HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/CS/CS/HB 687	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Health & Human Services Committee; Government Operations Appropriations Subcommittee; Health Quality Subcommittee; Magar and others	115 **Y's**	1 **N's**
COMPANION BILLS:	CS/CS/SB 836	**GOVERNOR'S ACTION:**	Approved

SUMMARY ANALYSIS

CS/CS/CS/HB 687 passed the House on April 28, 2014, as CS/CS/SB 836.

Part I of ch. 499, F.S., requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics. Most of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits to operate in the state.

In Florida, medical gases, such as oxygen, nitrous oxide, nitrogen, and helium, are prescription drugs and subject to regulation under part I of ch. 499, F.S., and the rules adopted thereunder in ch. 61N-1, F.A.C. However, many of the provisions and requirements of part I are difficult to apply to medical gases because of the nature of storage, shipment, and maintenance of medical gas, primarily in large tanks or canisters.

The bill creates part III of ch. 499, F.S., which separates the regulation, including permit requirements, of manufacturers and wholesale distributors of medical gases, as well as medical oxygen retail establishments, from the provisions of part I and part II of the chapter, which regulate the manufacturers and distributors of other drugs, devices, and cosmetics. The bill includes many provisions governing medical gases that are substantially similar to existing provisions in part I, but revises those provisions for applicability to medical gases. The provisions of new part III require:

- Permits for medical gas manufacturers and wholesale distributors and medical oxygen retail establishments;
- Minimum qualifications for obtaining a permit to deal in medical gases;
- Certain procedures to change a permit;
- Security and storage of medical gases;
- Returned, damaged, and outdated medical gases to be handled in a certain manner;
- Penalties for committing prohibited and criminal acts associated with medical gases; and
- Inspections of facilities that manufacture medical gases.

The bill requires rules adopted under part III to be consistent with the law and rules governing the possession and use of medical oxygen by emergency medical service providers in part III of ch. 401, F.S.

The bill has an insignificant negative fiscal impact on DBPR's Division of Drug, Devices and Cosmetics.

The bill was approved by the Governor on June 13, 2014, ch. 2014-89, L.O.F., and will become effective on October 1, 2014.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

Regulation of Drugs, Devices, and Cosmetics

Part I of ch. 499, F.S., requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[1] Most of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits. In total, Florida has 20 distinct permits for these entities. Among many other provisions, the chapter provides for:

- Criminal prohibitions against the distribution of contraband and misbranded prescription drugs;
- Regulation of the advertising and labeling of drugs, devices, and cosmetics;
- Permits for manufacturing and distributing drugs, devices, and cosmetics;
- Regulation of the wholesale distribution of prescription drugs, which includes pedigree papers;
- Regulation of the provision of drug samples;
- The Cancer Drug Donation Program; and
- Numerous enforcement avenues for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

Many of these regulations have been significantly strengthened in recent years, including:

- More stringent requirements to obtain a wholesale distributor permit, requiring, among other items, a posting of a bond and extensive background information for various employees of the wholesale distributor;[2]
- More thorough documentation requirements for the distribution of prescription drugs, including broader application of the pedigree paper[3] to most wholesale distributions;[4]
- Enhanced criminal penalties for, among other things, distribution of contraband prescription drugs;[5] and
- Stronger departmental enforcement authority to protect the prescription drug supply chain.[6]

Compressed medical gases are also regulated under part I of ch. 499, F.S.

Medical Gases

[1] S. 27, ch. 2010-161, Law of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.
[2] S. 499.01(2)(d), F.S. (requiring a bond of $100,000 or other means of equivalent security) and s. 499.012(8) and (9), F.S. (requiring, in addition to other information, place of residence for the past 7 years, fingerprints, photograph taken within 30 days, and name, address, occupation, and date and place of birth of each member of the person's immediate family who is 18 years of age or older).
[3] A pedigree paper is a record that documents the movement of drugs, devices or cosmetics through the chain of commerce. A pedigree paper must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component. Rule 61N-1.012(1)(a), F.A.C.
[4] S. 499.01212, F.S. ("Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.")
[5] S. 499.0051(6), F.S. (imposing a second degree felony for "a person who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription drugs").
[6] S. 499.0051(12) and (13), F.S.

