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Bill Analysis
Legislative Service Commission

S.B. 117

124th General Assembly
(As Introduced)

Sens. Austria, Randy Gardner, Mumper

BILL SUMMARY

- Requires the State Board of Pharmacy to operate a medical gases safety program.
- Requires all devices that contain medical gases to be color coded.
- Requires all employees who handle medical gases to be trained.

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 devices containing medical gases meet the bill's requirements and are properly handled. 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.).

Color coding of containers

The bill requires each device that contains a medical gas to be color coded and specifies the colors that must be used. The colors specified by the bill cannot be used for any gas other than the gas specified.

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

The device must be color coded by having the appropriate color appear on the top one-fourth of the device, which may include a hand grip, or by having the name of the medical gas printed in the appropriate color on a transparent wrap that completely encircles the device.

Connectors

If only a transparent wrap is used to color code a device containing a medical gas, the bill requires the connector between the device and the valve through which the gas is delivered to be one of the following:

- (1) A threaded or socket connection that is welded to the valve or silver brazed with at least a 43% silver content;
- (2) A permanent and integral part of the valve;
- (3) A device that indicates when it has been tampered with.

Reuse of containers

If a device is to be used for a medical gas other than the medical gas the device previously held, a new label must be affixed to the device. If possible, the old label must be completely removed and replaced with the new label. If removal is not possible, the new label, at a minimum, must completely cover the old label.

The bill prohibits a device that previously contained a medical gas from being used to hold a nonmedical gas. It likewise prohibits a container that held a nonmedical gas from being used to hold a medical gas. The bill does not specify a penalty for violating either prohibition.

Modification of containers

The rules to be adopted by State Board of Pharmacy under the bill must include criteria to ensure that individuals who modify existing containers are qualified individuals who know proper safety precautions concerning medical

gases and devices that deliver medical gases. Unless a person meets the standards established by the Board, the person is prohibited from doing either of the following: (1) removing a connector between a device that contains medical gas and the valve through which the medical gas is delivered or (2) replacing the connector with another connector.

A person who modifies an existing container 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 that all employees who are responsible for installing or changing a device that contains a medical gas be trained in the proper handling of medical gases. The training must include training in recognizing the labeling required by the bill.

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
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