The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 836
INTRODUCER:	Regulated Industries Committee and Senator Bean
SUBJECT:	Medical Gas
DATE:	March 21, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Niles	Imhof	RI	**Fav/CS**
2.	Looke	Stovall	HP	**Pre-meeting**

Please see Section IX. for Additional Information:

PLEASE MAKE SELECTION

I. Summary:

CS/SB 836 removes the regulation of medical gas from Part I of the "Florida Drug and Cosmetic Act" and creates a new Part III of ch. 499, F.S., consisting of ss. 499.81 - 499.95, F.S., entitled "Medical gas."

The bill provides permit application procedures and permit requirements for medical gas wholesale distributors, medical gas manufacturers, and medical oxygen retail establishments. The bill grants the Department of Business and Professional Regulation (department) the authority to adopt rules related to the form and content of a permit application. The department is also granted authority to deny applications and revoke or refuse to renew permits.

The bill requires specific storage and security procedures related to medical gas. The bill requires wholesale distributors of medical gas to examine medical gas containers, act in due diligence, establish and maintain records regarding receipt and distribution of medical gas, and to establish specific policies and procedures to deal with normal business activity as well as emergency and theft situations. The bill also lays out prohibited and criminal acts in relation to medical gas and enforcement regarding these acts and this part.

II. Present Situation:

Currently, ch. 499, F.S., consists of two parts that cover drug, cosmetic, and household products and ether. Medical gas is covered in the first part under drug, cosmetic and household products of the "Florida Drug and Cosmetic Act" found in ss. 499.001 - 499.079, F.S.

Definitions

Section 499.003(11), F.S., defines "compressed medical gas" as any liquefied or vaporized gas that is a prescription drug, whether it is alone or in combination with other gases.

Section 499.003(46), F.S., defines "prescription medical oxygen" as oxygen USP[1] which is a drug that can only be sold by the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.

Section 499.003(55), F.S., defines a "wholesale distributor" as any person engaged in wholesale distribution of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

Section 409.9201(1), F.S., describes medical fraud with s. 409.9201(1)(a), F.S., defining "prescription drug" as any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described in the Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(46) or (53) or s. 499.007(13), F.S.

Permits

Section 499.01, F.S., lists the entities that require permits under the Florida Drug and Cosmetics Act and describes them in detail. These permitted entities include medical oxygen retail establishments, compressed medical gas wholesale distributors, and compressed medical gas manufacturers, among others.

A compressed medical gas wholesale distributor is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient.[2] A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases or repackages compressed medical gases from one container to another.[3] A medical gas retail establishment permit is required for any person who sells medical oxygen to patients only.[4] Permit holders are overseen by the department under the Division of Drugs, Devices and Cosmetics.

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[1] The United States Pharmacopoeia (USP) is a list of drugs licensed for use in the U.S. with standards necessary to determine purity suitable for persons.
[2]Florida Department of Business and Professional Regulation, Compressed Medical Gas Wholesale Distributor, *available at* www.myfloridalicense.com/dbpr/ddc/CompressedMedicalGasesWholesaleDistributor.html (Last visited March 21, 2014).
[3] Florida Department of Business and Professional Regulation, Compressed Medical Gas Manufacturer, available at www.myfloridalicense.com/dbpr/ddc/CompressedMedicalGasesManufacturer.html (Last visited March 21, 2014).
[4] Florida Department of Business and Professional Regulation, Medical Oxygen Retail Establishment, available at http://www.myfloridalicense.com/dbpr/ddc/MedicalOxygenRetail.html (Last visited March 21, 2014).

Drug Wholesale Distributor Advisory Council

Section 499.01211, F.S., creates the Drug Wholesale Distributor Advisory Council (council). The council meets each calendar quarter to review Part I of ch. 499, F.S., and the rules adopted to administer that part, to annually provide input to the department, and to make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health. The council consists of eleven members including the Secretary of Business and Professional Regulation, or his or her designee, and the Secretary of Health Care Administration, or her or his designee. The remaining nine members are appointed by the Secretary of Business and Professional Regulation to a term of four years each, as follows:

- Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003(47), F.S.;
- One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003(52), F.S.;
- One person employed by a retail pharmacy chain located in this state;
- One person who is a member of the Board of Pharmacy and is a pharmacist licensed under ch. 465, F.S.;
- One person who is a physician licensed under ch. 458, F.S., or ch. 459, F.S.;
- One person who is an employee of a hospital licensed under ch.395, F.S., and is a pharmacist licensed under ch.465, F.S.; and
- One person who is an employee of a pharmaceutical manufacturer.

