



## Ohio Administrative Code

### Rule 4729:5-17-04 Compressed Medical Gasses - General Provisions and Safety Program.

Effective: September 1, 2019

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(A) Each person, whether located within or outside this state, who seeks to possess or sell compressed medical gases in this state shall maintain, based upon the person's business activities, a wholesale distributor of dangerous drugs license in accordance with section 4729.52 of the Revised Code or terminal distributor of dangerous drugs license in accordance with section 4729.54 of the Revised Code.

(B) Wholesale or terminal distributors of dangerous drugs who fill containers with compressed medical gases must comply with the current good manufacturing practice regulations issued pursuant to the Federal Food, Drug and Cosmetic Act (4/1/2018) and the current regulations and guidelines issued pursuant to Title 21 CFR 10.90 (4/1/2018).

(C) Records required by state and federal laws, rules, and regulations governing the sale of dangerous drugs and the filling of containers with compressed medical gases shall be maintained for a period of three years at the licensed location. All records shall be readily retrievable.

(1) A wholesale or terminal distributor of dangerous drugs 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 wholesale or terminal distributor of dangerous drugs.

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

(E) A wholesale distributor of dangerous drugs shall report the theft or significant loss of compressed medical gasses pursuant to rule 4729:6-3-02 of the Administrative Code.



(F) A medical gases safety program developed pursuant to section 4729.70 of the Revised Code shall comply with the following requirements:

(1) The instructors shall have the appropriate education and experience to teach a program in medical gas safety.

(2) The program shall be presented to all individuals who fill, install, connect, or disconnect medical gases contained in cryogenic vessels that are portable and intended for use in administering direct treatment to one or more individuals.

(3) Successful participation and demonstrated competency in a program must be completed prior to an individual filling, installing, connecting, or disconnecting a medical gas contained within a cryogenic vessel.

(4) The program must include the following:

(a) The description of a cryogenic vessel, including:

(i) Valve inlet and outlet connections;

(ii) Safety systems associated with each outlet;

(iii) Proper labeling;

(iv) Color coding; and

(v) Gas identification.

(b) A review of each medical gas listed in division (C)(2) of section 4729.70 of the Revised Code that may be contained in a cryogenic vessel, including:

(i) A description of the properties of the gas or liquid;



- (ii) The precautions and warnings associated with the gas or liquid;
  - (iii) Procedures for handling exposure to the gas or liquid; and
  - (iv) Procedures to handling the gas or liquid during an emergency.
- (c) The proper installation of cryogenic vessels, including the following:
- (i) Connecting and disconnecting supply lines;
  - (ii) Recognizing silver-brazed fittings or other acceptable mechanical means that make the connection a permanent and integral part of the valve;
  - (iii) Recognizing that changing or adapting the fittings for another gas service is strictly prohibited except in accordance paragraph (H) of this rule;
  - (iv) Recognizing the appropriate devices through which medical gases are delivered from cryogenic vessels;
  - (v) Detecting and reporting leaks;
  - (vi) Transporting cryogenic vessels appropriately within a facility; and
  - (vii) Appropriate storage of cryogenic vessels.
- (5) The program instructor must document the participation of an individual in a medical gases safety program. The documentation must be maintained by the individual's employer for a period of at least three years and made readily retrievable.
- (6) Individuals who install, connect, or disconnect medical gases from cryogenic vessels must attend a medical gases safety program at least once every two years.
- (G) No person shall modify a cryogenic vessel, connection, or valve or adapt a connection for



another gas service pursuant to division (D) of section 4729.70 of the Revised Code.

(H) Paragraph (G) of this rule does not apply to an employee or agent of a firm owning the cryogenic vessel and who is charged with the responsibility of conducting applicable vessel maintenance, changing service from one medical gas to another, or bringing a vessel into compliance with section 4729.70 of the Revised Code.

(1) Such employee or agent shall meet the following requirements:

(a) Successful completion of a medical gases safety program pursuant to paragraph (F) of this rule.

(b) Successful participation and demonstrated competency in a cryogenic vessel modification program administered by an instructor with the appropriate education and experience. The program must be based on written and validated procedures. The employee or agent must participate in the program annually and the program shall include the following:

(i) Removing, adding, or adapting cryogenic vessel connections and valves;

(ii) Modifying cryogenic vessels;

(iii) Conducting cryogenic vessel maintenance;

(iv) Changing the cryogenic vessel from one medical gas to another;

(v) Bringing a cryogenic vessel into compliance with section 4729.70 of the Revised Code;

(vi) Silver brazing or welding techniques and certification of the individual if applicable; and

(vii) Removing and adding suitable mechanical means to make a connection a permanent and integral part of the valve.

(2) An employer must document the successful participation and demonstrated competency of an employee or agent in a cryogenic vessel modification program. The documentation must be



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maintained by the employer for a period of at least three years and made available, upon request, to those business entities receiving service and to the state board of pharmacy.