According to the United States Food and Drug Administration (FDA), medical gases include:

- Oxygen;
- Nitrogen;
- Nitrous oxide;
- Carbon dioxide;
- Helium;
- Medical air;[7] and
- Any mixture of these gases or other gas products approved under a New Drug Application.[8]

Medical gases have a variety of uses. For example, nitrous oxide, a clear and colorless gas with a slightly sweet odor, is blended with oxygen for use as medical or dental anesthesia or analgesia.[9] Over 80 percent of manufactured nitrous oxide is used in medicine or dentistry.[10] Helium, due to its light weight, is used as a therapy in many respiratory conditions, such as asthma, chronic obstructive pulmonary disorder (COPD), and croup.[11] Helium has also been used as a more effective treatment of decompression illness, or "the bends."[12] Xenon, a colorless, heavy, and odorless noble gas, is used in anesthesia and in medical imaging, such as enhanced CT scans.[13]

Regulation of Medical Gases in Florida

In Florida, compressed medical gases are prescription drugs,[14] and fall under the regulatory provisions of part I of ch. 499, F.S., and the rules adopted thereunder in ch. 61N-1, F.A.C. A permit is required to manufacture or repackage, or to wholesale distribute, compressed medical gases within the state.[15] A business seeking either permit must submit an application, pass an onsite inspection by the DBPR, and pay the appropriate fee.[16] For a business located outside of Florida that wishes to manufacture and distribute or wholesale distribute compressed medical gases into the state, a nonresident prescription drug manufacturer permit[17] or an out-of-state prescription drug wholesale distributor permit[18] is required.

A compressed medical gases manufacturer or a medical oxygen retailer who manufacturers or refills compressed medical gases must comply with the current good manufacturing practice regulations promulgated by the FDA[19] and the "Compressed Medical Gases Guideline"[20] issued by the Center for Drug Evaluation and Research at the FDA.[21]

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[7] Medical air is a nonflammable, colorless, and odorless gas consisting of a mixture of various elements, mostly nitrogen and oxygen. Medical air is most often used for respiratory therapy and to power pneumatic medical devices. Airgas, *Medical Air U.S.P.*, available at www.airgas.com/content/products.aspx?id=9002003001003 (last viewed on April 8, 2014).
[8] U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *About FDA-Questions and Answers on the Proposed Rule for Medical Gas Containers (2006)*, available at www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm096373.htm (last viewed on April 8, 2014).
[9] Compressed Gas Association, *Nitrous oxide fact sheet*, available at www.cganet.com/n20guidelines.php (last viewed on March 21, 2014).
[10] Norco, Inc., *Medical Gases-Nitrous Oxide*, available at www.norco-inc.com/content/medical-gases (last viewed on April 8, 2014).
[11] Berganza, C., and Zhang, J., *The role of helium gas in medicine*, Medical Gas Research 2013, 3:18, page 2, available at www.medicalgasresearch.com/content/pdf/2045-9912-3-18.pdf (last viewed on April 8, 2014).
[12] Id. at page 1.
[13] Esencan, E., Yuksel, S., et al., *Xenon in medical area: emphasis on neuroprotection in hypoxia and anesthesia*, Medical Gas Research 2013, 3:4, pages 2, 6, available at www.medicalgasresearch.com/content/pdf/2045-9912-3-4.pdf (last viewed on April 8, 2014).
[14] S. 499.003(11), F.S., see also s. 499.003(46), F.S. (defining "prescription medical oxygen").
[15] S. 499.01(2)(o), F.S., and s. 499.01(2)(n), F.S., respectively.
[16] Applications require detailed information pursuant to Rule 61N-1.015(1) and (7)(d), F.A.C. An onsite inspection is required pursuant to Rule 61N-1.015(3), F.A.C. Appropriate fees are outlined in Rule 61N-1.018, F.A.C.
[17] S. 499.01(2)(c), F.S.
[18] S. 499.01(2)(d), F.S.
[19] 21 C.F.R. Parts 200-299

A medical oxygen retail establishment permit is required for any person that sells medical oxygen only to patients.[22] A sale of medical oxygen under the permit must be based on an order from a health care practitioner authorized to prescribe medical oxygen.[23] A permittee must comply with all state and federal good manufacturing practices and all of the wholesale distribution requirements in s. 499.0121, F.S.[24] An applicant for this permit must submit an application, submit to and pass a fire inspection and DBPR inspection, and pay the appropriate fee.[25]

Trade Secret Information

In general, any confidential information which provides a business a competitive edge may be considered a trade secret. Trade secrets encompass manufacturing secrets, industrial secrets, and commercial secrets, and include sales methods, distribution methods, consumer profiles, advertising strategies, lists of suppliers and clients, and manufacturing processes.[26]

