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/CS/SB 836
INTRODUCER:	Health Policy Committee; Regulated Industries Committee; and Senator Bean
SUBJECT:	Medical Gas
DATE:	April 1, 2014 REVISED:

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/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 chapter 499, F.S., consisting of sections 499.81 - 499.94, 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 and take the full breadth of regulatory actions regarding the new part III.

The bill requires specific storage and security procedures related to medical gas. The bill requires permitted 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.

[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*, www.myfloridalicense.com/department/ddc/CompressedMedicalGasesWholesaleDistributor.html (Last visited Mar. 21, 2014).
[3] Florida Department of Business and Professional Regulation, *Compressed Medical Gas Manufacturer*, www.myfloridalicense.com/department/ddc/CompressedMedicalGasesManufacturer.html (Last visited Mar. 21, 2014).
[4] Florida Department of Business and Professional Regulation, *Medical Oxygen Retail Establishment*, http://www.myfloridalicense.com/department/ddc/MedicalOxygenRetail.html (Last visited Mar. 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 11 members including the Secretary of the Department of Business and Professional Regulation, or his or her designee, and the Secretary of the Agency for Health Care Administration, or his or her designee. The remaining nine members are appointed by the Secretary of the Department of Business and Professional Regulation to a term of 4 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. 499.81-499.94, F.S. The regulation of medical gases is separated from the regulation of other types of prescription drugs

[5] Compressed Gas Association, *About Us*, http://www.cganet.com/about.php (Last visited April 2, 2014).
[6] Compressed Gas Association, *CGA Mission*, http://www.cganet.com/mission.php (last visited April 2, 2014).
[7] *Id.*
[8] *Id*.

in order to reduce the regulatory impact while more specifically regulating activities related to medical gases.

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 number of new definitions related to medical gas in s. 499.82, F.S.[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 reestablishes these permits as wholesale distributor, manufacturer, and medical oxygen retail establishment permits in s. 499.83, F.S. A person or entity intending to distribute medical gas within or into this state must obtain the applicable permit before operating.

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 to be in the same container as obtained with no further manufacturing operations performed, unless the wholesale distributor is also permitted as a manufacturer; and,
- Prohibits a distributor from possessing or engaging in the wholesale distribution of other prescription drugs unless otherwise authorized under ch. 499, F.S.

The bill also establishes requirements for wholesale distributors including:

- Wholesale distributors may not operate from a residence, except for the on-call delivery of home care oxygen if the wholesale distributor also maintains a medical oxygen retail establishment permit;
- Each separate location must be permitted individually; and,
- Out-of-state wholesale distributors must be legally authorized to operate as a wholesale distributor in their state of residence to provide services in Florida.

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

[9] Section 499.81, F.S., defines the terms "adulterated," "department," "distribute" or "distribution," "emergency medical reasons," "emergency use oxygen," "federal act," "medical gas," "medical gas-related equipment," "misbranded," "medical oxygen," "product labeling," "USP," "USP-NF," "wholesale distribution," and "wholesale distributor." Some of the definitions duplicate those in s. 499.003, F.S.

[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.

- May not manufacture or possess another prescription drug unless otherwise authorized under ch. 499, F.S.;
- May engage in the wholesale distribution of medical gas it manufactured without obtaining a wholesale distributor permit if it complies with the requirements of the part and applicable rules; and,
- Must comply with all the requirements of a wholesale distributor and any appropriate good manufacturing practices.

A *medical oxygen retail establishment permit* is required for a person, except a pharmacy under ch. 465, F.S., who dispenses medical oxygen directly to patients. Sales and delivery 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 unless otherwise authorized by ch. 499, F.S.;
- May not receive back into its inventory any prescription medical oxygen sold pursuant to a licensed practitioner's order;
- May fill and deliver medical oxygen to an individual based on an authorized order or prescription, and shall comply with all appropriate good manufacturing practices if doing so; and
- Must comply with all of the requirements in the part that are applicable to a wholesale distributor except for the requirements specifically related to nitrous oxide.

The bill creates s. 499.831, F.S., requiring the department to adopt rules to establish the form and content of medical gas permit applications and describing the application requirements and fees[11] for permits listed in s. 499.83, F.S. Section 499.832, F.S., provides that permits expire after 2 years, establishes renewal procedures, and requires the department to adopt rules and a reasonable fee for renewal.[12]

The bill creates s. 499.833, F.S., restricting permit use to the person or entity granted but allowing specific changes to be made upon approval of the department. The bill grants the department authority to approve:

- *A change of location*. The department must approve the change before the permit holder effectuates the change and the department may charge a change of location fee of up to $100;
- *A change in ownership*. The department must approve the change of ownership before the permitted entity changes owners. An exception is made if the new owner has held a permit that allows the wholesale distribution of medical gas for the preceding 18 months without any violations. In such a case the new owner must notify the department no later than one business day after the change in ownership.

Permit holders who are changing the permitted entity's name or closing must notify the department before the change in the status of the permit takes place. If a permit holder is closing he or she must also provide the department with an indication of the disposition of any medical

[11] The fee for initial and renewal permits are removed from s. 499.041, F.S., and added to s. 499.831(5), F.S. The fees may be between $200 and $300 annually for medical gas wholesale distributors and medical oxygen retail establishments between $400 and $500 annually for medical gas manufacturers. Fees collected will be deposited in the Professional Regulation Trust Fund and be used to administer the part.
[12] *Id*.

gas that was authorized to be distributed or dispensed under the permit. The department must also be notified of any other unspecified changes affecting the permit within 30 days after such a change is made. A permit holder in good standing may also change the type of permit held by submitting a new application and paying the difference in the permitting fees between the two permit types.