Compressed Gas Association

The Compressed Gas Association (association) has been dedicated to the development and promotion of safety standards and safe practices in the industrial gas industry since 1913.[5] Their mission is to promote safe, secure, and environmentally responsible manufacture, transportation, storage, transfilling, and disposal of industrial and medical gases and their containers.[6] Their activities include the manufacture, transportation, storage, transfilling, and disposal of compressed gas and the containers and valves which hold the compressed gases. Their scope includes related apparatus if such apparatus is necessary for the safe dispensing or delivery of the gases in a commercial, industrial, research, or medical application along with providing safety information or warnings about the chemical or physical properties of gases and their containers.[7] The association defines industrial and medical gases as liquefied, nonliquefied, dissolved, or cryogenic gases.[8]

III. Effect of Proposed Changes:

The bill creates Part III of ch. 499, F.S., entitled "Medical Gas," ss. 499.81-499.95, F.S.

[5] Compressed Gas Association, About Us, *available at* http://www.cganet.com/about.php (Last visited March 4, 2014).
[6] Compressed Gas Association, CGA Mission, *available at* http://www.cganet.com/mission.php (last visited March 4, 2014).
[7] *Id.*
[8] *Id.*

Definitions

The bill deletes s. 499.003(11), F.S., defining "compressed medical gas," and s. 499.003(46), F.S., defining "prescription medical oxygen." The bill adds a new definition to s. 499.003(32), F.S., for "Medical gas" which is defined "in accordance with the federal act and means a liquefied or vaporized gas that is a prescription drug, regardless of whether it is alone or combined with other gases." The bill creates a new definitions section for Part III of ch. 499, F.S., that contains numerous definitions related to medical gas.[9] The bill deletes cross-references to the old sections and adds the new section throughout the bill where necessary.

Permits

The bill deletes medical oxygen retail establishment, compressed medical gas wholesale distributor, and compressed medical gas manufacturer as entities requiring permits under s. 499.01(1), F.S. The bill creates s. 499.82, F.S., providing for permits associated with medical gas. A person or establishment intending to distribute medical gas within or into this state must obtain the applicable permit before operating. The following are authorized to receive medical gas:

- Permitted medical gas manufacturers or permitted wholesale distributors;
- Licensed pharmacies or health care entities;
- People authorized to receive emergency use oxygen without a prescription;
- Locations with automated external defibrillation machines where emergency use oxygen is intended to be used with such machines; or
- Companies that need medical gas in the installation and refurbishment of piping and equipment used to contain or administer medical gas.

The bill establishes requirements for wholesale distributors. Wholesale distributors may not operate from a residence, except delivery by home respiratory care technicians. Each location must be permitted. Out-of-state wholesale distributors must be legally authorized as a wholesale distributor in their state of residence or incorporation to provide services in Florida.

The bill establishes three types of permits, a medical gas wholesale distributor permit, a medical gas manufacturer permit, and a medical oxygen retail establishment permit.

A *medical gas wholesale distributor permit* is required for wholesale distribution within or into Florida. The permit:

- Does not authorize distribution to a consumer or patient;
- Requires medical gas be in the same container as obtained with no further manufacturing operations performed; and
- Prohibits distributor to possess or engage in the wholesale distribution of other prescription drugs.

[9] Section 499.81, F.S., defines the terms "adulterated", "department", "distribute" or "distribution", "emergency use oxygen", "FDA", "federal act", "health care entity", "immediate container", "intracompany transaction", "label", "manufacturer", "medical gas", "medical gas-related equipment", "misbranded", "prescription medical oxygen, "USP-NF" or "USP", "wholesale distribution", and "wholesale distributor". Some of the definitions duplicate those in s. 499.003, F.S.

A *medical gas manufacturer permit* is required for a person manufacturing[10] medical gas and distributing such medical gas within or into this state. A medical gas manufacturer:

- May not manufacture or possess another prescription drug without obtaining the appropriate permit;
- May engage in the wholesale distribution of medical gas manufactured at permitted establishment if complying with this part and applicable rules; and
- Must comply with all appropriate good manufacturing practices.