In Florida, a trade secret is similarly defined in statute.[27] A trade secret is considered to be secret, of value, for use or in use by a business, and of advantage to the business, or providing the opportunity to obtain an advantage, over those who do not know or use it.[28] A trade secret includes any scientific, technical, or commercial information, including any design, process, procedure, list of suppliers, list of customers, business code, or improvements thereof.[29]

The DBPR is required by statute to keep confidential all trade secret information contained in an application for a new permit or renewal of a permit under part I of ch. 499, F.S.[30] The DBPR is also required to keep confidential all trade secret information contained in a complaint to the department alleging a violation by a permittee under part I of ch. 499, F.S., and any trade secret information received from the resulting investigation of the complaint.[31]

Drug Wholesale Distributor Advisory Council

The Drug Wholesale Distributor Advisory Council (Council) was established by the Prescription Drug Protection Act[32] in s. 499.01211, F.S. The Council reviews the Florida Drug and Cosmetic Act[33] and associated rules and:

- Provides input to the DBPR regarding all proposed rules;
- Makes recommendations to the Secretary of the DBPR regarding the listing of all specified drugs;[34]
- Makes recommendations to improve the protection of prescription drugs and public health;
- Makes recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs; and

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[20] Available at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124716.htm (last viewed on April 8, 2014).
[21] Rule 61N-1.007(1), F.A.C.
[22] S. 499.01(2)(m), F.S.
[23] S. 499.01(2)(m)2., F.S.
[24] S. 499.01(2)(m)2. and 3., F.S.
[25] Rules 61N-1.015(1) and (3), F.A.C., and Rule 61N-1.018(4), F.A.C.
[26] World Intellectual Property Organization, *What is a Trade Secret?*, available at www.wipo.int/sme/en/ip_business/trade_secrets/trade_secrets.htm (last viewed on April 8, 2014).
[27] S. 812.081(1)(c), F.S.
[28] Id.
[29] Id.
[30] S. 499.012(8)(g), F.S.
[31] S. 499.051(7), F.S.
[32] Ch. 2003-155, Laws of Fla.
[33] Chapter 499, F.S.
[34] S. 499.0121(6)(e), F.S.

- Makes recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.[35]

The Secretary of the DBPR, or her or his designee, and the Secretary of the Agency for Health Care Administration, or her or his designee, both serve as members of the Council.[36] The Secretary of the DBPR appoints nine members to the Council to serve four year terms.[37] The remaining nine members of the Council are:

- 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;
- One person employed by a licensed prescription drug wholesale distributor which is a secondary wholesale distributor;
- One person employed by a retail pharmacy chain;
- One member of the Florida Board of Pharmacy who is a licensed pharmacist;
- One licensed physician;
- One person who is an employee of a hospital who is a licensed pharmacist; and
- One person who is an employee of a pharmaceutical manufacturer.[38]

Effect of Proposed Changes

The bill creates part III of ch. 499, F.S., which separates the regulation of manufacturers and wholesale distributors of medical gases, as well as medical oxygen retail establishments, from the provisions of part I and part II of the chapter, which regulate the manufacturers and distributors of other drugs, devices, and cosmetics. The bill creates the following new sections of law.

Definitions

The bill revises the current definition of “compressed medical gas” to “medical gas” in part I and refers to the definition of the term in the federal Food, Drug, and Cosmetic Act (Act). The bill deletes the definition of “prescription medical oxygen” in part I.

The following terms are defined for part III: “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,”[39] “USP-NF,”[40] “wholesale distribution,” and “wholesale distributor.” Under the definition of “wholesale distribution,” the bill provides several exceptions that do not constitute wholesale distribution, including the sale, purchase, or trade of a medical gas, or the offer to do so, or the dispensing of a medical gas pursuant to a prescription or for emergency medical reasons; activities exempt from wholesale distribution as defined in s. 499.003(54), F.S., in part I; and other transactions exempted from the definition of wholesale distribution in the Act or federal regulations adopted pursuant to the Act.

