board of Regents adopted the proposed amendment, as an emergency measure, effective March 28, 2017. A Notice of Emergency Adoption was published in the State Register on April 12, 2017. The proposed amendment is being presented to the full Board for adoption as a second emergency rule at its June 2017 meeting in order to ensure that the emergency rule adopted at the March 2017 meeting remains continuously in effect until it can be permanently adopted at the September 2017 meeting. A Notice of Emergency Adoption will be published in the State Register on July 5, 2017. A copy of the proposed amendment and a statement of facts and circumstances justifying the emergency are attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

Procedural History

A Notice of Proposed Rulemaking was published in the State Register on January 25, 2017. A Notice of Emergency Adoption was published in the State Register on April 12, 2017 relating to Commissioner's regulation §136.6. A Notice of Revised Rulemaking was published in the State Register on May 24, 2017. It is anticipated that the proposed amendment will be presented for permanent adoption at the September 11-12, 2017 Regents meeting. However, the emergency rule published on April 12, 2017 will expire on June 25, 2017. A second emergency action is, therefore, necessary at the June 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 along with the other proposed amendments to Part 136. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

This proposed rule was presented along with other proposed amendments to Part 136 of the Commissioner's regulations to the P-12 Education Committee for discussion at the January 2017 Regents meeting. However, in order to timely implement the provisions of Chapter 373 of the Laws of 2016, the amendments to Commissioner's regulation §136.6 were adopted as an emergency rule at the March 2017 Regents meeting. Subsequently, the proposed amendments to the other portions of Part 136 were revised at the May 2017 meeting, requiring an additional 30-day public comment period. Therefore, the second emergency action is necessary to ensure that the amendments to Commissioner's regulation §136.6 remain in effect until the broader package of amendments to Part 136 can be permanently adopted. A copy of the proposed amendment is attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

On-site epinephrine auto-injectors

Education Law §921 was added by Chapter 424 of the Laws of 2014 to allow school districts, boards of cooperative educational services (BOCES) and county vocational education and extension boards (CVEEBs), charter schools, and non-public elementary and secondary schools in this state to provide and maintain epinephrine auto-injectors on-site in quantities and types deemed by the Commissioner, in consultation with the Commissioner of Health, to be adequate to ensure ready and appropriate access for use during emergencies to any student or staff having anaphylactic symptoms whether or not there is a previous history of severe allergic reaction.¹ Education Law §921 also authorizes school districts, BOCES, CVEEBs, charter schools, and non-public elementary and secondary schools, or any person employed by any such entity, to administer epinephrine auto-injectors in the event of an emergency pursuant to the requirements of Public Health Law §3000-c. Part 136 of the Commissioner's regulations was amended in 2014 to implement these provisions. On September 29, 2016, the Governor signed Chapter 373 of the Laws of 2016, which made certain changes to the use of emergency epinephrine auto-injectors. In order to timely implement the provisions

¹ Public Health Law section 3000-c was subsequently amended by Chapter 373 of the Laws of 2016.

of Chapter 373 of the Laws of 2016, the proposed amendment makes the following changes to section 136.6 of the Commissioner's regulations:

- Amends the definition of epinephrine auto-injector device to conform to the definition in the new law (a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body for the purpose of emergency treatment of a person appearing to experience anaphylactic symptoms approved by the Food and Drug Administration).
- Eliminates the requirement for a school district to enter into a collaborative agreement with an emergency health care provider in order to purchase, acquire, possess and use epinephrine auto-injector devices.
- In addition, school districts are no longer required to report every use of an epinephrine auto-injector to an emergency health care provider.

Related Regents Items

<http://www.regents.nysed.gov/common/regents/files/317p12a3.pdf>
<http://www.regents.nysed.gov/common/regents/files/215p12a2.pdf>
<http://www.regents.nysed.gov/common/regents/files/meetings/Mar%202015/315brca5.pdf>
<http://www.regents.nysed.gov/common/regents/files/117p12d1.pdf>

Recommendation

Staff recommends that the Regents take the following action:

VOTED: That section 136.6 of the Regulations of the Commissioner be amended, as submitted, effective June 20, 2017, as an emergency action upon a finding by the Board of Regents that such action is necessary for the preservation of the general welfare to immediately establish standards for the provision, maintenance and administration of epinephrine auto-injectors pursuant to Public Health Law §3000-c, as amended by Chapter 373 of the Laws of 2016, and to ensure that the emergency rule adopted at the March 2017 meeting remains continuously in effect until it can be adopted as a permanent rule.

Timetable for Implementation

If adopted at the June Regents meeting, the emergency rule will continue to be in effect for a 60-day period beginning on June 20, 2017. It is anticipated that the proposed rule will be presented for a third emergency action at the July meeting in order to ensure that the emergency rule will continue to be in effect until the rule is presented for permanent adoption at the September 2017 Regents meeting.