A *medical oxygen retail establishment permit* is required for a person, except a pharmacy under chapter 465, F.S., who sells prescription medical oxygen directly to patients. Sales must be based upon an order or prescription. A medical oxygen retail establishment:

- May not possess, purchase, sell, or trade a prescription drug other than medical oxygen without obtaining other appropriate permits;
- May not receive back into its inventory any prescription medical oxygen sold pursuant to a licensed practitioner's order;
- May refill a prescription medical oxygen container for a patient based on an authorized order or prescription, and shall comply with all appropriate good manufacturing practices if doing so; and
- Must comply with storage and handling requirements under s. 499.84, F.S.

The bill creates s. 499.821, F.S., granting the department the authority to adopt rules relating to permit applications and describing the application requirements for permits listed in s. 499.82, F.S. The fee for permits are removed from s. 499.041, F.S., and added to s. 499.821(4), F.S. Section 499.822, F.S., provides for permits to expire after two years, provides renewal procedures, and authorizes the department to adopt rules and a reasonable fee for renewal. Section 499.821, F.S., sets annual fees of between $200 and $300 for medical gas wholesale distributors and medical oxygen retail establishments and annual fees of between $400 and $500 for medical gas manufacturers.

The bill creates s. 499.823, F.S., granting the department the authority to deny a permit or renewal application based on relevant factors including the applicant's past experience, previous noncompliance, criminal background, and other qualifications that the department considers relevant to and consistent with public health and safety.

The bill creates s. 499.824, F.S., restricting permit use to the person or entity granted but allowing specific changes to be made by the approval of the department. A change of location may be made with 30 days prior notification and payment of a change-of-location fee not to exceed $100. Change of ownership requires a new permit application 30 days prior to the transfer of the majority of the ownership, controlling interest, or legal liability. If the new-owner-applicant is already a permit holder, the application is not required until the date of the transfer, sale, assignment or lease and this applicant may distribute under the permit number of the previous owner from the date of transfer until the date of application approval. A change of name does not require a new permit, but does require the permit holder to notify the department 30

[10]Manufacturing can be done by physical air separation, chemical action, purification, or filling containers using a liquid-to-liquid, liquid-to-gas, or gas-to-gas process.

days prior to the change. Closure of the business requires a permit holder to notify the department and indicate how the inventory will be dispersed.

Any change in information, other than relating to location, ownership, name, or closure, must be submitted to the department within 30 days of such change. A permit holder in good standing may apply to change the type of permit held and will be required to pay the difference in fees. The department may revoke a permit for noncompliance with these requirements.

Medical Gas Storage and Security Measures

The bill creates s. 499.84, F.S., setting out the minimum requirements for storage and handling of medical gas and mandating that medical gas be stored in accordance to manufacturers' recommendations, or in their absence, according to applicable industry standards. Medical gas must be packaged in accordance with official compendium standards such as the United States Pharmacopeia and The National Formulary (USP-NF).[11]

The bill creates s. 499.85, F.S., requiring security measures for wholesale distribution facilities and vehicles used for delivering oxygen-related equipment. Under this section, the department is granted the authority to adopt rules governing wholesale distribution of prescription medical oxygen for emergency use by persons authorized to receive emergency use oxygen so long as the rules are consistent with federal rules, unless state law specifically directs otherwise.

Wholesale Distributor Requirements

The bill creates s. 499.86, F.S., that requires examination of medical gas containers by wholesale distributors and review of records documenting the acquisition of the medical gas. The bill also creates s. 499.87, F.S., that provides procedures to handle defective gas or containers, and requires damaged, misbranded or adulterated medical gas to be quarantined until returned to the manufacturer or wholesale distributor, or until it is destroyed. If medical gas is adulterated or misbranded, or suspected as such, notice shall be provided to the manufacturer or wholesale distributor from which the medical gas was acquired and to the appropriate boards and federal regulatory bodies.

The bill creates s. 499.88, F.S., to require wholesale distributors to act with due diligence, obtaining appropriate documentation of registration from the wholesale distributor or manufacturer before an initial acquisition of medical gas from that distributor or manufacturer, except from a manufacturer that is registered with the FDA and proof of the registration is provided along with proof of inspection within the last three years or proof of compliance with industry standards or guidelines as identified by the department.

The bill creates s. 499.89, F.S., that requires wholesale distributors to establish and maintain a record of transactions regarding the receipt and distribution, or other disposition, of medical gases, and the information to be included. These records constitute an audit trail and must contain information sufficient to perform a recall of medical gas in compliance with 21 C.F.R.

[11] The USP–NF is a book of public pharmacopeial standards. See U.S. Pharmacopial Convention, USP-NF, *available at* http://www.usp.org/usp-nf (Last visited March 21, 2014).

s. 211.196 and 21 C.F.R. s. 820.160(b). A pedigree paper is not required for the wholesale distribution of medical gas.