Administration and Enforcement

The bill asserts that the provisions of part III regulating medical gas control over any other provision purporting to regulate medical gas. The bill grants power to the DBPR to administer and enforce part III

[35] S. 499.01211(3), F.S.
[36] S. 499.01211(2), F.S.
[37] Id.
[38] S. 499.01211(2)(a)-(g), F.S.
[39] 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.
[40] The United States Pharmacopeia and The National Formulary (USP–NF) is a book of public pharmacopeial standards. It is available at http://www.usp.org/usp-nf (last viewed on April 8, 2014).

and grants specific authority to the DBPR to, during the course of an investigation or proceeding regarding a violation of part III, administer oaths, take depositions, subpoena witnesses, and conduct discovery. The bill also requires each state, county, or municipal attorney to investigate and, if proper, prosecute any report made by the DBPR relating to a violation of the part. Minor violations may be disposed by written notice or warning. Lastly, the bill ensures that the DBPR has appropriate authority to make rules regarding permitting fees, pre-permitting onsite inspection fees, and other medical gas regulations, identical to its authority over other drugs, devices, and cosmetics granted in part I.

Permits

The bill deletes the medical oxygen retail establishment permit, the compressed medical gas wholesale distributor permit, and the compressed medical gas manufacturer permit from s. 499.01, F.S., and moves them to s. 499.83, F.S. The provision for the medical gas wholesale distributor permit is substantially similar to the same provision in current law at s. 499.01(2)(n), F.S. The provisions for the medical gas manufacturer permit and the medical oxygen retail establishment permit are similar to the same provisions in current law at s. 499.01(2)(o), F.S., and s. 499.01(2)(m), F.S., respectively. The bill allows a person or entity holding a medical gas wholesale distributor permit to possess or wholesale distribute a prescription drug other than a medical gas if it is authorized under part I of chapter 499, F.S., through the appropriate permit. A medical gas manufacturer permit is also allowed to manufacture or possess a prescription drug other than a medical gas if it holds the appropriate permit. Finally, a medical oxygen retail establishment is allowed to possess, purchase, sell, or trade a medical gas other than oxygen if it has the appropriate permit under part I of chapter 499, F.S.

The bill provides for specific information that must be included in an application for a medical oxygen retail establishment permit, a compressed medical gas wholesale distributor permit, and a compressed medical gas manufacturer permit under the s. 499.83, F.S., which is similar to the provisions in current law in s. 499.012(3) and (4), F.S. The bill outlines the fee structure for each permit, which is identical to current law in s. 499.041(1)(e), (2)(b), and (3)(b), F.S. The permit renewal process and fee is similar to current law in s. 499.012(5)(c), F.S. Also, the expiration date of a permit two years after the last day of the month it was issued, and the process for reapplying for a permit after failing to timely renew it, is identical to the provisions of current law in s. 499.012(5)(c) and (d), F.S.

The bill includes the same process for changing a permit type for a permittee in good standing, which exists in s. 499.012(2), F.S. However, the bill establishes a new expiration date for a changed permit. Current law sets the expiration date as the date the original permit was to expire or one year from the date the new permit was issued, whichever is earlier. The bill sets the expiration date as the date the original permit was to expire, eliminating the earlier expiration date provision.

The bill contains similar language to current law in s. 499.012(6), F.S., regarding non-transferability of medical gas-related permits issued by the DBPR, but adds language authorizing the DBPR to approve a change in permit holder. The bill retains the change of location provision and the $100 fee for doing so.

The bill requires advance notice to the DBPR prior to any change of business name, change of location, or change of ownership by a medical gas manufacturer, medical gas wholesale distributor, or medical oxygen retail establishment. The bill provides an exception in the case of a change of ownership. If a purchasing permittee buys another permittee and has been licensed for at least 18 months prior to purchase, and has had no violations during that time period, the purchasing permittee may operate under the permit of the purchased permittee prior to filing an application for a new permit. The application for the new permit must be filed within one business day of the transfer or assignment of ownership. Any other change in information must be reported to the DBPR within 30 days of the change.

Additional Requirements for Licensure of a Wholesale Distributor of Medical Gas

The bill includes similar language as found in s. 499.01(13), F.S., which requires a permit and biennial renewal of a permit to wholesale distribute medical gas within or into the state. The bill includes substantially similar provisions related to minimum qualifications of persons seeking a permit to engage in the wholesale distribution of medical gas as is currently found in s. 499.012(4)(d), F.S.

