HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 687 Florida Drug and Cosmetic Act
SPONSOR(S): Health Quality Subcommittee; Magar
TIED BILLS: HB 689 **IDEN./SIM. BILLS:** SB 836

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Poche	O'Callaghan
2) Government Operations Appropriations Subcommittee		Topp	Topp
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Part I of chapter 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 chapter 499, F.S., and the rules adopted thereunder in chapter 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.

House Bill 687 creates part III of chapter 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- Returned, damaged, and outdated medical gases to be handled in a certain manner;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 has a significant fiscal impact on reducing revenues to DBPR's Division of Drug, Devices and Cosmetics. See Fiscal Impact Section.

The bill provides an effective date of October 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Regulation of Drugs, Devices, and Cosmetics

Part I of Chapter 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 chapter 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 chapter 499, F.S., and the rules adopted thereunder in chapter 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 March 21, 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 March 21, 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 March 21, 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 March 21, 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 March 21, 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
[20] Available at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124716.htm (last viewed on March 21, 2014).
[21] Rule 61N-1.007(1), F.A.C.

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 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 chapter 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 chapter 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
- 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

[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 March 25, 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.
[35] S. 499.01211(3), F.S.
[36] S. 499.01211(2), F.S.

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 chapter 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. The bill deletes the definition of "prescription medical oxygen" in part I.

The following terms are defined for part III: "adulterated," "distribution," "emergency," "emergency use oxygen," "federal act," "intracompany transaction," "medical gas," "misbranded," "prescription 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, pursuant to a prescription or for emergency medical reasons; intracompany transactions; 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 federal act or federal regulations adopted pursuant to the federal 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 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.

Permits

The bill deletes the medical oxygen retail establishment permit, the compressed medical gas wholesale distributor permit, and the compressed medical gas manufacturer from s. 499.01, F.S., and moves

[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 March 22, 2014).

them to s. 499.831, 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 provides for specific information that must be included in an application for permit under the section, 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 change in permit type. 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 30 days of 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.

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 permitting and biennially renewal to wholesale distribute medical gas within or into the state. The bill requires out-of-state wholesale distributors to maintain permit requirements in the state where they are located and all other states in which they distribute, if applicable. If the state where an out-of-state wholesale distributor of medical gas is located does not require a permit to engage in wholesale distributing, the wholesale distributor will not be required to obtain a permit to operate in Florida.

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.

Registered Agent

The bill includes new language that requires each applicant or licensee under part III to designate and maintain a registered agent in Florida for purposes of service of process. If an applicant or licensee does not have a registered agent in Florida or, if after reasonable diligence, service of process cannot be completed, service may be made on the Secretary of State and relevant information regarding service mailed to the applicant or licensee.

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.

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 chapter 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 chapter 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 federal 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. The bill also changes references to the term "part" to "chapter" to reflect application of provisions in part I of chapter 499, F.S., to the new part III, regarding medical gases.

B. SECTION DIRECTORY:

Section 1: Amends s. 499.003, F.S., relating to definitions of terms used in this part.
Section 2: Amends s. 499.01, F.S., relating to permits.
Section 3: Amends s. 499.0121, F.S., relating to storage and handling of prescription drugs; recordkeeping.
Section 4: Amends s. 499.01211, F.S., relating to Drug Wholesale Distributor Advisory Council.
Section 5: Amends s. 499.041, F.S., relating to schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.
Section 6: Amends s. 499.051, F.S., relating to inspections and investigations.
Section 7: Amends s. 499.066, F.S., relating to penalties; remedies.
Section 8: Amends s. 499.0661, F.S., relating to cease and desist orders; removal of certain persons.
Section 9: Amends s. 499.067, F.S., relating to denial, suspension, or revocation of permit, certification, or registration.
Section 10: Creates Part III of chapter 499, F.S., relating to medical gases.
Section 11: Amends s. 409.9201, F.S., relating to Medicaid fraud.
Section 12: Amends s. 460.403, F.S., relating to definitions.
Section 13: Amends s. 465.0265, F.S., relating to centralized prescription filling.
Section 14: Amends s. 499.01212, F.S., relating to pedigree paper.
Section 15: Amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.
Section 16: Amends s. 499.024, F.S., relating to drug product classification.
Section 17: Amends s. 499.05, F.S., relating to rules.
Section 18: Provides an effective date of October 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill has a significant negative fiscal impact on revenues to the Division of Drugs, Devices and Cosmetics. DBPR estimates a recurring annual revenue loss of $134,200.

