TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: Proposed Amendment to Section 63.6 of the Regulations of the Commissioner of Education Relating to the Certification of Manufacturers and Wholesalers for Export Purposes

DATE: April 25, 2019

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents amend paragraph (6) of subdivision (c) of section 63.6 of the Regulations of the Commissioner of Education relating to the certification of manufacturers and wholesalers for export purposes?

Reason for Consideration

Review of policy.

Proposed Handling

The proposed amendment is presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency rule at the May 2019 meeting of the Board of Regents. A copy of the proposed rule and a statement of facts and circumstances justifying the emergency action are attached.

Procedural History

A Notice of Emergency Action and Proposed Rulemaking will be published in the State Register on May 22, 2019. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

Education Law §6808(4) requires that any drug manufacturer or wholesaler of drugs be registered with the Department prior to offering such drugs and/or devices for sale in New York. Additionally, if such New York State registered manufacturer or wholesaler wishes to sell drugs[1] and/or devices[2] in foreign countries the registered manufacturer or wholesaler must, inter alia, obtain a certificate from the Department that verifies that it is currently registered as a manufacturer, wholesaler-repacker and/or wholesaler of drugs and/or devices and that it offers the drugs and/or devices listed on the certificate for sale in New York State. These certificates are commonly referred to as "free sale certificates."

To obtain such authorization, a registered manufacturer or wholesaler must submit an application for a free sale certificate to the New York State Board of Pharmacy Office (pharmacy board office) with the required fee. The application requires the manufacturer or wholesaler to provide, among other things, its name and address; identify the type of establishment (manufacturer, wholesaler-repacker and/or wholesaler); the name of the country in which the certificate will be used; the name of each drug and/or device (product) it intends to export; and attach copies of the labels for each product. If the product will be sold under a different name in the identified foreign country, the English name under which the product is sold in New York State must also appear on the label. Finally, the products for which the entity seeks the free sale certificate must appear in a domestic catalog or price list that clearly indicates that they are offered for sale in New York State, for the Department to consider issuing a free sale certificate.

Currently, paragraph (6) of subdivision (c) of section 63.6 of the Regulations of the Commissioner of Education provides that "[a]ny registered manufacturer or wholesaler may be issued a certificate by the executive secretary of the State Board of Pharmacy, authenticating said registration and identifying the specified drugs and/or devices as articles regularly offered for sale in New York. . . ."

The pharmacy board office receives approximately 20 free sale certificate applications a year. Currently, there are three pending applications. However, since the departure of the former executive secretary of the State Board of Pharmacy in January

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[1] Education Law §6802(7) defines "drugs" as:
a. Articles recognized in the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, or official national formulary.
b. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals.
c. Articles (other than food) intended to affect the structure or any function of the body of man or animals.
d. Articles intended for use as a component of any article specified in paragraphs a, b, or c; but does not include devices or their components, parts or accessories.

[2] Pursuant to Education Law §6802(16), "device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended:
a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; or
b. To affect the structure or any function of the body of man or animals.

2019, the Department has been unable to issue any free sale certificates because the regulation only permits the executive secretary to issue such certificates. The proposed amendment to paragraph (6) of subdivision (c) of section 63.6 of the Regulations of the Commissioner of Education is designed to address this issue by permitting either the executive secretary or a designee of the Commissioner of Education to issue these certificates.

Related Regents Items

None.

Recommendation

VOTED: That paragraph (6) of subdivision (c) of section 63.6 of the Regulations of the Commissioner of Education be amended, as submitted, effective May 7, 2019, as an emergency action upon the finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare so that the Department can immediately resume performing the function of issuing free sale certificates to New York State registered manufacturers or wholesalers seeking to sell their drugs and/or devices in foreign countries.

Timetable for Implementation

If adopted at the May 2019 Regents meeting, the emergency rule will become effective on May 7, 2019. It is anticipated that the proposed rule will be presented to the Board of Regents for permanent adoption at the September 9-10, 2019 Regents meeting, after publication of the proposed amendment in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act. However, it is anticipated that an additional emergency action will be presented for adoption at the July 2019 Regents meeting to keep the rule continuously in effect until it can be adopted as a permanent rule at the September meeting, effective September 25, 2019.

Attachment A

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6801, 6802, and 6808 of the Education Law

1. Paragraph (6) of subdivision (c) of section 63.6 of the Regulations of the Commissioner of Education is amended, as follows:

Certification of manufacturers and wholesalers for export purposes. Any registered manufacturer or wholesaler may be issued a certificate by the executive secretary of the State Board of Pharmacy[,] or a designee of the Commissioner of Education, authenticating said registration and identifying the specified drugs and/or devices as articles regularly offered for sale in New York. The fee for each certificate shall be $5.

Attachment B

8 NYCRR §63.6
STATEMENT OF FACTS AND CIRCUMSTANCES
WHICH NECESSITATE EMERGENCY ACTION

The proposed amendment to the Regulations of the Commissioner of Education is necessary, so that the Department can immediately resume performing the function of issuing free sale certificates to New York State registered manufacturers or wholesalers seeking to sell their drugs and/or devices in foreign countries. Education Law §6808(4) requires that in order to sell drugs and/or devices in foreign countries, a New York State manufacturer or wholesaler must, inter alia, obtain a certificate from the Department that verifies that it is currently registered as a manufacturer, wholesaler-repacker and/or wholesaler of drugs and/or devices and that it offers the drugs and/or devices listed on the certificate for sale in New York State. These certificates are commonly referred to as "free sale certificates."

Currently, paragraph (6) of subdivision (c) of section 63.6 of the Regulations of the Commissioner of Education states that "[a]ny registered manufacturer or wholesaler may be issued a certificate by the executive secretary of the State Board of Pharmacy, authenticating said registration and identifying the specified drugs and/or devices as articles regularly offered for sale in New York. . . ."

However, since departure of the former executive secretary of the State Board of Pharmacy in January 2019, the Department has been unable to issue any free sale certificates because 8 NYCRR §63.6(c)(6) only permits the executive secretary to do so. Therefore, the proposed amendment paragraph (6) of subdivision (c) of section 63.6 of the Regulations of the Commissioner of Education is designed to address this issue by permitting either the executive secretary or a designee of the Commissioner of Education to issue these certificates.

Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for adoption, after expiration of the required 60-day comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the September 9-10, 2019 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 25, 2019 the date the Notice of Adoption would be published in the State Register.

Therefore, emergency action is necessary at the May 2019 Regents meeting for the preservation of the public health and general welfare so that the Department can immediately resume performing the function of issuing free sale certificates to New York State registered manufacturers or wholesalers seeking to sell their drugs and/or devices in foreign countries.

It is anticipated that the proposed rule will be presented for adoption as a permanent rule at the September 9-10, 2019 Regents meeting, which is the first scheduled meeting after the 60-day public comment period prescribed in SAPA for State agency rule makings.