Minimum Requirements for the Storage and Handling of Medical Gases; Establishment and Maintenance of Medical Gas Records

The bill includes minimum requirements for the storage, handling, transport, and shipment of medical gases that are substantially similar to the requirements found in current law at s. 499.0121(1)-(3), F.S. The bill also includes the following requirements for a facility handling medical gas to ensure the identity, strength, quality, or purity of the medical gas:

- The facility must be of suitable construction to ensure the medical gas is maintained according to the label instructions or in compliance with the USP-NF.
- The facility must be a commercial location and not a residence, except that a personal residence may be used for on-call delivery of medical oxygen for home use pursuant to a permit.
- The facility must protect and keep confidential patient information.
- The facility must have appropriate inventory controls to detect and document the theft of nitrous oxide.

The bill requires that medical gases be packaged according to applicable guidelines in the USP-NF.

Security

The bill requires strict security measures to protect medical gases from unauthorized entry into a facility that stores medical gases. The provisions are substantially similar to the security measures included in s. 499.0121(2), F.S. The bill adds a provision for on-call delivery of medical oxygen which requires a vehicle containing the medical oxygen to be parked at a residence and be equipped with an audible alarm when not attended.

The bill requires the DBPR to adopt rules that govern the distribution of medical oxygen for emergency use to individuals who are authorized to receive emergency use oxygen. However, the rules must be consistent with the provisions in part III of ch. 401, F.S., regarding medical transportation services, and the rules adopted under those provisions.

Examination of Materials

The bill includes requirements for inspection of medical gases containers that are similar to provisions in current law in s. 499.0121(4) and (5)(b), F.S., that require the examination of containers of prescription drugs to reveal damage that may compromise the prescription drugs in the container. The bill adds provisions to this section that have particular application to the containers for medical gases, which are typically metal tanks or canisters. The bill requires a damaged or unfit container to be quarantined in a separate area of the facility until a more thorough inspection can be done to determine if the medical gas has been misbranded or adulterated by the damage to the container. Also, a pedigree paper is not required for the wholesale distribution of medical gas, with is consistent with current law.

Returned, Damaged, and Outdated Medical Gases

The bill establishes procedures for handling returned, damaged, and outdated medical gases that are substantially similar to the procedures found in s. 499.0121(5), F.S., for handling prescription drugs that have been returned or damaged or are outdated. The bill includes a new provision that requires a

medical gas, its container, or associated documentation and labeling that is suspected of being involved in criminal activity must be preserved until law enforcement or the DBPR directs its disposition.

Salvaging and Reprocessing

The bill prohibits the salvaging or reprocessing of a medical gas that has been subject to improper conditions such as fire, accident, or natural disaster. The bill also permits the return of a medical gas container to the manufacturer and reprocessed if the manufacturer has appropriate controls in place to confirm the identity, strength, quality, and purity of the reprocessed gas.

Due Diligence

The bill establishes due diligence requirements for a wholesale distributor or manufacturer seeking to acquire medical gas and for a wholesale distributor or manufacturer seeking to supply medical gas. These provisions are similar to the requirements in current law in s. 499.0121(13) and (15), F.S. The bill exempts a wholesale distributor from the due diligence requirements in this section if the manufacturer from whom medical gas is received is registered with the FDA under s. 501 of the federal Food, Drug, and Cosmetics Act, can provide proof of registration, and can provide proof of an inspection by the FDA within the past three years which demonstrates substantial compliance with current good manufacturing processes for medical gases.

Recordkeeping

The bill includes provisions for the establishment and maintenance of certain records by a wholesale distributor of medical gas. The provisions are substantially similar to the recordkeeping requirements in current law in s. 499.0121(6), F.S., but slightly changed to account for the difference between medical gas and prescription drugs. For example, the bill requires certain records for high pressure medical gas to be kept for three years, while records for cryogenic or refrigerated liquid medical gas must be kept for one year. Also, the bill requires a wholesale distributor to maintain sufficient records to aid in the reporting of any loss of theft, or suspected theft, of nitrous oxide to the DBPR or an appropriate law enforcement agency.

Policies and Procedures

The bill mandates the creation and maintenance of policies and procedures by a wholesale distributor of medical gas to handle certain circumstances, such as the recall of a medical gas, an action initiated by the FDA, or the security or operation of a facility during a natural disaster or other emergency. The provisions are substantially similar to the requirements in current law in s. 499.0121(8), F.S. The bill adds a provision that requires a wholesale distributor to have policies and procedures in place for reporting criminal activities involving nitrous oxide to the DBPR and law enforcement within three days of becoming aware of, or suspecting, criminal activity.

