

Committee on Regulated Industries

CS/CS/SB 836 — Medical Gas

by Health Policy Committee; Regulated Industries Committee; and Senator Bean

The bill adds a member to the Drug Wholesale Distributor Advisor Council who is an employee of a permit holding medical gas manufacturer or wholesale distributor and who is recommended by the Compressed Gas Association.

The bill creates part III of ch. 499, F.S., entitled “Medical Gas,” administered and enforced by the Department of Business and Professional Regulation (department). The bill creates definitions under this part and sets forth requirements for obtaining and renewing a permit as a medical gas wholesale distributor, a medical gas manufacturer, or a medical oxygen retail establishment. The department shall adopt rules to establish the form, content, and fee for the application to obtain a permit and to renew a permit listed under this part. The bill provides for changes in permit holder status or information, allowing certain changes with notice and acceptance by the department.

The bill sets forth minimum requirements for the permitting, storage, handling and distribution to safeguard the identity, strength, quality and purity of medical gas. The bill provides for specific security measures be taken to protect against unauthorized access to medical gas, theft of confidential information, and theft of nitrous oxide. The department is required to adopt rules that govern the distribution of medical oxygen for emergency use by persons authorized to receive emergency use oxygen, which must be consistent with federal regulations.

The bill requires inspection of the medical gas containers and the records documenting the acquisition of medical gas. All permit holders are required to establish and maintain a record of transactions regarding the receipt and the disposition of medical gases constituting an audit trail sufficient to perform a recall of medical gas. A wholesale distributor must act with due diligence and must also keep records sufficient to aid in the mandatory reporting of theft or loss of nitrous oxide.

The bill provides that trade secret information required to be submitted under this part must be maintained by the department. The fees collected under this part are to be deposited into a separate account established for the Drugs, Devices, and Cosmetics Program in the Professional Regulation Trust Fund. These funds are required to be used for the administration of this part.

If approved by the Governor, these provisions take effect October 1, 2014.

Vote: Senate 36-0; House 115-1