



TO: The Honorable Members of the Board of Regents

FROM: David H. Hamilton *David H. Hamilton*

SUBJECT: Proposed Amendment of Section 63.6 of the Regulations of the Commissioner of Education Relating to the Supervisor Requirements for Wholesalers Transfilling Medical Oxygen

DATE: May 30, 2024

AUTHORIZATION(S): *Donna B. Bell*

SUMMARY

Issue for Decision (Consent)

Should the Board of Regents amend section 63.6 of the Regulations of the Commissioner of Education relating to the supervisor requirements for wholesalers transfilling medical oxygen?

Reasons for Consideration

Review of policy and required by State statute (Chapter 590 of the Laws of 2023).

Proposed Handling

The proposed rule is submitted to the Full Board for adoption as an emergency rule at the June 2024 meeting. A copy of the proposed rule (Attachment A) and a statement of facts and circumstances justifying the emergency action (Attachment B) are attached.

Procedural History

The proposed amendment was presented to the Professional Practice Committee for discussion and recommendation to the Full Board for adoption as an emergency rule at the April 2024 meeting of the Board of Regents. A Notice of Emergency Adoption and Proposed Rulemaking was published in the State Register on May 1, 2024, for a 60-day public comment period.

Because the April 2024 emergency rule will expire on July 14, 2024, a second emergency action is necessary to ensure that the emergency rule remains continuously in effect until it can be permanently adopted at the September 2024 meeting.

A Notice of Emergency Adoption will be published in the State Register on July 31, 2024. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

Wholesalers that transfill medical oxygen are finding it increasingly difficult to attract and retain individuals qualified to supervise the process of transfilling medical oxygen. Generally, transfilling means the process of transferring a gas, either in compressed or liquid form from one cylinder or container to another cylinder or container.

To address this issue, Chapter 590 of the Laws of 2023 (Chapter 590), effective April 22, 2024, amends section 6808 of the Education Law, by establishing the specific requirements for individuals who supervise the transfilling of medical oxygen. Chapter 590 requires that any person responsible for supervising the transfilling of medical oxygen must be either: (1) a respiratory therapist certified by a national accrediting body; (2) a person holding a bachelor's degree in chemistry, microbiology, chemical engineering or a related field; (3) a person having two years of education beyond high school and two years of experience in the handling of compressed medical gases satisfactory to the State Board of Pharmacy; or (4) a person having training in accordance with the requirements established in section 211.25 of Title 21 of the Code of Federal Regulations (CFR). It is anticipated that these supervisory requirements will facilitate the identifying, hiring and retaining of qualified supervisors for the transfilling of medical oxygen. The proposed amendment of section 63.6 of the Commissioner's regulation implements Chapter 590 by requiring that any person responsible for supervising the transfilling of medical oxygen meet one of the criteria described above.

Additionally, the proposed rule also makes a technical amendment to update the location where a copy of the Code of Federal Regulations referenced in section 63.6 can be obtained.

Related Regents Items

April 2024: [Proposed Amendment of Section 63.6 of the Regulations of the Commissioner of Education Relating to the Supervisor Requirements for Wholesalers Transfilling Medical Oxygen](https://www.regents.nysed.gov/sites/regents/files/424ppca1.pdf)
(<https://www.regents.nysed.gov/sites/regents/files/424ppca1.pdf>)

Recommendation

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

VOTED: That section 63.6 of the Regulations of the Commissioner of Education be amended, as submitted, effective July 15, 2024, as an emergency action, upon the finding of the Board of Regents that such action is necessary for the preservation of the public health and general welfare to timely conform the Commissioner's regulations to implement the provisions of Chapter 590 of the Laws of 2023, which became effective April 22, 2024, to ensure that the emergency action taken at the April 2024 meeting remains continuously in effect.

Timetable for Implementation

If adopted as an emergency rule at the June 2024 Regents meeting, the emergency rule will be effective July 15, 2024. It is anticipated the proposed rule will be presented to the Board of Regents for permanent adoption at the September 2024 meeting, after publication in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act. If adopted at the September 2024 meeting, the proposed rule will become effective as a permanent rule on September 25, 2024. Because the emergency action will expire before the rule can take effect as a permanent rule after adoption at the September 2024 Regents meeting, an additional emergency action will also be presented at the September 2024 meeting.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6801, 6808 of the Education Law and Chapter 590 of the Laws of 2023.