Trade Secret Information

The new law requires the DBPR to keep confidential trade secret information, as that term is defined in s. 812.081(1)(c), F.S. The entity permitted under part III of ch. 499, F.S., must designate the information a trade secret when supplying information to the department in an application or in response to a complaint or investigation, pursuant to provisions in part I of ch. 499, F.S., which currently require the DBPR to keep confidential trade secret information received from other permittees under the Drugs, Devices, and Cosmetics Program.

Prohibited Acts

The new law includes a list of prohibited acts associated with medical gas. The prohibitions are substantially similar to those that are found in s. 499.005, F.S., and are revised to apply to circumstances involving medical gas. Such prohibited acts include, but are not limited to:

- Manufacturing, sale, delivery, handling, or offering adulterated or misbranded medical gas.
- Adulterating or misbranding medical gas.
- Obtaining or attempting to obtain a medical gas by fraud, deceit, or misrepresentation in the distribution of medical gas.
- Knowing and willful sale of a medical gas to a person who is not legally authorized to receive a medical gas, except that no violation exists if a permitted wholesale distributor provides oxygen to a medical oxygen retail establishment permit holder that is out of compliance with the notice of location change requirements in the bill, provided that the wholesale distributor notifies the DBPR of the transaction and knowledge of the violation within the next business day.

Criminal Acts

The bill provides a list of criminal acts associated with medical gas. The provisions are substantially similar to those provisions that appear in current law in s. 499.0051, F.S., and are revised to apply to circumstances involving medical gas. The bill includes a provision that requires the forfeiture to the state, upon a finding of guilt for any criminal act in the section, any real or personal property used to commit, facilitate, or promote the crime. The provision includes the forfeiture of property or assets purchased or obtained using the proceeds of the criminal act. Lastly, the subsection provides for the disposition of property or assets to the DBPR, law enforcement, or other agencies involved in the investigation and prosecution of the criminal act that resulted in conviction.

Inspections

The bill allows the DBPR to recognize the inspection of a wholesale distributor by a third party in another state. The bill also authorizes the DBPR to recognize the inspection of a wholesale distributor by another state agency, if the DBPR determines the laws of the state are substantially equivalent to Florida law.

The bill provides an exemption from DBPR inspection to a manufacturing facility if the following conditions are met:

- The facility is registered with the FDA under s. 510 of the Act;
- The facility provides proof of FDA registration; and
- The facility provides proof of inspection by the FDA within the last three years or, if the facility is in another state, proof of inspection by the FDA or another governmental agency which regulates current good manufacturing processes within the same timeframe.

The bill requires a wholesale distributor to exhibit or have readily available all state licenses and the most recent inspection report from the DBPR. Lastly, the bill gives the DBPR discretion to issue a written notice of minor violations of part III if it determines the public interest is served by doing so.

Deposit of Fees

The bill requires all fees for licenses and permits collected under part III to be deposited into the Professional Regulation Trust Fund, in a separate account for the Drug, Devices, and Cosmetics program, for administration of part III.

Drug Wholesale Distributor Advisory Council

The bill adds another member to the Council, bringing the total number of members to 12. The new member must be an employee of either a medical gas manufacturer or a medical gas wholesale distributor and must be recommended by the Compressed Gas Association.

Conforming Changes

The bill conforms cross-references in ss. 409.9201, 460.403, 465.0265, 499.01, 499.01211, 499.01212, 499.015, 499.024, and 499.05, F.S. The bill also changes references to the term "part" to "chapter" to reflect application of provisions in part I of ch. 499, F.S., to the new part III, regarding medical gases.

The bill has an insignificant negative fiscal impact on DBPR's Division of Drug, Devices and Cosmetics.

Subject to the Governor's veto powers, the effective date of this bill is October 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DBPR indicates that the costs associated with the additional Drug Wholesale Distributor Advisory Council member are indeterminate, but are expected to be insignificant and can be funded within existing resources. The members of the Council are not paid employees; they serve without compensation. DBPR is responsible for expenses associated with the logistics of the Council meetings (e.g., procuring meeting space, sending out agenda materials, recording the meetings, etc.).[41]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The revision of the permitting process and the easing of other regulations for medical gas manufacturers and wholesale distributors and medical oxygen retail establishments may result in lower administrative costs for these entities. Also, a revised permitting process and less regulation may prove attractive for medical gas manufacturers, medical gas wholesale distributors, and medical oxygen retail establishments to relocate to Florida.

D. FISCAL COMMENTS:

[41] Department of Business and Professional Regulation Bill Analysis, February 11, 2014 (on file with the Health and Human Services Committee).

None.