AMENDMENT OF THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to Education Law sections 207, 305, 921, Public Health Law section 3000-c and Chapter 373 of the Laws of 2016.

1. Section 136.6 of the Regulations of the Commissioner of Education is amended, effective March 28, 2017, as follows:

(a) Definitions. As used in this section:

(1) Epinephrine auto-injector device means [an automated injection delivery device, approved by the United States Food and Drug Administration, for injecting a measured dose of the drug epinephrine] a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body for the purpose of emergency treatment of a person appearing to experience anaphylactic symptoms approved by the United States Food and Drug Administration.

(2) Trained school personnel means any person employed by a school district, board of cooperative educational services, county vocational education and extension board, charter school or non-public elementary and secondary school, including but not limited to, health professionals who have successfully completed a training course in the use of epinephrine auto-injector devices approved by the Department of Health pursuant to Public Health Law section 3000-c.

[(3) Collaborative agreement means a written agreement with an emergency health care provider pursuant to Public Health Law section 3000-c that incorporates written practice protocols, and policies and procedures that shall ensure compliance with the provisions of Public Health Law section 3000-c.

(4) Emergency health care provider means:

(i) a physician with knowledge and experience in the delivery of emergency care;

or

(ii) a hospital licensed under Article 28 of the Public Health Law that provides emergency care.

(5) Regional Council means a regional emergency medical services council established pursuant to Public Health Law section 3003.

(6)] (3) Instructional school facility means a building or other facility maintained by a school district, board of cooperative educational services, a county vocational education and extension board, charter school, or non-public elementary and secondary school where instruction is provided to students pursuant to its curriculum.

(b) Each school district, board of cooperative educational services, county vocational education and extension board, charter school, and non-public elementary and secondary school may provide and maintain on-site in each instructional school facility epinephrine auto-injectors for use during emergencies in accordance with Public Health Law section 3000-c. Each such facility shall have sufficient epinephrine auto-injectors available to ensure ready and appropriate access for use during emergencies to any student or staff having symptoms of anaphylaxis whether or not there is a previous history of severe allergic reaction. In determining the quantity and placement of epinephrine auto-injectors [in collaboration with the emergency health care provider,] consideration shall be given to:

(1) the number of students, staff and other individuals that are customarily or reasonably anticipated to be within such facility; and

(2) the physical layout of the facility, including but not limited to:

(i) location of stairways and elevators;

(ii) number of floors in the facility;

(iii) location of classrooms and other areas of the facility where large congregations of individuals may occur; and

(iv) any other unique design features of the facility.

[(c) The school district, board of cooperative educational services, county vocational education and extension board, charter school, or non-public elementary and secondary school shall file a copy of the collaborative agreement with the appropriate Regional Council. Trained school personnel shall not administer an epinephrine auto-injector in accordance with Public Health Law 3000-c prior to the filing of the collaborative agreement with the Regional Council.

(d) (c) In the event of an emergency, trained school personnel or school personnel directed in a specific instance to use an epinephrine auto-injector device by a health care practitioner as defined in Public Health Law section 3000-c, may administer an epinephrine auto-injector to any student or school personnel having symptoms of anaphylaxis in an instructional school facility, whether or not there is a previous history of severe allergic reaction pursuant to Public Health Law section 3000-c.

[(e) Every use of an epinephrine auto-injector device pursuant to this section and Public Health Law section 3000-c shall immediately be reported to the emergency health care provider.]

8 NYCRR §136.6

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH
NECESSITATE EMERGENCY ACTION

The proposed rule is necessary to implement Chapter 373 of the Laws of 2016, which amends section 3000-c of the Public Health Law, which became effective on March 28, 2017, which permits school districts, boards of cooperative educational services (BOCES), county vocational education and extension boards, charter schools, and non-public elementary and secondary schools in the State to possess and use epinephrine auto-injector devices for emergency treatment of a person appearing to experience anaphylactic symptoms.

Since the Board of Regents meets at fixed intervals, the earliest the proposed rule 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) sections 201(1) and (5), would be the September 11-12, 2017 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 September 27, 2017, the date a Notice of Adoption would be published in the State Register. However, the provisions of Chapter 373 became effective on March 28, 2017 and section 3 of the statute directs the Commissioner to promulgate necessary regulations for the timely implementation of the statute on its effective date.

Therefore, emergency action is necessary at the June 2017 Regents meeting for the preservation of the general welfare in order to continue to implement the provisions of Chapter 373 of the Laws of 2016, and thus ensure the continuous implementation of the statute.

It is also necessary to ensure that the emergency rule adopted at the March meeting, which will expire on June 10, 2017, remains continuously in effect until it can be adopted as a permanent rule. A Notice of Emergency Adoption was published in the State Register on April 12, 2017 and will expire on June 25, 2017. It is anticipated that the proposed rule will be presented for adoption as a permanent rule at the September 11-12, 2017 Regents meeting, effective September 27, 2017.