Government Operations Appropriations Subcommittee

Tuesday, April 8, 2014
9:00 AM – 11:00 AM
Morris Hall (17 HOB)

MEETING PACKET

Will Weatherford
Speaker

Clay Ingram
Chair

The Florida House of Representatives

Appropriations Committee

Government Operations Appropriations Subcommittee

Will Weatherford
Speaker

Clay Ingram
Chair

April 8, 2014

AGENDA
9:00 AM – 11:00 AM
Morris Hall

I. Call to Order/Roll Call

II. Consideration of Bills

PCS for CS/HB 391 Florida Catastrophic Storm Risk Management Center

CS/HB 687 Florida Drug and Cosmetic Act by Rep. Magar

CS/HB 1153 Citizen Support and Direct-Support Organizations by Rep. Hager

CS/HB 1235 Florida Homeowners' Construction Recovery Fund by Rep. Dudley

CS/HB 7001 Administrative Procedures by Rep. Santiago

III. Closing Remarks/Adjourn

221 The Capitol, 402 South Monroe Street, Tallahassee, Florida 32399-1300
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HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for CS/HB 391 Florida Catastrophic Storm Risk Management Center
SPONSOR(S): Government Operations Appropriations Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:** SB 482

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Government Operations Appropriations Subcommittee		Keith AK	Topp BJT

SUMMARY ANALYSIS

The Florida Hurricane Catastrophe Fund (FHCF or Fund) is a tax-exempt trust fund created in 1993 as a form of reinsurance for residential property insurers. For solvency reasons, property insurers are required by the Office of Insurance Regulation (OIR) to purchase a certain amount of reinsurance. The amount of reinsurance purchased varies from insurer to insurer and is based on an insurer's financial situation and exposure.

The FHCF sells reinsurance to property insurance companies significantly cheaper than reinsurance sold by private reinsurance companies. Each insurance company writing insurance policies covering residential property or any policy covering a residential structure or its contents must participate in the FHCF. The Fund, which is administered by the State Board of Administration, reimburses insurers for a portion of their hurricane losses to residential property above the insurer's retention (deductible). The deductible on reinsurance sold by the Fund is set by statute and the maximum amount the Fund reinsures (the Fund coverage) is also set by statute.

The Fund does not receive any state funding (from the General Revenue Fund or other state trust funds) and receives its funding from the reinsurance premium it charges insurers and investment income from investing the reinsurance premium received.

The Florida Catastrophic Storm Risk Management Center (center) was created by the Florida Legislature in 2007. The center is housed within the Department of Risk Management/Insurance, Real Estate & Legal Studies in the College of Business located at The Florida State University. The center's primary focus is to support the state's ability to prepare for, respond to, and recover from catastrophic storms.

The bill provides that the State Board of Administration shall annually transfer a portion of the investment income from the Florida Hurricane Catastrophe Fund to the Florida Catastrophic Storm Risk Management Center located at The Florida State University. The amount of funding to be transferred shall be the lesser amount of $1 million, or 35 percent of the fund's investment income minus $10 million, as determined by using the most recent fiscal year-end audited financial statements of the Fund. The bill specifies that any funds transferred must solely be used for and consistent with the center's statutory purpose of supporting the state's ability to prepare for, respond to, and recover from catastrophic storms.

Other than the transfer of a portion of the investment income from the Florida Hurricane Catastrophe Fund to the Florida Catastrophic Storm Risk Management Center at The Florida State University, the bill has no fiscal impact on state or local governments.

The bill is effective July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background on the Florida Hurricane Catastrophe Fund

The Florida Hurricane Catastrophe Fund (FHCF or Fund) is a tax-exempt trust fund created in 1993 as a form of reinsurance for residential property insurers.[1] The purpose of the FHCF is to protect and advance the state's interest in maintaining insurance capacity in Florida by providing reimbursements to insurers for a portion of their catastrophic hurricane losses.

The FHCF sells reinsurance to property insurance companies significantly cheaper than reinsurance sold by private reinsurance companies. It is estimated that coverage purchased through the FHCF costs insurers one-fourth to one-third what it would cost in the private reinsurance market.[2] There are several reasons for these cost savings:[3]

1. The FHCF operating cost is less than 1% of the annual premium collected, whereas, the operating costs for private reinsurance can range from 10% to 15% of the premium collected.
2. The FHCF does not pay reinsurance brokerage commissions.
3. The FHCF has no underwriting costs.
4. The FHCF is a tax-exempt entity that does not pay federal income taxes or state taxes.
5. The FHCF has the ability to issue tax-exempt debt which results in lower financing costs should it become necessary to finance losses with revenue bonds.
6. The FHCF does not include a factor for profit for reinsurance sold by the FHCF.
7. The FHCF does not include a risk load for reinsurance sold by the FHCF.

Each insurance company writing insurance policies covering residential property or any policy covering a residential structure or its contents must participate in the FHCF (s. 215.555(4)(a), F.S. and s. 215.555(2)(c), F.S.). Residential property is defined in s. 627.4025(1), F.S., to include personal lines and commercial lines residential coverage. This coverage includes the following insurance policies: homeowner's, mobile homeowner's, dwelling, tenant's, condominium unit owner's, condominium association, cooperative association, and apartment building.

The FHCF is administered by the State Board of Administration and reimburses property insurers for a selected percentage (45, 75, or 90%) of hurricane losses to residential property above the insurer's retention (deductible).[4] The amount of hurricane losses the FHCF will not reimburse (45, 25, or 10%) is the insurer's co-pay for FHCF reinsurance. Insurers finance the co-pay with funds from insurance premiums paid by homeowners or with private reinsurance. Most property insurers select the 90% coverage level, meaning the FHCF will reimburse the insurer 90% of the insurer's specified hurricane losses with the insurer paying the remaining co-pay of 10% from other sources.

A reimbursement contract between the FHCF and the property insurer governs an insurer's participation in the FHCF and the percentage of the insurer's reimbursement. Reimbursement contracts run from June 1st–May 30th. The current contract year (2013-2014 contract year) runs from June 1, 2013–May 30, 2014.

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[1] s. 215.555, F.S. The FHCF was created after Hurricane Andrew in 1992.

[2] Annual Report of the Florida Hurricane Catastrophe Fund Fiscal Year 2011-2012, p. 16, available at http://www.sbafla.com/fhcf/Home/FHCFReports/tabid/315/Default.aspx (last viewed December 20, 2013).

[3] Annual Report of the Florida Hurricane Catastrophe Fund Fiscal Year 2011-2012, p. 16, available at http://www.sbafla.com/fhcf/Home/FHCFReports/tabid/315/Default.aspx (last viewed December 20, 2013).

[4] Retention is defined to mean the amount of losses below which an insurer is not entitled to reimbursement from the Fund. A retention is calculated for each insurer based on its proportionate share of Fund premiums.

The FHCF must offer two options for reinsurance coverage for all residential property insurers. One of the two options is mandatory and thus must be purchased by all insurers on their residential property exposure. The voluntary coverage option, Temporary Increase In Coverage Limit Options (TICL), offers reinsurance to insurers above the mandatory coverage.

For the mandatory coverage, the FHCF charges insurers the "actuarially indicated" premium for the coverage provided by the FHCF, based on hurricane loss projection models found acceptable by the Florida Commission on Hurricane Loss Projection Methodology. Each insurer's premium amount for mandatory coverage is different because the premium is based on the insured value of the residential property the insurer insures, the location of the property insured, the construction type of the property insured, the deductible amounts for the property insured, and other factors. The premium for mandatory coverage also includes a cash build-up factor which is charged on top of the actuarially indicated premium. For the 2013-2014 contract year, the cash build-up factor is 25%, meaning an insurer's premium is 25% greater than the actuarially indicated premium. By law, the cash build-up factor will remain at 25% for all future years.

Florida law sets the maximum amount the FHCF reimburses insurers each year for the mandatory coverage.[5] This is the FHCF's capacity. Under current law, the FHCF's capacity is $17 billion for each contract year. The capacity does not increase until the FHCF's cash and bonding ability exceeds $34 billion. This allows the FHCF to accumulate funds to pay the maximum mandatory coverage FHCF obligations ($17 billion a year) for claims resulting from hurricanes in back-to-back seasons.[6] Once a $34 billion funding level is reached by the FHCF, the FHCF's capacity will increase. The method for calculating the Fund's capacity under current law allows the FCHF's cash balance to grow in years where there are no hurricanes while keeping the FHCF's exposure (capacity) frozen so that the FHCF is less reliant on bonding to meet its mandatory coverage obligations. For the current contract year, the insurance industry as a whole is covered for losses up to $17 billion by the mandatory coverage.

Before FHCF monies are available to pay claims each insurer must meet a retention/deductible. The retention amount for each insurer is different because the amount is based on the amount of premium the insurer pays to the FHCF. For the 2013-2014 contract year, the insurance industry as a whole has an aggregate retention of $7.213 billion for mandatory coverage, meaning the total of all individual insurer retentions/deductibles will total $7.213 billion per hurricane event if all participating insurers reached their retention. Although the insurance industry's aggregate deductible/retention totals $7.213 billion, insurers can obtain reimbursement from the FHCF before the insurance industry losses total $7.213 billion because loss recovery from the FHCF is based on an individual insurer meeting its own retention for mandatory coverage prior to losses being reimbursed.

The TICL options were added to the FHCF in 2007.[7] The purchase of these options is voluntary and, if purchased, provides the insurer a share of additional coverage above the mandatory FHCF coverage in $1 billion increments. When the TICL options were created in 2007, $12 billion of additional FHCF coverage was available for purchase. However, due to statutory reductions in TICL options available, for the 2013-2014 Fund contract year, the last year TICL coverage is available, only $2 billion is available for purchase.[8] Of the $2 billion available in TICL coverage, $207,280 was purchased by insurance companies.

