



Am. Sub. S.B. 117

124th General Assembly

(As Reported by H. Health & Family Services)

Sens. Austria, Randy Gardner, Mumper, Robert Gardner, Coughlin, Spada, Jacobson, Mead, White, Prentiss, Hagan, Armbruster, Oelslager, Herington, McLin, Brady, DiDonato, Hottinger, Harris, Nein, Carnes, Ryan, Mallory

Reps. Jolivette, Kearns, Aslanides, Barnes, Beatty, Cirelli, Gilb, D. Miller, R. Miller, Patton, Raga, Schneider, Seitz, S. Smith, Sullivan, Williams, Kilbane, Roman

BILL SUMMARY

- Requires the State Board of Pharmacy to operate a medical gases safety program.
- Requires specified cryogenic vessels that contain medical gases to be properly labeled and color coded.
- Requires training for all employees who handle medical gases and cryogenic vessels.

CONTENT AND OPERATION

Medical gases safety program

(sec. 4729.70)

Under the bill, the State Board of Pharmacy is required to establish and implement a medical gases safety program. The bill specifies that the program is to ensure that cryogenic vessels containing medical gases meet the bill's requirements and are properly handled. A cryogenic vessel is an insulated metal container in the form of a cylinder or other design used to hold gases that have been liquefied by extreme reductions in temperature.

The bill specifies that the medical gases safety program applies only to cryogenic vessels that are portable and contain medical gases in a volume intended

for use in administering direct treatment to one or more individuals. The program does not apply to cylinders or containers of other designs that contain medical gases that are only compressed.

The Board must adopt rules to implement the program. All rules adopted under the bill must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.).

Labeling and color coding

The bill requires each cryogenic vessel to be properly labeled according to the medical gas contained in the vessel. Further, the bill requires each vessel to be color coded. The bill provides that the colors it specifies for each medical gas cannot be used for any other medical gas.

<i>Color coding</i>	
Air	Yellow
Carbon dioxide	Gray
Cyclopropane	Orange
Helium	Brown
Nitrogen	Black
Nitrous oxide	Blue
Oxygen	Green

The color coding required by the bill must be applied to the vessel by doing one of the following:

- (1) Applying the appropriate color to the top six inches of the body of the vessel;
- (2) Affixing a wrap to the vessel that encircles the vessel completely, has the identity of the contained gas printed completely or continuously around the wrap, and uses the appropriate color as the print or background for the identity of the gas.

Reuse of vessels

Under the bill, a cryogenic vessel must not have previously held a nonmedical gas. When a vessel is reused for a medical gas other than the one previously contained, new labeling and color coding must be applied and all old labeling and color coding must be completely removed.

Connectors

The bill requires the connector between a cryogenic vessel and the valve through which the medical gas is delivered to be either of the following:

- (1) A threaded or socket connection that is silver brazed or welded to the valve;
- (2) A permanent and integral part of the valve.

Unless a person meets the standards established by the Board in rules adopted under the bill, the person is prohibited from doing any of the following: (1) removing a connector, (2) replacing the connector with another connector, or (3) attaching an adapter to the vessel or connector. A person who takes any of these actions without meeting the Board's standards is guilty of the existing crime of tampering with drugs. Tampering with drugs is a felony of the third degree, unless the violation results in physical harm to a person, in which case tampering with drugs is a felony of the second degree.

Employee training

The bill requires all employees who are responsible for installing or changing cryogenic vessels to be trained in the proper handling of medical gases and cryogenic vessels. The training must include training in understanding the labeling and color coding required by the bill.

Modification of existing containers

The rules adopted by the Board under the bill must include standards and procedures to be followed in ensuring that the individuals who modify existing cryogenic vessels for purposes of bringing the vessels into compliance with the bill are qualified individuals. The Board's standards for being considered qualified must include requirements for knowledge in proper safety precautions concerning medical gases, cryogenic vessels containing medical gases, and devices through which medical gases are delivered from cryogenic vessels.

COMMENT

Under administrative rules adopted by the State Board of Pharmacy, all dangerous drug distributors, wholesale and terminal, who fill containers with compressed medical gases are required to comply with the current good manufacturing practice regulations for drug products issued by the Federal Food and Drug Administration (FDA), as well as the current guidelines for compressed medical gases issued by the FDA's Division of Manufacturing and Product

Quality. Any deviation from the guidelines must be submitted to the FDA for written approval before implementation. (Ohio Administrative Code sec. 4729-21-02.)

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	05-22-01	pp. 396-397
Reported, S. Health, Human Services and Aging	06-14-01	pp. 662-663
Passed Senate (33-0)	06-14-01	p. 665
Reported, H. Health & Family Services	10-11-01	p. 906

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