The current fund balance for the Division of Drugs, Devices and Cosmetics is projected to be $243,987 in Fiscal Year 2014-15, ($229,649) in Fiscal Year 2015-16 and ($711,908) in Fiscal Year 2016-17. The revenue reductions anticipated due to this bill will decrease the positive fund balance in Fiscal Year 2014-15 to $120,433 and increase the deficit in Fiscal Year 2015-16 to ($478,849) and in Fiscal Year 2016-17 to ($1,089,157).[41]

[41] Department of Business and Professional Regulation bill analysis (April 1, 2014) on file with the Government Operations Appropriations Subcommittee.

Specific revenue impacts on the Division of Drugs, Devices and Cosmetics include:[42]

Fee Authority
The bill deletes from Part I of chapter 499, F.S., the range of fees the department may charge for issuing the various permit types and would insert substantively identical fee authority language in the newly created Part III of chapter 499, F.S. However, DBPR's rulemaking authority in s. 499.05(1)(c), F.S., to establish fees is specific to Part I, and the bill does not appear to grant similar authority as regards to the new Part III. As such, DBPR could only charge the minimum established fee by statute for the various permit types, which results in an estimated negative fiscal impact annually of $102,900.

Licensing Exemption of Manufactures
The bill allows a medical gas manufacturer to engage in wholesale distribution of medical gases manufactured by other companies. Current law contains no such provision, so the bill would have a negative financial impact on DBPR resulting from the reduction in the total numbers of Medical Gas Wholesale Distributor permits. The department estimates the minimum annual negative impacts of the licensing exemption of manufactures to be $19,000.

Pre-Permit Inspection Fees
Under current law the DBPR may and does charge a $150 fee for conducting a pre-permit inspection for applicants in all three categories made the subject of this bill. The bill would transfer the permit categories out of Part I and into a newly created Part III of chapter 499, F.S., and does not provide authority to assess an inspection fee, which results in a loss annually of $12,000.

Licensing Exemption: Intra-company Transactions
The bill would exempt "intracompany transactions" from the definition of "wholesale distribution" with respect to medical gases. Current law contains no such exemption, so the bill would have a negative financial impact on the department resulting from the reduction in the total number of permits issued. Indeterminate fiscal impact.

Revenue source and expenditure information	Impact Amount
Drug Wholesale Distributor Advisory Council (see Expenditures below)	Indeterminate - Minimal
Fee Authority	($102,900)
Licensing Exemption: Manufacturers	($19,000)
Pre-Permit Inspection Fees	($12,300)
Licensing Exemption: Intracompany Transactions	Indeterminate
Minimum Total Impact (Annual/Recurring)	**($134,200)**

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 with 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.).[43]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

[42] Department of Business and Professional Regulation Bill Analysis (April 1, 2014) on file with the Government Operations Appropriations Subcommittee.
[43] Department of Business and Professional Regulation Bill Analysis (February 11, 2014) on file with the Government Operations Appropriations Subcommittee.

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:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to the DBPR to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 24, 2014, the Health Quality Subcommittee adopted one strike-all amendment and reported the bill favorable as a committee substitute. The strike-all amendment made the following changes to the bill:

- Defined “intracompany transfer;”

- Clarified the definition of “emergency” to mean a state of emergency declared under s. 252.36, F.S.;
- Required 30 days of advance notice to the DBPR prior a change in business name, change of location, or change of ownership by a permittee under part III of chapter 499, F.S.;
- Allowed a permitted buyer to purchase another permittee under part III and operate under the purchased permittee’s permit if the buyer had a permit for at least 18 months with no violation during that time and an application for a new permit is filed within one business day following the transfer or assignment of ownership;
- Deleted the list of persons legally authorized to possess medical gas;
- Removed the exemption from the FDA inspection requirement under due diligence if the manufacturer attests to conformance with industry standards or guidelines as identified by the DBPR;
- Required an FDA inspection, for due diligence purposes, to reflect substantial compliance by the manufacturer with current good manufacturing processes regarding medical gases;
- Required the DBPR to keep confidential all trade secret information, designated as such by a permittee under part III providing the information to the department in an application or as a result of a complaint or investigation, in a manner similar to the requirements in s. 499.012(8)(g), F.S., and s. 499.051(7), F.S., for information provided to the department by permittees under part I;
- Provides an exception to the prohibited act of knowingly and willfully selling or transferring medical gas to an unauthorized person;
- Changed the term “part” to “chapter,” where applicable, to ensure relevant portions of part I of chapter 499, F.S., applied to part III; and
- Made other technical changes.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.