[5] s. 215.555(4)(c)1., F.S.
[6] The funds may be accumulated from premiums and bonding.
[7] Ch. 2007-1, L.O.F.
[8] Under current law, the maximum amount of TICL coverage offered for purchase by the FHCF decreases by $2 billion each contract year.

For the 2013-14 contract year (June 1, 2013–May 31, 2014), the maximum amount the FHCF would have to reimburse insurers is $17.0002 billion, allocated as follows:

- $17 billion for the mandatory coverage.
- $207,208 for the TICL coverage option.[9]

To fund its obligations of $17.0002 billion the FHCF has $9.764 billion in cash.

Because the obligations of the FHCF exceed its cash on hand by approximately $7.24 billion, if the FHCF had to pay its maximum actual obligations of $17.0002 billion this contract year, it would have to bond for $7.24 billion to have enough money to pay claims. The Fund already has $2 billion in pre-event bonds that will be used to pay claims during this contract year. After accounting for these bonds, the Fund must bond for $5.24 billion this year. In October 2013, the Fund estimated it could borrow $6.1 billion through bonding, which is more than the $5.24 billion needed.[10] Thus, it is anticipated that the Fund has sufficient resources from cash and bonding to pay its obligations in the current contract year.

Revenue bonds issued by the FHCF to pay claims when the FHCF's funds are inadequate are funded by emergency assessments on property and casualty policyholders.[11] The FHCF is authorized to levy emergency assessments against all property and casualty insurance premiums paid by policyholders (other than workers' compensation, accident and health, federal flood and, until May 31, 2016, medical malpractice), including surplus lines policyholders, when reimbursement premiums and other FHCF resources are insufficient to cover the FHCF's obligations.[12] Annual assessments are capped at 6% of premium with respect to losses from any one year and a maximum of 10% of premium to fund hurricane losses from multiple years.[13] Revenue bonds issued by the FHCF may be amortized over a term up to 30 years. Thus, the FHCF may levy assessments for as long as 30 years.

Currently, the FHCF is levying an assessment of 1.3% of premium against all property and casualty insurance policyholders subject to the assessment.[14] Typically, insurers pass this assessment directly to policyholders. The current FHCF assessment is due to a deficit in the Fund associated with the 2005 hurricanes. This is the first assessment the FHCF has had to levy to cover a deficit since its creation in 1993. The current assessment of 1.3% will be levied until December 31, 2016.

The State Board of Administration (SBA) invests funds from the FHCF in accordance with s. 215.47, F.S. and the Fund's investment policy statement. The primary objective of the policy statement can be defined by the following goals: liquidity, safety of principal, and competitive return. These goals are intended to enhance the Fund's investment income by investing in securities that are highly liquid, relatively short term, and have a credit quality in accordance with the policy in order to maintain safety of principal.

The Fund's investment income varies by year but has accounted for $506,211,000 in income over the last ten years as shown in the following historical income chart:

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[9] Report of Claims-Paying Capacity Estimates dated October 15, 2013, available at http://www.sbafla.com/fhcf/BondingProgram/BondingCapacityAnalysisReports/tabid/318/Default.aspxlast (last accessed December 20, 2013).
[10] https://www.flrules.org/Gateway/View_notice.asp?id=13718436 (last accessed November 18, 2013).
[11] s. 215.555(6)(a)1., F.S.; s. 215.555(6)(b)1., F.S.
[12] s. 215.555(6)(b)1., F.S.; s. 215.555(6)(b)(10), F.S.
[13] s. 215.555(6)(b)2., F.S.
[14] A 1% assessment was levied and paid by insurers from January 1, 2007–December 31, 2010. The 1% assessment was increased to 1.3% on January 1, 2011 due to increasing losses from the 2005 hurricanes.

Florida Hurricane Catastrophe Fund Investment Income[15] (Excluding FHCF Finance Corporation)	
Ten Year History of Audited Financial Statements	
Fiscal Year Ending:	**Investment Income:**
June 30, 2004	$58,127,000
June 30, 2005	$108,672,000
June 30, 2006	$103,175,000
June 30, 2007	$36,065,000
June 30, 2008	$46,816,000
June 30, 2009	$7,803,000
June 30, 2010	$54,298,000
June 30, 2011	$29,983,000
June 30, 2012	$26,634,000
June 30, 2013	$34,638,000
Grand Total	**$506,211,000**

Background on The Florida Catastrophic Storm Risk Management Center

The Florida Legislature created the Florida Catastrophic Storm Risk Management Center (center) in 2007.[16] The center is housed within the Department of Risk Management/Insurance, Real Estate & Legal Studies in the College of Business located at The Florida State University. The center's primary focus is to support the state's ability to prepare for, respond to, and recover from catastrophic storms. The support the center provides includes:[17]

- Coordinating and disseminating research efforts that are expected to have an immediate impact on policy and practices related to catastrophic storm preparedness.
- Coordinating and disseminating information related to catastrophic storm risk management, including but not limited to research and information that benefits business, consumers and public policy makers.
- Facilitating Florida's preparedness and responsiveness to catastrophic storms and collaborating with other public and private institutions.
- Creating and promoting studies that enhance the educational options available to risk management and insurance students.
- Publishing and disseminating findings primarily related to risk management.
- Organizing and sponsoring conferences, symposiums, and workshops to educate consumers and policymakers.

Effect of Proposed Changes

The bill provides that the State Board of Administration shall annually transfer a portion of the investment income from the Florida Hurricane Catastrophe Fund to the Florida Catastrophic Storm Risk Management Center (center) located at The Florida State University. The amount of funding to be transferred shall be the lesser amount of $1 million, or 35 percent of the funds' investment income minus $10 million, as determined by using the most recent fiscal year-end audited financial statements of the Fund. The bill specifies that any funds transferred must solely be used for and consistent with the center's statutory purpose of supporting the state's ability to prepare for, respond to, and recover from catastrophic storms. In addition, the bill is not intended to limit or supplant any funding otherwise available to the center.

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[15] Investment income amounts gathered from the Florida Hurricane Catastrophe Fund Audited Financial Statements available at: http://www.sbafla.com/fhcf/Home/AuditedFinancials/tabid/319/Default.aspx (Last accessed April 2, 2014.)

[16] Ch. 2007-90, s.24, L.O.F. (creating s. 1004.647, F.S., effective June 11, 2007)

[17] Information gathered from the Florida Catastrophic Storm Risk Management Center webpage available at: http://www.stormrisk.org/about-the-center (Last accessed April 2, 2014.)

Based on provisions of the bill requiring the transfer of the lesser amount of $1 million, or 35 percent of the Florida Hurricane Catastrophe Fund's investment income minus $10 million, the approximate annual average transfer that would have occurred over the previous five years would have been $498,810. The calculation of this figure is shown as follows:

Florida Hurricane Catastrophe Fund Investment Income (Excluding FHCF Finance Corporation)			
Audited Financial Statements			
		The lessor of:	
Fiscal Year Ending:	**Investment Income:**	35 percent of Investment Income less $10,000,000	$1,000,000
June 30, 2009	$7,803,000	$2,731,050 - $10,000,000 = ***$0***	$1,000,000
June 30, 2010	$54,298,000	$19,004,300 - $10,000,000 = $9,004,300	***$1,000,000***
June 30, 2011	$29,983,000	$10,494,050 - $10,000,000 = ***$494,050***	$1,000,000
June 30, 2012	$26,634,000	$9,321,900 - $10,000,000 = ***$0***	$1,000,000
June 30, 2013	$34,638,000	$12,123,300 - $10,000,000 = $2,123,300	***$1,000,000***
Total amount of investment income that would have been transferred for the previous five years:			$2,494,050
Five year average of investment income that would have been transferred:			***$498,810***

[18]

B. SECTION DIRECTORY:

Section 1: Amends s. 215.555, F.S., relating to the Florida Hurricane Catastrophe Fund.

Section 2: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

[18] Investment income amounts gathered from the Florida Hurricane Catastrophe Fund Audited Financial Statements available at: http://www.sbafla.com/fhcf/Home/AuditedFinancials/tabid/319/Default.aspx (Last accessed April 2, 2014.)

D. FISCAL COMMENTS:

The bill provides that the State Board of Administration shall annually transfer a portion of the investment income from the Florida Hurricane Catastrophe Fund to the Florida Catastrophic Storm Risk Management Center located at The Florida State University. The amount of funding to be transferred shall be the lesser amount of $1 million, or 35 percent of the fund's investment income minus $10 million, as determined by using the most recent fiscal year-end audited financial statements of the Fund. The bill specifies that any funds transferred must solely be used for and consistent with the center's statutory purpose of supporting the state's ability to prepare for, respond to, and recover from catastrophic storms.

Other than the transfer of a portion of the investment income from the Florida Hurricane Catastrophe Fund to the Florida Catastrophic Storm Risk Management Center at The Florida State University, the bill has no fiscal impact on state or local governments.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

2. Other:

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the Florida Catastrophic Storm Risk Management Center; amending s. 215.555, F.S.; transferring a portion of the investment income of the Florida Hurricane Catastrophe Fund to the Florida Catastrophic Storm Risk Management Center to support the center's ongoing operations; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraphs (d), (e), and (f) of subsection (7) of section 215.555, Florida Statutes, are redesignated as paragraphs (e), (f), and (g), respectively, and a new paragraph (d) is added to that subsection, to read:

215.555 Florida Hurricane Catastrophe Fund.—

(7) ADDITIONAL POWERS AND DUTIES.—

(d) Beginning with the 2014-2015 fiscal year, the State Board of Administration shall annually transfer a portion of the investment income of the Florida Hurricane Catastrophe Fund to the Florida Catastrophic Storm Risk Management Center created by s. 1004.647 to fund the center's ongoing operations. The amount of the transfer for a particular fiscal year shall be the lesser of $1 million, or 35 percent of the fund's investment income minus $10 million, as determined by using the most recent fiscal year-end audited financial statements. The amount transferred

must be used solely for and consistent with the center's statutory purpose of supporting the state's ability to prepare for, respond to, and recover from catastrophic storms. This paragraph is not intended to limit or supplant any funding otherwise available to the center.