The bill creates s. 499.90, F.S., that requires wholesale distributors to establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, transport, shipping, and wholesale distribution of medical gas and for maintaining inventory and correcting all errors in inventory associated with nitrous oxide. Procedures are required for handling recalls and withdrawals, preparing for and avoiding crisis, and reporting criminal activity involving nitrous oxide.

Prohibited and Criminal Acts

The bill creates s. 499.91, F.S., that prohibits a person from performing or aiding the performance of the following:

- Manufacture, sale, or delivery, or the holding or offering for sale, of medical gas that is adulterated, misbranded, or has otherwise been rendered unfit for distribution;
- Adulterating or misbranding of medical gas;
- The receipt of adulterated or fraudulently obtained medical gas;
- Altering, mutilating, destroying, obliterating, or removing the whole or any part of the product labeling of medical gas or the willful commission of any other act of misbranding;
- Purchasing or receiving medical gas from a person who is not authorized by permit to distribute wholesale medical gas or who is exempted from permitting requirements to distribute wholesale medical gas to such purchaser or recipient;
- Knowing and willful sale or transfer of medical gas to a recipient who is not legally authorized to receive medical gas, except for limited distributions as necessary to protect the health, safety, or welfare of a patient in his or her home;
- Failing to maintain or provide records required under this part;
- Providing the department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding this part and its implementing regulations;
- Wholesale distribution of medical gas that was purchased by a health care entity without an authorized recipient, donated or supplied at a reduced price to a charitable organization, or stolen or obtained by fraud or deceit;
- Operating without a valid permit;
- Obtaining of medical gas by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of medical gas;
- Except for oxygen USP in emergency situations, the distribution of medical gas to a patient without an order or prescription from a licensed practitioner authorized by law to prescribe;
- Distributing medical gas that was previously dispensed by a pharmacy or a licensed practitioner authorized by law to prescribe;
- Distributing medical gas or medical gas-related equipment to a patient, unless the patient has been provided with the appropriate information and counseling on the use, storage, and disposal of medical gas;
- Failing to report an act prohibited under this part and its implementing regulations; and,
- Failing to exercise due diligence as provided in s. 499.88, F.S.

The bill creates s. 499.92, F.S., that provides that a person commits a felony in the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, F.S., if he or she:

- With intent to defraud or deceive adulterates or misbrands medical gas;
- Engages in the wholesale distribution of, and knowingly purchases or receives, medical gas from a person not legally authorized to distribute medical gas;
- Engages in the wholesale distribution of, and knowingly sells, barters, brokers, or transfers, medical gas to a person not legally authorized to purchase medical gas in the jurisdiction in which the person receives the medical gas. However a violation is not committed by a distributor that provides oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement.
- Knowingly, falsely creates a label for medical gas or knowingly, falsely represents a factual matter contained in a label for medical gas.

A court with authority over a person that convicts a person who violates this section shall order that person to forfeit to the state real or personal property used or intended to be used to commit such a violation and that is constituting, derived from, or traceable to the gross proceeds gained as a result of the violation. Moneys or proceeds from the sale of assets ordered to be forfeited shall be equitably divided between the department and agencies involved in the investigation and prosecution that led to the conviction. Other property ordered to be forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution.

Drug Wholesale Distributor Advisory Council

The bill adds an additional position on the council, now twelve members, appointed by the *Compressed Gas Association* who is an employee of a permitted medical gas wholesale distributor or manufacturer.

Inspections

The bill creates s. 499.93, F.S., that allows the department to require a facility engaged in the manufacturing, retail sale, or wholesale distribution of medical gas to undergo an inspection, and the department may recognize other state inspections if that state's laws are determined to be substantially equivalent with this state's laws. A manufacturing facility registered with the FDA and verified as such and providing proof of an inspection within the past three years is exempt from inspection.

The bill requires a wholesale distributor to have readily available its state permits and its most recent inspection report administered by the department.

The bill allows the department to authorize a third party to inspect wholesale distributors who distribute within or into this state.

The bill requires the department to ensure that information identified as a trade secret, as defined in s. 812.081, F.S., is maintained and remains confidential as required under s. 499.015, F.S., while it is retained by the department.

Enforcement

The bill allows the department to collect evidence and testimony for the purposes of initiating an investigation or proceeding under this part. A state, county, or municipal attorney shall timely institute proceedings and prosecute violations reported to them by the department or designated agent in a manner required by law.

