Ohio Administrative Code

Rule 4729:5-17-02 Medical Oxygen - General Provisions.

Effective: September 1, 2019

(A) Except as provided in paragraph (H) of this rule, each person, whether located within or outside of this state, who conducts retail sales of medical oxygen in this state shall obtain a limited category II terminal distributor of dangerous drugs license. The requirements of this paragraph do not apply to persons currently licensed to purchase, possess, and sell dangerous drugs at retail in accordance with division 4729:5 of the Administrative Code.

(B) All areas where medical oxygen is stored shall be maintained in a clean and orderly condition. Storage areas shall be maintained at conditions and temperatures which will ensure the integrity of the medical oxygen prior to use as stipulated by the manufacturer's or distributor's labeling.

(C) Medical oxygen shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All retail sellers of medical oxygen shall maintain records of the purchase of oxygen at wholesale and the sale of oxygen at retail, including prescriber orders, for three years at the licensed location. All records shall be readily retrievable.

(1) A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(E) A terminal distributor of dangerous drugs shall report the theft or significant loss of medical oxygen pursuant to rule 4729:5-3-02 of the Administrative Code.

(F) Except as provided in paragraphs (G) and (H) of this rule, prior to making an initial sale of medical oxygen to a patient, a terminal distributor of dangerous drugs must have an order issued by

a prescriber.

(1) The order must include the full name and address of the patient, the signature of the prescriber, the manually printed, typewritten, electronically generated or preprinted full name and address of the prescriber, the telephone number where the prescriber can be personally contacted during normal business hours, the date of issuance, and documentation of need. A terminal distributor may add the patient's address, prescriber's address, and prescriber's phone number to the order if incomplete on the original order.

(2) The prescriber's order may be transmitted electronically to the retail seller.

(3) All orders issued in accordance with this paragraph are valid for a period of one year from the date of issuance.

(G) S.C.U.B.A. divers who hold a valid certificate in the following nationally recognized S.C.U.B.A. diving certifying organization programs may purchase, possess, and use medical oxygen for the purpose of emergency care or treatment at the scene of a diving emergency pursuant to section 4729.541 of the Revised Code:

(1) Diver alert network (DAN): oxygen first aid for scuba diving injuries;

(2) International association of nitrox and technical divers: oxygen provider course;

(3) Professional association of diving instructors (PADI): emergency first response;

(4) PADI: PADI oxygen first aid;

(5) PADI: rescue diver course;

(6) PADI: tec deep diver;

(7) Scuba schools international: medic first aid emergency oxygen administration;

(8) Technical diving international-S.C.U.B.A. diving international: diver advanced development program as a CPROX administrator;

(9) YMCA: slam rescue;

(10) National association of underwater instructors (NAUI) first aid;

(11) NAUI rescue scuba diver;

(12) NAUI advanced rescue scuba diver;

(13) NAUI first aid instructor;

(14) NAUI oxygen administration;

(15) NAUI instructor; and

(16) Any other program as approved by the board.

(1) In accordance with policy guidance issued by the United States food and drug administration, oxygen equipment intended for emergency use may be sold without a prescription.

(a) Such equipment shall deliver a minimum flow rate of six liters of oxygen per minute for a minimum of fifteen minutes.

(b) Labeling for emergency oxygen shall not contain references to heart attacks, strokes, shock or any other medical condition amenable to diagnosis or treatment only by a licensed health care professional.

(c) Oxygen units delivering a minimum flow rate of less than six liters of oxygen per minute for a period less than fifteen minutes and labeled for emergency use are considered adulterated and misbranded.

(d) If the units are not intended for emergency use and provide less than six liters of oxygen per minute or are labeled for human use for other than emergency use, such units are regarded as a dangerous drug and shall bear the prescription legend.

(e) The units shall contain no more than eighty minutes (four hundred eighty liters) of USP oxygen.

(2) Persons that only sell oxygen equipment intended for emergency use that meet the criteria listed in paragraph (H)(1) of this rule shall not be required to obtain licensure as a terminal distributor of dangerous drugs in accordance with paragraph (A) of this rule.

(3) Persons that possess and administer oxygen equipment intended for emergency use that meet the criteria listed in paragraph (H)(1) of this rule shall not be required to obtain licensure as a terminal distributor of dangerous drugs.