Section 2. This act shall take effect July 1, 2014.

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 BDT
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.

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[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.

Medical Gases

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

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

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[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.
[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.

- 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 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

[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 March 22, 2014).

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 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]

[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.

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:

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.

A bill to be entitled

An act relating to the Florida Drug and Cosmetic Act; reordering and amending s. 499.003, F.S.; revising definitions; amending s. 499.01, F.S.; deleting permit requirements for medical oxygen retail establishments, compressed medical gas wholesale distributors, and compressed medical gas manufacturers; conforming cross-references; amending s. 499.0121, F.S.; deleting reference to establishments that handle medical oxygen; amending s. 499.01211, F.S.; revising membership of the Drug Wholesale Distributor Advisory Council; conforming cross-references; amending s. 499.041, F.S.; deleting certain permitting fees for compressed medical gas manufacturers, medical gas wholesale distributors, or medical oxygen retail establishments; amending ss. 499.051, 499.066, 499.0661, and 499.067, F.S.; conforming provisions to changes made by the act; creating part III of chapter 499, F.S., relating to medical gases; providing for applicability and preemption; authorizing the department to administer and enforce the part; requiring a state, county, or municipal attorney to institute appropriate proceedings for a violation; providing notice requirements for the department; providing definitions; requiring a permit for distribution of medical gas as a wholesale

distributor, manufacturer, or medical oxygen retail establishment; authorizing the department to adopt rules; providing permitting standards; providing requirements to obtain a permit; providing for permit renewal; providing guidelines to change certain information; authorizing the department to revoke permits for failure to comply; requiring certain distributors of medical gases to obtain a permit and maintain permit renewal; requiring an applicant to provide a sworn statement disclosing certain information; providing minimum qualifications for licensure; requiring an applicant or permittee to designate and maintain a registered agent for service of process; providing minimum requirements for the storage and handling of gases and patient information; requiring a facility of wholesale distribution of medical gases to secure the facility from unauthorized entry; providing recommended security measures; requiring medical gases to be stored and packaged in accordance with certain regulations or standards; requiring a visual examination of a medical gas container upon receipt; requiring that a damaged or unfit medical gas be quarantined; requiring inspection of outgoing shipments; requiring a wholesale distributor of medical gases to review the records that accompany a medical gas received by the

distributor; requiring returned medical gases to be reprocessed for resale; requiring certain medical gases to be quarantined; requiring an acquiring distributor or manufacturer to provide notice of adulteration, misbranding, or suspected adulteration or misbranding; requiring certain medical gases to be retained; requiring a wholesale distributor of medical gases to comply with certain due diligence requirements; requiring that certain information must be provided by the supplying distributor to the acquiring distributor; providing an exception; requiring a wholesale distribution of medical gases to establish and maintain certain records; requiring the records to be made available for a certain amount of time; providing requirements related to trade secret information; requiring a wholesale distributor to establish, maintain, and adhere to written policies and procedures; providing certain mandatory policies; prohibiting certain acts; providing that certain acts are felonies of the third degree; providing additional penalties of forfeiture; providing requirements related to salvaging and reprocessing; authorizing the department to recognize a third party inspection of wholesale distributors of medical gases or recognize other states inspections; providing for a right of review; providing notice requirements; providing for

the deposit of fees in a trust fund and authorizing the department to use such funds; amending ss. 409.9201, 460.403, 465.0265, 499.01212, 499.015, 499.024, and 499.05, F.S.; conforming cross-references; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (12) through (32) and subsections (47) through (55) of section 499.003, Florida Statutes are renumbered as sections (11) through (31) and subsections (46) through (54), respectively, present subsection (11) is reordered and amended, and present subsections (43) and (46) of that section are amended, to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(32) ~~(11)~~ "~~Compressed~~ Medical gas" means any liquefied or vaporized gas that is a prescription drug, whether ~~it is~~ alone or in combination with other gases, and as defined in the federal act.

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal ~~Food, Drug, and Cosmetic~~ act or s. 465.003(8), s. 499.007(13), or subsection (32) ~~(11), subsection (46),~~ or subsection (52) ~~(53)~~, except that

an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

~~(46) "Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on 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 2. Paragraphs (m), (n), and (o) of subsection (1), paragraphs (a), (c), (g), (m), (n), and (o) of subsection (2), and subsection (5) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(1) Prior to operating, a permit is required for each person and establishment that intends to operate as:

~~(m) A medical oxygen retail establishment;~~

~~(n) A compressed medical gas wholesale distributor;~~

~~(o) A compressed medical gas manufacturer;~~

(2) The following permits are established:

(a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a

prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which apply to a wholesale distributor.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(53)(d) ~~499.003(54)(d)~~ is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(c) Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-

state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(30)(e) ~~499.003(31)(e)~~.

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

(g) Restricted prescription drug distributor permit.—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(53)(a) ~~499.003(54)(a)~~.

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription

drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(53)(d) ~~499.003(54)(d)~~ to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs

necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

3. A person who applies for a permit as a restricted

prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

~~(m) Medical oxygen retail establishment permit.—A medical oxygen retail establishment permit is required for any person that sells medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a pharmacy licensed under chapter 465.~~

~~1. A medical oxygen retail establishment may not possess, purchase, sell, or trade any prescription drug other than medical oxygen.~~

~~2. A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.~~

~~3. A medical oxygen retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.~~

~~4. Prescription medical oxygen sold by a medical oxygen retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.~~

~~(n) Compressed medical gas wholesale distributor permit.—A compressed medical gas wholesale distributor is a wholesale distributor that is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient. The compressed medical gas must be in the original sealed container that was purchased by that wholesale distributor. A compressed medical gas wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than compressed medical gases. The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use. With respect to the emergency use of prescription medical oxygen, those rules may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.~~

~~(o) Compressed medical gas manufacturer permit.—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.~~

~~1. A compressed medical gas manufacturer may not manufacture or possess any prescription drug other than compressed medical gases.~~

~~2. A compressed medical gas manufacturer may engage in~~

~~wholesale distribution of compressed medical gases manufactured at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.~~

~~3. A compressed medical gas manufacturer must comply with all appropriate state and federal good manufacturing practices.~~

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(53)(a)3. ~~499.003(54)(a)3.~~, if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the

prescription drugs in accordance with current state and federal good manufacturing practices; and

(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection.

Section 3. Paragraph (b) of subsection (2) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(2) SECURITY.—

(b) An establishment that is used for wholesale drug distribution must be equipped with:

1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers. ~~and establishments that only handle medical oxygen; and~~

2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Section 4. Subsection (2) of section 499.01211, Florida Statutes, is amended, and paragraph (h) is added to that subsection, to read:

499.01211 Drug Wholesale Distributor Advisory Council.—

(2) The Secretary of Business and Professional Regulation or his or her designee and the Secretary of Health Care Administration or her or his designee shall be members of the council. The Secretary of Business and Professional Regulation shall appoint 10 ~~nine~~ additional members to the council who shall be appointed to a term of 4 years each, as follows:

(a) Three different persons each of whom is employed by a different prescription drug wholesale distributor permitted ~~licensed~~ under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003(46) ~~499.003(47)~~.

(b) One person employed by a prescription drug wholesale distributor permitted ~~licensed~~ under this part which is a secondary wholesale distributor, as defined in s. 499.003(51) ~~499.003(52)~~.

(c) One person employed by a retail pharmacy chain located in this state.

(d) One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.

(e) One person who is a physician licensed pursuant to chapter 458 or chapter 459.

(f) One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.

(g) One person who is an employee of a pharmaceutical manufacturer.

(h) One person who is an employee of a medical gas manufacturer or medical gas wholesale distributor and who has been recommended by the Compressed Gas Association.

Section 5. Paragraph (e) of subsection (1), paragraph (b) of subsection (2), and paragraph (b) of subsection (3) of section 499.041, Florida Statutes, are amended to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(1) The department shall assess applicants requiring a manufacturing permit an annual fee within the ranges established in this section for the specific type of manufacturer.

~~(e) The fee for a compressed medical gas manufacturer permit may not be less than $400 or more than $500 annually.~~

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of

wholesaling.

~~(b) The fee for a compressed medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.~~

(3) The department shall assess an applicant that is required to have a retail establishment permit an annual fee within the ranges established in this section for the specific type of retail establishment.

~~(b) The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.~~

Section 6. Subsections (1) through (4) of section 499.051, Florida Statutes, are amended to read:

499.051 Inspections and investigations.—

(1) The agents of the department and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this chapter ~~part~~ during business hours for the purpose of enforcing this chapter ~~part~~, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this chapter ~~part~~ and rules adopted under this chapter ~~part~~ regarding any drug, device, or cosmetic product.

(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this chapter ~~part~~ and rules adopted under this chapter ~~part~~ constitutes permission for any entry or inspection of the premises in order to verify compliance with this chapter ~~part~~ and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(4) Any application for a permit made pursuant to s. 499.012 or s. 499.831 and rules adopted under those sections ~~that section~~ constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this chapter ~~part~~ and the rules adopted by the department to administer this chapter ~~part~~, in order to discover, investigate, and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

Section 7. Subsections (1) through (4) of section 499.066, Florida Statutes, are amended to read:

499.066 Penalties; remedies.—In addition to other penalties and other enforcement provisions:

(1) The department may institute such suits or other legal proceedings as are required to enforce any provision of this chapter ~~part~~. If it appears that a person has violated any

provision of this chapter ~~part~~ for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department's possession.