The bill provides that the provisions of part III are cumulative and do not repeal or affect the power, duty, or authority of the department, but establishes that part III controls where it conflicts with other law.

Sections 22-38 of the bill conform those sections to changes made in the bill

Section 31 establishes an effective date of October 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

This bill may have an indeterminate fiscal impact on private sector entities who are affected by the regulations implemented by the bill.

C. Government Sector Impact:

Expenses associated with the additional Drug Wholesale Distributor Advisory Council member are indeterminate but are expected to be minimal and can be funded with existing resources.[12] The members of the council are not paid employees; they serve without compensation.[13] The Drugs, Devices and Cosmetics Division under the

[12] *2014 Legislative Bill Analysis for SB 836*, Department of Business and Professional Regulation (Mar. 21, 2014).
[13] *Id.*

department is responsible for expenses associated with the logistics of the council meetings.[14]

The bill provides that fees collected under part III are to be used to administer "this part," which seems to limit the fees and monies collected to use for administering only part III. This may require separate accounting and recordkeeping to be set up by the department's fiscal unit. It is unclear at this time what the estimated fees and costs associated with medical gas regulation would be, and this is a change from the way the division currently operates.[15]

VI. Technical Deficiencies:

The bill allows the Compressed Gas Association to appoint a person to the Drug Wholesale Distributor Advisory Council. Currently, the Secretary makes the appointments of these members, with the exception of the Agency for Health Care Administration's representative.[16]

VII. Related Issues:

The bill sets forth a list of entities authorized to receive medical gas, but does not clearly indicate if these entities must reside in Florida. The presumption is that they must reside in Florida, but the wording could be interpreted as otherwise.[17]

The definition of "adulteration" in the bill does not include transfer or possession by an unauthorized source.[18] Generally under the current law, if an unauthorized person holds, transfers, purchases, or sells a prescription drug, that drug becomes adulterated.[19] Currently, if medical oxygen is delivered to a patient who does not have a current, valid prescription for medical oxygen, then the medical oxygen could be deemed adulterated and thus unfit for consumption.[20] The bill may reduce the incentive of providers to verify current prescriptions before making deliveries.[21]

The bill provides that "people authorized to receive emergency use oxygen without a prescription" are legally authorized to receive medical gas. One interpretation of that passage might allow anyone authorized to receive emergency use oxygen without a prescription to receive any medical gas.[22]

The bill removes any requirement to show the transaction history in one document. This may make it more difficult to review an audit trail, especially in cases of product recalls.[23]

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[14] *Id.*
[15] *Id.*
[16] *Id.*, also *see* s. 20.052(5)(a), F.S., requiring private citizen members of an advisory board that is adjunct to an agency be appointed by the governor, the head of the department, the executive director of the department, or a cabinet officer.
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *2014 Legislative Bill Analysis for SB 836*, Department of Business and Professional Regulation (Mar. 21, 2014).
[23] *Id.*

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 499.001, 499.003, 409.9201, 460.403, 465.0265, 499.01, 499.0121, 499.01211, 499.01212, 499.015, 499.024, 499.041, 499.05, 499.051, 499.066, 499.0661, and 499.067.

This bill creates the following sections of the Florida Statutes: 499.81, 499.95, 499.82, 499.821, 499.822, 499.823, 499.824, 499.83, 499.84, 499.85, 499.86, 499.87, 499.88, 499.89, 499.90, 499.91, 499.92, 499.93, and 499.94.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Regulated Industries Committee on March 6, 2014:
The CS adds that a permit holder under this section must notify the department 30 days prior to change in location, ownership, or name. The CS also adds a requirement that such permit holder notify the department within 30 days of change in information required under this part but not falling within one of those categories or closure.

The CS adds an exception under criminal acts, excluding as a violation a distributor providing oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement.

The CS adds a facility that engages in the retail sale of medical gas to the list of facilities that the department may require to undergo an inspection.

The CS removes the trade secret provisions created s. 499.93(5), F.S. The bill creates section 499.931, F.S., which requires the department to maintain trade secrets as provided in s. 499.051, F.S.[24]

B. Amendments:

None.

[24] Section 499.051, F.S., provides that trade secrets must be confidential and exempt from disclosure under ch. 119, F.S., and s. 24(a), Art. I, Florida Constitution. The department is allowed to use this information for regulatory and enforcement proceedings and to provide the information to law enforcement and regulatory agencies.