

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), (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., 2<sup>nd</sup> 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) ...