(2) If any person engaged in any activity covered by this chapter ~~part~~ violates any provision of this chapter ~~part~~, any rule adopted under this chapter ~~part~~, or a cease and desist order as provided by this chapter ~~part~~, the department may obtain an injunction in the circuit court of the county in which the violation occurred or in which the person resides or has its principal place of business, and may apply in that court for such temporary and permanent orders as the department considers necessary to restrain the person from engaging in any such activities until the person complies with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and the orders of the department authorized by this chapter ~~part~~ or to mandate compliance with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and any order or permit issued by the department under this chapter ~~part~~.

(3) The department may impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of any provision of this chapter ~~part~~ or rules adopted under this chapter ~~part~~. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section

shall be deposited into the Professional Regulation Trust Fund and are appropriated for the use of the department in administering this chapter ~~part~~. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a) The severity of the violation;

(b) Any actions taken by the person to correct the violation or to remedy complaints; and

(c) Any previous violations.

(4) The department shall deposit any rewards, fines, or collections that are due the department and which derive from joint enforcement activities with other state and federal agencies which relate to this chapter ~~part~~, chapter 893, or the federal act, into the Professional Regulation Trust Fund. The proceeds of those rewards, fines, and collections are appropriated for the use of the department in administering this chapter ~~part~~.

Section 8. Paragraph (a) of subsection (1) and paragraph (a) of subsection (2) of section 499.0661, Florida Statutes, are amended to read:

499.0661 Cease and desist orders; removal of certain persons.—

(1) CEASE AND DESIST ORDERS.—

(a) In addition to any authority otherwise provided in this chapter, the department may issue and serve a complaint stating charges upon a ~~any~~ permittee or upon an ~~any~~ affiliated

party, whenever the department has reasonable cause to believe that the person or individual named therein is engaging in or has engaged in conduct that is:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A violation of a ~~any~~ provision of this chapter ~~part~~;

3. A violation of a ~~any~~ rule of the department;

4. A violation of an ~~any~~ order of the department; or

5. A breach of a ~~any~~ written agreement with the department.

(2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

(a) The department may issue and serve a complaint stating charges upon an ~~any~~ affiliated party and upon the permittee involved whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A willful violation of this chapter ~~part~~; however, if the violation constitutes a misdemeanor, a complaint may not be

served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;

3. A violation of a ~~any other~~ law involving fraud or moral turpitude which constitutes a felony;

4. A willful violation of a ~~any~~ rule of the department;

5. A willful violation of an ~~any~~ order of the department; or

6. A material misrepresentation of fact, made knowingly and willfully or made with reckless disregard for the truth of the matter.

Section 9. Subsections (1) and (2), paragraph (c) of subsection (3), and subsections (4) through (9) of section 499.067, Florida Statutes, are amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(1)(a) The department may deny, suspend, or revoke a permit if it finds that there has been a substantial failure to comply with this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, the rules adopted under ~~this part or~~ those chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.

(b) The department may deny an application for a permit or certification, or suspend or revoke a permit or certification,

if the department finds that:

1. The applicant is not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification.

2. The applicant has not met the requirements for the permit or certification.

3. The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.012.

4. The applicant, permittee, or person certified under s. 499.012(16) demonstrates any of the conditions enumerated in s. 499.012.

5. The applicant, permittee, or person certified under s. 499.012(16) has committed any violation of ss. 499.005-499.0054 or this chapter.

(2) The department may deny, suspend, or revoke any registration required by the provisions of this chapter ~~part~~ for the violation of any provision of this chapter ~~part~~ or of any rules adopted under this chapter ~~part~~.

(3) The department may revoke or suspend a permit:

(c) If the permittee has violated a ~~any~~ provision of this chapter ~~part~~ or rules adopted under this chapter ~~part~~.

(4) If a ~~any~~ permit issued under this chapter ~~part~~ is revoked or suspended, the owner, manager, operator, or proprietor of the establishment shall cease to operate as the permit authorized, from the effective date of the suspension or

revocation until the person is again registered with the department and possesses the required permit. If a permit is revoked or suspended, the owner, manager, or proprietor shall remove all signs and symbols that identify the operation as premises permitted as a drug wholesaling establishment; drug, device, or cosmetic manufacturing establishment; or retail establishment. The department shall determine the length of time for which the permit is to be suspended. If a permit is revoked, the person that owns or operates the establishment may not apply for a ~~any~~ permit under this chapter ~~part~~ for a period of 1 year after the date of the revocation. A revocation of a permit may be permanent if the department considers that to be in the best interest of the public health.

(5) The department may deny, suspend, or revoke a permit issued under this part which authorizes the permittee to purchase prescription drugs if an ~~any~~ owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of a ~~any~~ violation of this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, any rules adopted under ~~this part or~~ those chapters, or any federal or state drug law, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld.

(6) The department shall deny, suspend, or revoke the permit of a ~~any~~ person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under this

chapter ~~part~~ will avoid an administrative penalty, civil action, or criminal prosecution.

(7) Notwithstanding s. 120.60(5), if a permittee fails to comply with s. 499.012(6) or s. 499.831, as applicable, the department may revoke the permit of the permittee and shall provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department and, if the permittee is not a natural person, to the permittee's registered agent on file with the Department of State.

(8) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(15).

(9) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

Section 10. Part III of chapter 499, Florida Statutes, consisting of sections 499.81 through 499.99, is created to read:

PART III

MEDICAL GASES

499.81 Administration and enforcement.—

(1) The provisions of this part are cumulative and shall be construed and applied as being in addition to, and not in

substitution for or limitation of, any powers, duties, or authority of the department under any other law of this state; except that, with respect to the regulation of medical gas, the provisions of this part shall control over any conflicting provisions.

(2) The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the manufacture or distribution of medical gas.

(3) For the purpose of an investigation or proceeding conducted by the department under this part, the department may administer oaths, take depositions, subpoena witnesses, and compel the production of books, papers, documents, or other records. Challenges to, and enforcement of, subpoenas and orders shall be handled as provided in s. 120.569.

(4) Each state attorney, county attorney, or municipal attorney to whom the department or its designated agent reports a violation of this part shall cause appropriate proceedings to be instituted in the proper courts without delay and prosecuted in the manner required by law.

(5) This part does not require the department to report, for the institution of proceedings under this part, minor violations of this part when the department believes that the public interest will be adequately served by a written notice or warning.

499.82 Definitions.—As used in this part, the term:

(1) "Adulterated" means:

(a) Consisting in whole or in part of impurities or deleterious substances exceeding normal specifications;

(b) Produced, prepared, packed, or held under conditions whereby the medical gas may have been contaminated causing it to be rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to ensure that the medical gas meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it is represented to possess;

(c) Having a container interior that is composed in whole or in part of a poisonous or deleterious substance which may render the contents injurious to health; or

(d) Represented as a medical gas, with strength differing from, or quality or purity falling below, the standard set forth in the USP-NF. Such determination shall be made in accordance with the tests or methods of assay in the USP-NF, or validated equivalent, or in the absence of or inadequacy of these tests or methods of assay, tests or methods of assay prescribed under the federal act. No medical gas defined in USP-NF shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity set forth in the USP-NF, if its difference in strength, quality, or purity from that standard is plainly stated on its label.

(2) "Distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a medical gas, whether by passage of title, physical movement, or both. The term does not include:

(a) The dispensation or administration of medical gas;

(b) The delivery of, or an offer to deliver, a medical gas by a common carrier in the usual course of business as a common carrier; or

(c) Sales activities taking place in a location owned or controlled by, or staffed by persons employed by, a person or entity permitted in this state to distribute medical gas, where the locations where such sales activities are taking place do not physically store or move medical gas.

(3) "Emergency" means any act or circumstance during a state of emergency declared pursuant to s. 252.36, including, but not limited to:

(a) Transfer of a medical gas between wholesale distributors of medical gases or between a wholesale distributor of medical gases and a retail pharmacy or health care entity to alleviate a temporary shortage of a medical gas arising from a delay in or interruption of regular distribution schedules.

(b) Sales to licensed emergency medical services, including ambulance companies and firefighting organizations in this state, or licensed practitioners allowed to dispense medical gases in the treatment of acutely ill or injured persons.

(c) Provision of emergency supplies of medical gases to nursing homes during hours of the day when necessary medical gases cannot be obtained.

(d) Transfer of medical gases between retail pharmacies to alleviate a temporary shortage.

(4) "Emergency use oxygen" means oxygen USP administered in emergency situations without a prescription for oxygen deficiency and resuscitation. The container must be labeled in accordance with requirements of the United States Food and Drug Administration.

(5) "Federal act" means the Federal Food, Drug, and Cosmetic Act.

(6) "Intracompany transaction" means a transaction between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity.

(7) "Medical gas" means a liquefied or vaporized gas that is a prescription drug, whether alone or in combination with other gases, and as defined in the federal act.

(8) "Medical gas related equipment" means a device used as a component part or accessory used to contain or control the flow, delivery, or pressure during the administration of a medical gas, such as liquid oxygen base and portable units, pressure regulators and flow meters, and oxygen concentrators.

(9) "Misbranded " means having a label that is false or misleading; a label without the name and address of the manufacturer, packer, or distributor and without an accurate

statement of the quantities of active ingredients; or a label without an accurate monograph for the medical gas, except in the case of mixtures of designated medical gases where the label identifies the component percentages of each designated medical gas used to make the mixture.