1. Subdivision (c) of section 63.6 of the Regulations of the Commissioner of Education is amended to read as follows:

(c) Manufacturers, outsourcing facilities and wholesalers.

(1) ...

(2) ...

(3) Supervisor requirements for wholesalers transfilling medical oxygen.

Wholesalers that transfill medical oxygen shall ensure any person responsible for supervising the transfilling of medical oxygen is either:

(i) a respiratory therapist certified by a national accrediting body;

(ii) a person holding a bachelor's degree in chemistry, microbiology, chemical engineering or a related field;

(iii) a person having two years of education beyond high school and two years of experience in the handling of compressed medical gases satisfactory to the state board of pharmacy; or

(iv) a person having training in accordance with the requirements established in section 211.25 of title 21 of the code of federal regulations.

(4) The supervisor of an establishment designated pursuant to paragraphs (1), [and] (2), and (3) of this subdivision shall not be at the same time the supervisor of any other establishment registered by the board.

[(4)] (5) The size and facilities of a registered establishment shall be appropriate for the activities to be conducted therein. The area to be registered shall measure no less than 300 square feet. The registered area shall not be shared with or be devoted in

part to any other business. The registered establishment shall be in compliance with at least the minimum requirements as provided in section 205.50 of title 21 of the Code of Federal Regulations (Code of Federal Regulations, 1991 edition, Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402: 1991--available at New York State Board of Pharmacy, [Room 3035, Cultural Education Center] Office of the Professions, 89 Washington Ave., 2nd Floor, Albany, NY [12230] 12234).

[(5)] (6) Manufacturers, outsourcing facilities or wholesalers shall sell drugs and/or devices only to those purchasers authorized by law. Records of the receipt and disposition of all drugs and/or devices shall be maintained for a period of five years and shall be available to the department for review and copying upon request.

[(8)] (7) 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.

[(7)] (8) Additional requirements for outsourcing facilities.

(i) ...

(ii)

(iii)

(iv)

(v) ...

(vi) ...

(vii) ...

(viii) ...

(ix) ...

8 NYCRR §63.6

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE
EMERGENCY ACTION

Chapter 590 of the Laws of 2023 (Chapter 590), effective April 22, 2024, amends the Education Law by establishing the specific supervisor requirements for individuals who supervise the transfilling of medical oxygen. Chapter 590 requires that any person responsible for supervising the transfilling of medical oxygen must be either: (1) a respiratory therapist certified by a national accrediting body; (2) a person holding a bachelor's degree in chemistry, microbiology, chemical engineering or a related field; (3) a person having two years of education beyond high school and two years of experience in the handling of compressed medical gases satisfactory to the State Board of Pharmacy; or (4) a person having training in accordance with the requirements established in section 211.25 of Title 21 of the Code of Federal Regulations (CFR). It is anticipated that these supervisory requirements will facilitate the identifying, hiring, and retaining of qualified supervisors for the transfilling of medical oxygen, which has become increasingly difficult for wholesalers who transfill medical oxygen. The proposed amendment of section 63.6 of the Commissioner's regulation implements Chapter 590 by requiring that any person responsible for supervising the transfilling of medical oxygen meet one of the criteria described above.

The proposed amendment was presented to the Professional Practice Committee for recommendation to the Full Board for emergency adoption at the April 2024 meeting of the Board of Regents, effective April 22, 2024. Since the Board of Regents meets at fixed intervals, the earliest the proposed rule could be adopted by regular (nonemergency) action after expiration of the 60-day public comment period

provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the September 2024 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date for the proposed rule, if adopted at the September meeting, would be September 25, 2024, the date the Notice of Adoption would be published in the State Register.

However, the emergency rule will expire on July 14, 2024. Therefore, a second emergency action is necessary at the June 2024 meeting, effective July 15, 2024, for the public health and preservation of the general welfare in order to conform the Commissioner's regulations to implement the requirements of Chapter 590, which became effective April 22, 2024, and to ensure that the emergency action at the April 2024 meeting remains continuously in effect until it can be permanently adopted.

It is anticipated that the proposed rule will be presented to the Board of Regents for adoption as a permanent rule at the September 2024 Regents meeting, which is the first scheduled meeting after expiration of the 60-day public comment period mandated by SAPA for state agency rule making. Because the emergency action will expire before the rule can take effect as a permanent rule after adoption at the September 2024 Regents meeting, an additional emergency action will also be presented at the September 2024 meeting.