The bill creates s. 499.834, F.S., requiring the department to consider relevant factors when determining eligibility for, and renewal of, a permit application. Such factors include the applicant's past experience, previous noncompliance, felony convictions, and other qualifications that the department considers relevant to and consistent with public health and safety.

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).[13]

The bill creates s. 499.85, F.S., requiring security measures for medical gas distribution and retailing facilities and vehicles used for delivering oxygen and oxygen-related equipment. Under this section, the department is required to adopt rules governing distribution of 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., which 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 United States Food and Drug Administration (FDA) and proof of the registration is provided along with proof of inspection within the last 3 years or proof of substantial compliance with current good manufacturing practices applicable to medical gases.

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

The bill creates s. 499.89, F.S., which 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. A record containing all required elements related to the receipt of medical gas or a separate record containing all required elements related to the distribution of medical gas must be maintained for each transaction as applicable. A pedigree paper is not required for the distribution, or other disposition, 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 responding to natural disasters or other crisis-events, and reporting criminal activity involving nitrous oxide.

Medical oxygen retail establishments and medical gas manufacturers must also comply with all requirements that apply to wholesale distributors except that medical oxygen retail establishments need not comply with requirements that pertain solely to nitrous oxide.

Prohibited and Criminal Acts

The bill creates s. 499.91, F.S., which 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 or dispense medical gas or who is exempted from permitting requirements to wholesale distribute 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 when a wholesale distributor provides oxygen to a retail establishment that is only out of compliance with the change of location requirements if the wholesale distributor notifies the department by the next business day;
- 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;
- Distributing or dispensing 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 emergency use oxygen, the distribution of medical gas to a patient without an order or prescription from a licensed practitioner authorized by law to prescribe;
- Distributing or dispensing medical gas that was previously dispensed by a pharmacy or a licensed practitioner authorized by law to prescribe;
- Distributing or dispensing 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;
- Knowingly purchases or receives, medical gas from a person not legally authorized to distribute or dispense medical gas;
- Knowingly engages in the wholesale distribution of, 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 wholesale distributor that provides oxygen to a permitted medical oxygen retail establishment retail establishment is out of compliance with only the change of location notice requirement and the wholesale distributors notifies the department no later than the next business day.
- Knowingly, falsely creates a label for medical gas or knowingly, falsely represents a factual matter contained in a label for medical gas.

A person who is found guilty of one of the listed offenses in this section must forfeit to the state real or personal property used or intended to be used to commit such an offense and that is related to the gross proceeds gained as a result of the violation. The department and agencies involved in the investigation and prosecution that led to the conviction shall share equitably in the forfeiture proceeds. 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 12 members, recommended 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., which allows the department to require a facility engaged in the manufacturing, retail sale, or wholesale distribution of medical gas to undergo an inspection, including initial permitting, permit renewal, and change of location inspections. The department may recognize other state inspections if that state's laws are determined to be substantially

equivalent with this state's laws or may use a third party to inspect. A manufacturing facility registered with the FDA and verified as such and providing proof of an inspection with substantial compliance with current good manufacturing practices applicable to medical gas within the past 3 years is exempt from routine 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 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. 499.051, F.S., while it is retained by the department.

Rules, Enforcement and Additional Changes

The bill also makes numerous conforming changes and extends the department's rulemaking and regulatory authority in part I of ch. 499, F.S., to the whole chapter.

The bill 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:

CS/CS SB 836 may have an indeterminate fiscal impact on private sector entities that 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.[14]

The bill provides that fees collected under part III are to be used to administer "this part," which limits the fees and monies collected to use for administering only part III. The bill also requires the department to maintain a separate account in the trust fund for the Drugs, Devices, and Cosmetics program. 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:

None.

VII. Related Issues:

The definition of "adulteration" in the bill does not include transfer or possession by an unauthorized source.[16] Generally under the current law, if an unauthorized person holds, transfers, purchases, or sells a prescription drug, that drug becomes adulterated.[17] 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.[18] The bill may reduce the incentive of providers to verify current prescriptions before making deliveries.[19]

VIII. Statutes Affected:

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

This bill creates the following sections of the Florida Statutes: 499.81, 499.82, 499.83, 499.831, 499.832, 499.833, 499.834, 499.84, 499.85, 499.86, 499.87, 499.88, 499.89, 499.90, 499.91, 499.92, 499.93, 499.931, and 499.94.

IX. Additional Information:

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

CS/CS by Health Policy on April 1, 2014:
The CS makes numerous changes that provide greater clarity throughout the bill. The CS also amends the bill with changes that include:

[14] Department of Business and Professional Regulation, *Senate Bill 836 Legislative Bill Analysis* (Feb. 21, 2014) (on file with the Senate Committee on Health Policy).
[15] *Id.*

- Aligning the regulation of medical oxygen retail establishments and medical gas manufacturers with those for medical gas wholesale distributors in order to ensure they are responsible for security and recordkeeping;
- Changing the definition of "emergency" to "emergency medical reasons" and removing the requirement that the Governor declare an emergency in order to qualify as an "emergency medical reason" under the definition;
- Ensuring that the department has adequate rulemaking and enforcement authority to administer the provisions in the bill;
- Requiring that a permit holder receives prior approval from the department before changing their permitted location and ownership;
- Requiring that a permit holder notify department before changing the name of their business or closing and within 30 days after making any other change not listed that would affect their permit.

CS by Regulated Industries 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 s. 499.931, F.S., which requires the department to maintain trade secrets as provided in s. 499.051, F.S., which provides that trade secrets must be confidential and exempt from disclosure under ch. 119, F.S., and section 24(a), Article I of the State 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.

B. Amendments:

None.