(10) "Prescription medical oxygen" means oxygen USP which can only be sold on the order or prescription of a practitioner authorized to prescribe. The label of prescription medical oxygen must comply with labeling requirements for oxygen under the federal act.

(11) "Product labeling" means the labels and other written, printed, or graphic matter upon an article, or the containers or wrappers that accompany an article, except for letters, numbers, and symbols stamped into the container as required by the federal Department of Transportation.

(12) "USP" means United States Pharmacopeia.

(13) "USP-NF" means United States Pharmacopeia-National Formulary.

(14) "Wholesale distribution" means the distribution of medical gas by a wholesale distributor of medical gases to a person other than a consumer or patient. Wholesale distribution of medical gases does not include:

(a) The sale, purchase, or trade of a medical gas, an offer to sell, purchase, or trade a prescription drug or device, or the dispensing of a medical gas pursuant to a prescription;

(b) The sale, purchase, or trade of a medical gas or an

offer to sell, purchase, or trade a medical gas for emergency medical reasons;

(c) Intracompany transactions;

(d) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade a medical gas among hospitals, pharmacies, or other health care entities that are under common control;

(e) The sale, purchase, or trade of a medical gas or the offer to sell, purchase, or trade a medical gas by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(f) The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a medical gas for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of such organizations;

(g) The return of residual medical gas that may be reprocessed in accordance with manufacturer's procedures, or the return of recalled, expired, damaged, or otherwise nonsalable medical gas, when conducted by a hospital, health care entity, pharmacy, or charitable institution to a wholesale distributor of medical gases;

(h) Activities exempt from wholesale distribution as defined in s. 499.003(53); or

(i) Other transactions excluded from the definition of wholesale distribution under the federal act or regulations implemented under the federal act related to medical gas.

(15) "Wholesale distributor" means any person engaged in wholesale distribution of medical gas within or into this state, including, but not limited to, manufacturers, own-label distributors, private-label distributors, warehouses, including manufacturers' and distributors' warehouses, and wholesale medical gas warehouses.

499.831 Permits.—

(1) Before operating, unless exempted under this part, a permit is required for each person and establishment, whether inside or outside of this state, that intends to distribute medical gas within or into this state and operate as:

(a) A medical gas wholesale distributor;

(b) A medical gas manufacturer; or

(c) A medical oxygen retail establishment.

(2) The following permits are established:

(a) Medical gas wholesale distributor permit.—A medical gas wholesale distributor permit is required for the wholesale distribution of medical gases, whether within or into this state, to a person other than the consumer or patient. The medical gas must be in the original container obtained by the wholesale distributor without further manufacturing operations. A medical gas wholesale distributor may not possess or engage in the wholesale distribution of a prescription drug that is not a

medical gas. The department shall adopt rules to govern the wholesale distribution of prescription medical oxygen for emergency use. Rules regarding the emergency use of prescription medical oxygen may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.

(b) Medical gas manufacturer permit.—A medical gas manufacturer permit is required for a person that engages in the manufacture of medical gases by physical air separation, chemical action, purification, or filling containers by a liquid to liquid, liquid to gas, or gas to gas process and that distributes those medical gases within or into this state.

1. A medical gas manufacturer may not manufacture or possess a prescription drug that is not a medical gas.

2. A medical gas manufacturer may engage in wholesale distribution of medical gases manufactured without a medical gas wholesale distributor permit, but must comply with the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.

3. A medical gas manufacturer shall comply with all appropriate state and federal good manufacturing practices.

(c) Medical oxygen retail establishment permit.—A medical oxygen retail establishment permit is required for a person that sells medical oxygen directly to patients. The sale must be based on an order from a practitioner authorized by law to prescribe. The medical oxygen retail establishment permit

excludes a pharmacy licensed under chapter 465.

1. A medical oxygen retail establishment may not possess, purchase, sell, or trade a prescription drug that is not medical oxygen.

2. A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe.

3. Prescription medical oxygen sold by a medical oxygen retail establishment pursuant to an order from a practitioner may not be returned into the retail establishment's inventory.

4. A medical oxygen retail establishment that refills medical oxygen shall comply with all appropriate state and federal good manufacturing practices.

5. A medical oxygen retail establishment shall comply with the requirements of s. 499.87.

(3) The department shall adopt rules establishing the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct. An application for a permit must include:

(a) All trade or business terms used by the permittee, including "doing business as (d/b/a)" and "formerly known as," which cannot be identical to the name used by an unrelated wholesale distributor permitted to purchase medical gas in the state;

(b) The name of the owner and operator of the permittee

including:

1. The name, business address, and date of birth, if the permittee is an individual.

2. The name, business address, date of birth of each partner, the name of the partnership, and federal employer identification number, if the permittee is a partnership.

3. The name, business address, and title of each corporate officer and director, the corporate names, the state of incorporation, the federal employer identification number, and the name and business address of the parent company, if one exists, if the permittee is a corporation.

4. The full name and business address of the sole proprietor and the name and federal employer identification number of the business entity, if the permittee is a sole proprietorship.

5. The name, business address, and title of each company officer, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized, if the permittee is a limited liability company.

(c) A list of all disciplinary actions pertinent to wholesale distributors of prescription drugs or controlled substances by any state and federal agencies against the wholesale distributor distributing medical gas into the state and any disciplinary actions against principals, owners, directors, or officers; and

(d) An address and description of each facility and warehouse, including all locations used for medical gas storage or wholesale distribution including a description of the security system.

(4) A permit issued pursuant to this part may be issued to a natural person who is at least 18 years of age or to an applicant who is not a natural person if the person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

(5) An applicant for a permit shall submit the appropriate fee for the permit for which he or she is applying. The fee shall be determined by the department.

(a) The fee for a medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.

(b) The fee for a medical gas manufacturer permit may not be less than $400 or more than $500 annually.

(c) The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.

(6) Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant pursuant to the rules adopted under this part.

(7)(a) A permit issued under this part may be renewed by submitting an application for renewal on a form furnished by the department and paying the appropriate fee.

(b) If a renewal application and fee are submitted and postmarked after expiration of the permit, a late renewal

delinquent fee of $100, plus the required renewal fee must be paid within 60 days after expiration of the permit.

(c) Upon approval of the renewal application by the department and payment of the required renewal fee, the department shall issue a permit to the applicant pursuant to the rules adopted under this part.

(d) The department shall adopt rules for the biennial renewal of permits.

(8)(a) A permit, unless suspended or revoked, automatically expires 2 years after the last day of the month in which the permit was issued.

(b) Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this part has expired and cannot be renewed, the establishment must submit an application for a new permit, pay the application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department before the establishment may engage in activities that require a permit under this part.

(9) A permitted person in good standing may change permit type to a different permit under s. 499.831 by completing a new application for the requested permit, paying the additional amount due for the permit fee if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit shall expire on the expiration date of the original

permit. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(10)(a) A permit issued by the department is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily, and is not valid for any establishment other than the establishment for which it was originally issued except as provided in this part. The department is authorized to approve a change of the permit holder.

(b) Changes by authorized persons are permitted as follows:

1. A person permitted under this part must notify the department 30 days before making a change of location. The department shall set a change of location fee not to exceed $100.

2. When a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned, or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee, an application for a new permit shall be required. The application for the new permit must be made 30 days before the change of ownership. If the application for the new permit is not made 30 days before the change of ownership, and if the new owner acquires a permitted wholesale distributor or manufacturer, and the new owner has held another permit under this chapter for at least 18 months

and has not been found to have violated the provisions of this chapter in the preceding 18 months, the new owner can operate under the permit of the acquired entity if the application for a new permit is submitted by the first business day after ownership is transferred or assigned. The new owner is responsible for compliance with all laws and regulations governing medical gas. If the application is denied, the new owner shall immediately cease operation at the establishment until a permit is issued to the new owner.

3. A permit holder may make a change of business name without submitting a new permit application and must notify the department 30 days before making the name change. The permit holder may continue to operate the establishment under the old name until the department approves of the name change and issues a permit under the new name.

4. If an establishment permitted under this part closes, the owner must notify the department in writing before the effective date of the closure and must:

a. Return the permit to the department.

b. If the permittee is authorized to distribute medical gas, indicate the disposition of such medical gas, including the name, address, and inventory, and provide the name and address of a contact with access to records that are required to be maintained under this part. Transfer of ownership of medical gas may be made only to persons authorized to possess medical gas under this part.

(11) Any change in information required under this section shall be submitted to the department 30 days before such change. The department may revoke the permit of any person that fails to comply with this part.

499.841 Additional requirements for licensure of a wholesale distributor of medical gases.—

(1) A wholesale distributor of medical gases that resides in the state or provides services within or into this state must obtain a permit from the department and must renew the permit with the department biennially on an application provided by the department. In order to distribute medical gases into this state pursuant to this subsection, out-of-state medical gas wholesale distributors must maintain a valid license or permit in the state in which they reside, if required, and proof of registration set forth in s. 499.98(4)(a), if required.

(2) Wholesale distributors may not operate from or receive a permit for a residence, except that a place of residence may be used for on call delivery of homecare oxygen by a home respiratory care technician. If wholesale distribution operations are conducted at more than one location within the state or distributed from more than one location into the state, each location must be permitted by the department.

499.85 Minimum qualifications.—

(1) The department shall consider the following factors in determining the eligibility for, and renewal of, a permit of persons who engage in the wholesale distribution of medical gas:

(a) A finding by the department that the applicant has violated or been disciplined by a regulatory agency in any state for violating a federal, state, or local law relating to the wholesale distribution of medical gases.

(b) A criminal conviction of the applicant under a federal, state, or local law.

(c) The applicant's past experience in the manufacture or wholesale distribution of medical gases.

(d) False or fraudulent material provided by the applicant in an application made in connection with the manufacturing or wholesale distribution of medical gases.

(e) A suspension, sanction, or revocation by a federal, state, or local government against a license or permit currently or previously held by the applicant or its owners for violations of a federal, state, or local law regarding medical gas.

(f) Compliance with previously granted licenses or permits.

(g) Compliance with the requirements of wholesale distributors to medical gases to maintain records or make records available to the department licensing authority or federal, state, or local law enforcement officials.

(h) Other factors or qualifications the department considers relevant to and consistent with the public health and safety.

(2) The applicant shall provide a sworn statement providing complete disclosure of any past criminal convictions

and violations of federal, state, or local laws regarding medical gases or a sworn statement that the applicant has not been convicted of or disciplined for any criminal or prohibited acts.

499.86 Registered agent.—Each applicant or permittee under this part shall designate and maintain a registered agent in this state for service of process. If an applicant or permittee does not designate a registered agent, or if, after reasonable diligence, service of process cannot be completed, service of process may be effected by service upon the Secretary of State as agent of the applicant or permittee. A copy of the service of process shall be mailed to the applicant or permittee by the department by certified mail, return receipt requested, or postage prepaid, at the address such applicant or permittee has designated on the applicant's or permittee's application for licensure in this state.

499.87 Minimum requirements for the storage and handling of medical gases; establishment and maintenance of medical gas records.—

(1) Minimum requirements shall be established for the storage, handling, transport, and shipment of medical gases and for the maintenance of wholesale distribution records by wholesale distributors of medical gases and their officers, agents, representatives, and employees.

(2) A facility at which a medical gas is received, stored, warehoused, handled, held, offered, marketed, displayed, or

transported from, as necessary to avoid a negative effect on the identity, strength, quality, or purity of the medical gas, shall:

(a) Be of suitable construction to ensure that medical gases are maintained in accordance with the product labeling of the medical gas or in compliance with the USP-NF.

(b) Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations.

(c) Have adequate storage areas with appropriate lighting, ventilation, space, equipment, and security conditions.

(d) Have a quarantined area for storage of medical gases that are suspected of being misbranded, adulterated, or otherwise unfit for distribution.

(e) Be maintained in an orderly condition.

(f) Be a commercial location and not a personal dwelling or residence location, except for a personal dwelling location used for on-call delivery of oxygen USP for homecare use where the person providing on-call delivery is employed by or acting under a written contract with a permittee.

(g) Provide for the secure and confidential storage of patient information, if applicable, with restricted access and policies and procedures to protect the integrity and confidentiality of the patient information.

(h) Provide and maintain appropriate inventory controls to detect and document any theft of nitrous oxide.

499.88 Security.—

(1) A facility used for wholesale distribution of medical gases shall protect such gases within the facility from unauthorized entry by using the following security measures:

(a) Keep access from outside the premises well-controlled and to a minimum.

(b) Ensure the outside perimeter of the premises is well-lit.

(c) Limit entry into areas where medical gas is held to authorized personnel.

(d) Equip all facilities with a fence or other system to detect or deter entry after hours.

(2) A facility used for wholesale distribution of medical gases shall be equipped with a system that will provide suitable protection against theft, including when appropriate, protection against theft of computers or electronic records and that will protect the integrity and confidentiality of data and documents.

(3) A facility used for wholesale distribution of medical gases shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft of nitrous oxide.

(4) Where a wholesale distributor of medical gases uses electronic distribution records, the wholesale distributor shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

(5) Vehicles used for on-call delivery of oxygen USP and

oxygen related equipment for home care use by home care providers may be parked at a place of residence and must be locked and equipped with an audible alarm when not attended.

499.89 Storage.—

(1) All medical gases shall be stored under appropriate conditions in accordance with regulations created by the department or, in the absence of regulations, in accordance with applicable industry standards and the manufacturers' recommendations on the product labeling.

(2) Packaging of medical gas shall be in accordance with the USP-NF, if applicable.

(3) The record keeping requirements in s. 499.93 shall be followed for the wholesale distribution of all medical gases.

499.90 Examination of materials.—

(1) Upon receipt of a medical gas container, the container shall be visually examined to determine identity and whether the container is damaged or otherwise unfit for wholesale distribution.

(2) A medical gas container that is found to be damaged or unfit under subsection (1) shall be quarantined from the remaining stock until an examination is conducted and a determination is made that the medical gas is not misbranded or adulterated.

(3) Each outgoing shipment shall be carefully inspected for the identity of the medical gas and to ensure that no medical gas shipment has been damaged in storage or held under

improper conditions.

(4) Upon receipt of a medical gas, a wholesale distributor of medical gases must review the accompanying records for accuracy and completeness. A pedigree paper is not required for the wholesale distribution of a medical gas.

(5) The record keeping requirements in s. 499.93 shall be followed for all incoming and outgoing medical gases.

499.91 Returned, damaged, and outdated medical gases.—

(1) Medical gas that has left the control of the wholesale distributor may be returned to the wholesale distributor or manufacturer from which it was acquired but may not be resold as a medical gas unless it is reprocessed by the manufacturer using proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas.

(2) A medical gas, including its container, that is damaged, misbranded, or adulterated shall be quarantined and physically separated from other medical gases until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired. External contamination of medical gas containers or the container's closure system, not impacting the integrity of the medical gas, is not considered damage or adulteration for purposes of this paragraph.

(3) When medical gas is adulterated, misbranded, or suspected of being adulterated or misbranded, notice shall be provided to the manufacturer or wholesale distributer from which they were acquired and the appropriate boards and federal

regulatory bodies.

(4) A medical gas container that has been opened or used, but is not adulterated or misbranded, shall be considered empty, quarantined, and physically separated from nonempty medical gas containers and returned to the manufacturer for destruction or reprocessing.

(5) A medical gas, its container, or its associated documentation or labeling, that is suspected of being involved in a criminal activity shall be retained and not destroyed until its disposition is authorized by the department or applicable law enforcement agency.

(6) The record keeping requirements in s. 499.93 shall be followed for all misbranded or adulterated medical gases.

499.92 Due diligence.—A wholesale distributor of medical gases shall comply with the following due diligence requirements:

(1) Before the initial acquisition of medical gases from a wholesale distributor, including a manufacturer, the supplying wholesale distributor shall provide the following information to the acquiring wholesale distributor or manufacturer:

(a) If a manufacturer is distributing to a wholesale distributor, evidence that the manufacturer is registered and the medical gas is listed with the United States Food and Drug Administration.

(b) If a wholesale distributor is distributing to a wholesale distributor, evidence that the wholesale distributor

supplying the medical gas is licensed or permitted to distribute product into the state.

(c) The name of the responsible facility contact person at the supplying manufacturer or wholesale distributor.

(d) A certification that the manufacturer or wholesale distributor's policies and procedures comply with this part.

(2) A manufacturer or wholesale distributor that distributes or acquires medical gases to or from another wholesale distributor of medical gases shall provide to or obtain from the distributing or acquiring entities, as applicable, the information set forth in s. 499.93(1).

(3) A wholesale distributor of medical gases is exempt from obtaining the information from a manufacturer as required under subsection (1) if the manufacturer is registered with the United States Food and Drug Administration in accordance with s. 510 of the federal act and the manufacturer provides:

(a) Proof of such registration.

(b) Proof of inspection by the United States Food and Drug Administration or other regulatory body within the past 3 years demonstrating substantial compliance with current good manufacturing practices applicable to medical gases.

499.93 Recordkeeping.—

(1) A wholesale distributor of medical gases shall establish and maintain records of all transactions regarding the receipt and wholesale distribution or other disposition of medical gases. These records shall include the following, which

need not appear on the same document:

(a) Dates of receipt and wholesale distribution or other disposition of the medical gas.

(b) The name, address, license or permit number, and license or permit expiration date of the entity purchasing the medical gas.

(c) The name, address, license or permit number, and license or permit expiration date of the entity receiving the medical gas, if different from paragraph (b).

(d) Information sufficient to perform a recall of medical gases received and distributed.

(2) Such records shall be made available for inspection and copying by an authorized official of any federal, state, or local governmental agency for a period of:

(a) Three years following the creation date of high pressure medical gases.

(b) One year following the creation date for cryogenic or refrigerated liquid medical gases.

(3) Records kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of any state or federal governmental agency charged with enforcement of these rules.

(4) A wholesale distributor or manufacturers of medical gases shall maintain an ongoing list of persons from whom they receive or to whom they distribute medical gases.

(5) A wholesale distributor of medical gases shall maintain records sufficient to aid in the mandatory reporting of any theft, suspected theft, or other significant loss of nitrous oxide to the department and other appropriate law enforcement agencies.

499.931 Trade secret information.—The department shall ensure that information required to be provided as part of the application process or information obtained pursuant to an investigation by the department, which is a trade secret, as defined in s. 812.081, and designated as a trade secret by the entity supplying the information to the department, shall be maintained by the department as trade secret information as provided in ss. 499.012(8)(g) and 499.051(7).

499.94 Policies and procedures.—A wholesale distributor of medical gases shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, transport, and shipping and wholesale distribution of medical gases, including policies and procedures for maintaining inventories, identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. A wholesale distributor of medical gases shall include the following in the written policies and procedures:

(1) A process for handling recalls and withdrawals of medical gases. The process shall be adequate to deal with recalls and withdrawals due to:

(a) An action initiated at the request of the United States Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the department; or

(b) A volunteer action by the manufacturer of medical gases to remove defective or potentially defective medical gases from the market.

(2) A procedure to ensure that wholesale distributors of medical gases prepare for, protect against, and handle a crisis that affects the security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure for reporting criminal or suspected criminal activities involving the inventory of nitrous oxide to the department and applicable law enforcement agencies within 3 business days of becoming aware of the criminal or suspect criminal activity.

499.95 Prohibited acts.—It is unlawful for a person to perform, cause the performance of, or aid and abet the following acts in this state:

(1) The manufacture sale, delivery, or holding or offering for sale of a medical gas that is adulterated, misbranded, or has otherwise been rendered unfit for distribution or wholesale

distribution;

(2) The adulteration or misbranding of a medical gas;

(3) The receipt of a medical gas that is adulterated, misbranded, stolen, obtained by fraud or deceit, or the delivery or proffered delivery of such medical gas for pay or otherwise;

(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the product labeling of a medical gas or the willful commission of an act with respect to a medical gas that results in the medical gas being misbranded;

(5) The purchase or receipt of a medical gas from a person that is not licensed or permitted, or exempt from licensure or permitting, to distribute wholesale medical gas to that purchaser or recipient;

(6) The knowing and willful sale or transfer of a medical gas to a person or other recipient who is not legally authorized to receive a medical gas, except that it is not a violation if a permitted wholesale distributor, at its location, provides oxygen to a medical oxygen retail establishment permit holder that is out of compliance with the notice of location change requirements of s. 499.831(10)(b)1. and if the wholesale distributor with knowledge of the violation notifies the department of the transaction by the next business day;

(7) The failure to maintain or provide records as required by this part and its implementing regulations;

(8) Providing the department or its representatives or any federal, state, or local official with false or fraudulent

records or making false or fraudulent statements regarding a matter within the provisions of this part and its implementing regulations;

(9) The wholesale distribution of any medical gas that was:

(a) Purchased by a public or private hospital or other health care entity, except for physical distribution of such medical gas to an authorized recipient at the direction of the hospital or other health care entity;

(b) Donated or supplied at a reduced price to a charitable organization; or

(c) Stolen or obtained by fraud or deceit.

(10) The failure to obtain a license or permit or operating without a valid license or permit when a license or permit is required;

(11) The obtaining of or attempting to obtain a medical gas by fraud, deceit, or misrepresentation in the distribution of a medical gas;

(12) Except for oxygen USP in emergency situations, distribution of a medical gas to a patient without a prescription or prescription order from a practitioner licensed by law to use or prescribe the medical gas;

(13) Distribution of a medical gas that was previously dispensed by a pharmacy or distributed by a practitioner;

(14) Distribution of a medical gas or medical gas related equipment to a patient, unless the patient has been provided

with appropriate information and counseling on use, storage, and disposal;

(15) The failure to report an act prohibited by this part and its implementing regulations; or

(16) The failure to exercise due diligence as provided in s. 499.92.

499.96 Criminal acts.—

(1) A person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if he or she:

(a) With intent to defraud or deceive, adulterates or misbrands a medical gas.

(b) Engages in wholesale distribution and knowingly purchases or receives medical gas from a person not legally authorized to distribute medical gas.

(c) Engages in the wholesale distribution and knowingly sells, barters, brokers, or transfers medical gases to a person not legally authorized to purchase medical gases under the jurisdiction in which the person receives the medical gas, except that it is not a violation if a permitted wholesale distributor, at its location, provides oxygen to a medical oxygen retail establishment permit holder that is out of compliance with the notice of location change requirements of s. 499.831(10)(b)1. and if the wholesale distributor with knowledge of the violation notifies the department of the transaction by the next business day.

(d) Knowingly creates a false label for a medical gas or who falsely represents factual matter contained in a medical gas label.

(2) A person found guilty of an offense under this section, under the authority of the court convicting and sentencing the person, shall be ordered to forfeit to the state any real or personal property:

(a) Used or intended to be used to commit, to facilitate, or to promote the commission of such offense; and

(b) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense. Property or assets subject to forfeiture under this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited, shall be equitably divided between the department and other agencies involved in the investigation and prosecution that led to the conviction. Other property ordered 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 that led to the conviction.

499.97 Salvaging and reprocessing.—

(1) Medical gas that has been subjected to improper conditions such as a fire, accident or natural disaster, may not

be salvaged or reprocessed.

(2) Medical gas in a container that has left the control of the wholesale distributor may be returned to the manufacturer and reprocessed if the manufacturer employs proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas.

499.98 Inspections.—

(1) The department is authorized to recognize a third party to inspect wholesale distributors of medical gases in that state or in other states pursuant to a schedule to be determined by the department.

(2) The department is authorized to recognize state inspections of wholesale distributors of medical gases operations in another state, if the state's laws are deemed to be substantially equivalent by the department.

(3) The department's decision to deny issuance of a permit to an applicant is subject to review pursuant to chapter 120.

(4) A manufacturing facility of medical gases is exempt from inspection by the department if:

(a) The manufacturing facility is currently registered with the United States Food and Drug Administration under s. 510 of the federal act and can provide proof of registration, such as a copy of the internet verification page.

(b) The manufacturing facility can provide proof of inspection by the Food and Drug Administration, or if the facility is located in another state, inspection by the Food and

Drug Administration or other governmental entity charged with regulation of good manufacturing practices related to medical gases within the past 3 years.

(5) A wholesale distributor of medical gases must exhibit or have readily available all state licenses or permits and the most recent inspection report administered by the department.

(6) This part does not require the department to report minor violations of this part, including variances in good manufacturing practices, for the institution of proceedings under this part when the department believes that the public interest will be adequately served in the circumstances by written notice.

499.99 Deposit of fees.—All fees collected for licenses and permits required by this part shall be deposited in the Professional Regulation Trust Fund and shall be used by the department in the administration of this part. The Department of Business and Professional Regulation shall maintain a separate account in the Professional Regulation Trust Fund for the Drugs, Devices, and Cosmetics program.

Section 11. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

(1) As used in this section, the term:

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described by s. 503(b) of the Federal

Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(52), ~~499.003(46) or (53)~~ or s. 499.007(13).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 12. Paragraph (c) of subsection (9) of section 460.403, Florida Statutes, is amended to read:

460.403 Definitions.—As used in this chapter, the term:

(9)

(c)1. Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or natural methods; by the use of physical means or physiotherapy, including light, heat, water, or exercise; by the use of acupuncture; or by the administration of foods, food concentrates, food extracts, and items for which a prescription is not required and may apply first aid and hygiene, but chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug except as authorized under subparagraph 2., from performing any surgery except as stated herein, or from practicing obstetrics.

2. Notwithstanding the prohibition against prescribing and administering legend drugs under subparagraph 1. ~~or s. 499.01(2)(m)~~, pursuant to board rule chiropractic physicians may

order, store, and administer, for emergency purposes only at the chiropractic physician's office or place of business, prescription medical oxygen and may also order, store, and administer the following topical anesthetics in aerosol form:

a. Any solution consisting of 25 percent ethylchloride and 75 percent dichlorodifluoromethane.

b. Any solution consisting of 15 percent dichlorodifluoromethane and 85 percent trichloromonofluoromethane.

However, this paragraph does not authorize a chiropractic physician to prescribe medical oxygen as defined in chapter 499.

Section 13. Subsection (3) of section 465.0265, Florida Statutes, is amended to read:

465.0265 Centralized prescription filling.—

(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as set forth in s. 465.026 or as a wholesale distribution as set forth in s. 499.003(53) ~~499.003(54)~~.

Section 14. Paragraph (b) of subsection (2) of section 499.01212, Florida Statutes, is amended to read:

499.01212 Pedigree paper.—

(2) FORMAT.—A pedigree paper must contain the following information:

(b) For all other wholesale distributions of prescription

drugs:

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.

4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5. An invoice number, a shipping document number, or another number uniquely identifying the transaction.

6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8. The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer under s. 499.003(30)(e) ~~499.003(31)(e)~~, information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription

drug.

Section 15. Paragraph (a) of subsection (1) and subsection (3) of section 499.015, Florida Statutes, is amended to read:

499.015 Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003(30) ~~499.003(31)~~, any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, device, or cosmetic biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug, device, or cosmetic at the time of registration.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003(30) ~~499.003(31)~~, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug, device, or cosmetic product to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

Section 16. Subsection (3) of section 499.024, Florida Statutes, is amended to read:

499.024 Drug product classification.—The department shall adopt rules to classify drug products intended for use by humans which the United States Food and Drug Administration has not

classified in the federal act or the Code of Federal Regulations.

(3) Any product that falls under the definition of drug in s. 499.003(18) ~~499.003(19)~~ may be classified under the authority of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.

Section 17. Paragraphs (i) and (m) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this part with respect to:

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(53)(b)2. ~~499.003(54)(b)2.~~

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(53)(a)-(d) ~~499.003(54)(a)-(d)~~.

Section 18. This act shall take effect October 1, 2014.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Government Operations Appropriations Subcommittee
Representative Magar offered the following:

Amendment (with directory amendment)

Remove line 1572 and insert:

enforce this chapter ~~part~~ with respect to:

(a) The definition of terms used in this chapter ~~part~~, and used in the rules adopted under this chapter ~~part~~, when the use of the term is not its usual and ordinary meaning.

(c) The establishment of fees authorized in this chapter ~~part~~.

(d) The identification of permits that require an initial application and onsite inspection or other prerequisites for permitting which demonstrate that the establishment and person are in compliance with the requirements of this chapter ~~part~~.

D I R E C T O R Y A M E N D M E N T

Remove line 1568 and insert:

Section 17. Paragraphs (a), (c), (d), (i) and (m) of subsection (1) of

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1153 Citizen Support and Direct-Support Organizations
SPONSOR(S): Government Operations Subcommittee, Hager
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1194

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Government Operations Subcommittee	10 Y, 2 N, As CS	Stramski	Williamson
2) Government Operations Appropriations Subcommittee		White CCW	Topp BMT
3) State Affairs Committee			

SUMMARY ANALYSIS

Citizen support organizations (CSOs) and direct-support organizations (DSOs) are statutorily created entities that are generally required to be non-profit corporations and are authorized to carry out specific tasks in support of public entities or public causes. While CSOs and DSOs are subject to audits by the Auditor General and are subject to public records requirements, there is no single requirement for CSO and DSO reporting imposed by law.

There are many statutes that create or authorize the establishment of CSOs and DSOs. However, there is no formal review process in law to determine whether a CSO or DSO was established pursuant to such authorization, or whether the rationale for the authorization remains applicable.

The bill creates new reporting and transparency requirements for each CSO and DSO that is created or authorized pursuant to law or executive order and created, approved, or administered by a state agency. The bill requires each CSO and DSO to report information related to its organization, mission, and finances to the agency it was created to support. A contract between an agency and a CSO or DSO must require the CSO or DSO to provide such information to the agency, and must require the agency to terminate the contract if the CSO or DSO fails to provide the information for two consecutive years. The bill requires each agency receiving such information from a CSO or DSO to make the information available on its website, and to provide a link to the CSO's or DSO's website if such a website exists.

The bill requires each agency to annually report to the Governor, the Legislature, and the Office of Program Policy Analysis and Government Accountability the information provided to the agency by the CSO or DSO, and to make a recommendation on whether to continue, terminate, or modify the agency's association with the CSO or DSO.

The bill provides that a law creating or authorizing the creation of a CSO or DSO must state that the creation or authorization is repealed on October 1 of the fifth year after enactment, unless reviewed and saved from repeal through reenactment by the Legislature. The bill directs the Legislature to review CSOs and DSOs in existence on the effective date of the bill by July 1, 2019.

The bill provides for the future repeal of certain sections of law authorizing CSOs and DSOs unless those sections are reviewed and saved from repeal by the Legislature.

The bill may have an indeterminate fiscal impact on state government. The bill does not appear to have a fiscal impact on local government.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Citizen support organizations (CSOs) and direct-support organizations (DSOs) are statutorily created entities that are generally required to be non-profit corporations and are authorized to carry out specific tasks in support of public entities or public causes. While CSOs and DSOs are subject to audits by the Auditor General[1] and are subject to public records requirements, there is no single requirement for CSO and DSO reporting imposed by law.

Section 215.981, F.S., requires each CSO and DSO with annual expenditures in excess of $100,000, created or authorized pursuant to law, and created, approved, or administered by a state agency, other than a university, community college, or district school board, to provide for an annual financial audit of its accounts and records to be conducted by an independent certified public accountant in accordance with rules adopted by the Auditor General and the state agency that created, approved, or administers the CSO or DSO. The audit report must be submitted within nine months after the end of the fiscal year to the Auditor General and to the state agency. Additionally, the Auditor General may, pursuant to his or her own authority, or at the direction of the Legislative Auditing Committee, conduct audits or other engagements of the CSO's or DSO's accounts and records.[2] The Auditor General is authorized to require and receive any records from the CSO or DSO, or from its independent auditor.[3]

Notwithstanding the above, CSOs and DSOs for the Department of Environmental Protection (DEP) or the Department of Agriculture and Consumer Services that are not for profit and that have annual expenditures of less than $300,000 are not required to have an independent audit. These departments are required to establish accounting and financial management guidelines for the CSOs and DSOs under their jurisdiction, and must annually conduct operational and financial reviews of a selected number of CSOs or DSOs that fall below the $300,000 threshold.[4]

There are many statutes that create or authorize the establishment of CSOs and DSOs. However, there is no formal review process in law to determine whether a CSO or DSO was established pursuant to such authorization, or whether the rationale for the authorization remains applicable.

Statutes that create or authorize the establishment of CSOs and DSOs include in part the following:

- Section 14.29(9), F.S., assigns the Florida Commission on Community Service to the Executive Office of the Governor to serve as an advisory board on matters relating to volunteerism and community service. Pursuant to the law, the commission may establish a DSO to receive, hold, invest, and administer property and funds and to make expenditures to or for the benefit of community service programs.

- Section 16.616, F.S., requires the Department of Legal Affairs to establish a DSO that supports the Council on the Social Status of Black Men and Boys and develops funding initiatives.

- Section 20.2551, F.S., specifies the organizational requirements and duties for a CSO to support DEP or individual units of DEP.

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[1] Section 11.45(3), F.S.
[2] *Id.*
[3] Section 11.45(3)(d), F.S.
[4] Section 215.981, F.S.

- Section 39.0011, F.S., authorizes the Office of Adoption and Child Protection in the Executive Office of the Governor to establish a DSO to assist the state in carrying out its purposes and responsibilities regarding the promotion of adoption, support of adoptive families, and prevention of child abuse.

- Section 39.8298, F.S., authorizes the Statewide Guardian Ad Litem Office, which has oversight responsibilities for and provides technical assistance to all guardian ad litem and attorney ad litem programs located within the judicial circuits, to create a DSO tasked in part with raising funds and making expenditures to or for the direct or indirect benefit of the Statewide Guardian Ad Litem Office.

- Section 250.115, F.S., authorizes the creation of a DSO for the Department of Military Affairs tasked in part with raising funds and making expenditures to or for the direct or indirect benefit of the Department of Military Affairs. Section 250.116, F.S., specifies that the DSO may provide assistance in the operation of the Soldiers and Airmen Assistance Program, which provides financial assistance and services to eligible servicemembers of the Florida National Guard and eligible members of their families.

- Section 257.43, F.S., authorizes the Division of Library and Information Services of the Department of State to support the establishment of a CSO to provide assistance, funding, and promotional support for the library, archives, and records management programs of the division.

- Section 258.015, F.S., specifies the organizational requirements and duties of a CSO to support the state park system or individual units of the state park system.

- Section 259.10521, F.S., specifies the organizational requirements and duties of a CSO to support the Babcock Ranch Preserve, with approval of the Fish and Wildlife Conservation Commission and the Florida Forest Service.

- Section 265.703, F.S., authorizes the Division of Cultural Affairs of the Department of State to support the establishment of CSOs to provide assistance, funding, and promotional support for the cultural, arts, historical, and museum programs of the division.

- Section 267.17, F.S., authorizes the Division of Historical Resources of the Department of State to support the establishment of CSOs to provide assistance, funding, and promotional support for the archaeology, museum, folklife, and historic preservation programs of the division.

- Section 288.1226, F.S., establishes the Florida Tourism Industry Marketing Corporation as a DSO of Enterprise Florida, Inc., intended to perform duties necessary to carry out the four-year marketing plan of Enterprise Florida, and to support state programs that relate to the statewide, national, and international promotion and marketing of tourism. This DSO staffs the Division of Tourism Marketing in Enterprise Florida.[5]

- Section 288.809, F.S., establishes the Florida Intergovernmental Relations Foundation as a DSO organized and operated exclusively to solicit, receive, hold, invest, and administer property and, subject to the approval of the state protocol officer, to make expenditures to or for the promotion of intergovernmental relations programs.

- Section 288.923, F.S., authorizes Enterprise Florida, Inc. to contract with the Florida Tourism Industry Marketing Corporation, a direct-support organization established in s. 288.1226, F.S., to execute tourism promotion and marketing services, functions, and programs for the state.

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[5] Section 288.92, F.S., authorizes Enterprise Florida, Inc., to create and dissolve divisions as necessary to carry out its mission. At a minimum, Enterprise Florida, Inc., must have divisions related to certain areas, including Tourism Marketing. Section 288.923, F.S., also establishes the division of Tourism Marketing to be staffed by the DSO.

- Section 292.055, F.S., authorizes the Department of Veterans' Affairs to establish a DSO to provide assistance, funding, and support for the department, the veterans of the state, and congressionally chartered veteran service organizations having subdivisions that are incorporated in this state.

- Section 379.223, F.S., permits the Fish and Wildlife Conservation Commission to authorize the establishment of CSOs to provide assistance, funding, and promotional support for the programs of the commission.

- Section 413.0111, F.S., authorizes the Division of Blind Services to incorporate a DSO to conduct programs and activities, initiate developmental projects, raise and administer funds or property, and make expenditures for the direct or indirect benefit of the state and for blind persons in Florida.

- Section 413.615, F.S., authorizes the Florida Endowment Foundation for Vocational Rehabilitation as a DSO of the Division of Vocational Rehabilitation within the Department of Education to encourage public and private support to enhance vocational rehabilitation and employment of citizens who are disabled.

- Section 430.82, F.S., permits the Department of Elderly Affairs to establish a DSO to provide assistance, funding, and support for the department in carrying out its mission.

- Section 570.903, F.S., permits the Department of Agriculture and Consumer Services to authorize the establishment of DSOs to provide assistance, funding, and promotional support for the museums and other programs of the department.

- Section 570.9135, F.S., creates the Florida Beef Council, Inc., as a DSO of the Department of Agriculture and Consumer Services to conduct programs of promotion, research, and consumer or industry information designed to strengthen the cattle industry's market position in the state. The DSO may impose an assessment of up to $1 on each head of cattle sold in the state in order to fund its activities.

- Section 626.9895, F.S., authorizes the Division of Insurance Fraud of the Department of Financial Services to establish a DSO, to be known as the Automobile Insurance Fraud Strike Force, whose sole purpose is to support the prosecution, investigation, and prevention of motor vehicle insurance fraud.

- Section 683.231, F.S., authorizes the Department of Law Enforcement to establish a CSO to provide assistance, funding, and promotional support for activities authorized for Florida Missing Children's Day, designated each year in remembrance of Florida's past and present missing children and in recognition of continued state efforts to protect the safety of children through prevention, education, and community involvement.[6]

- Section 744.7082, F.S., specifies the organizational requirements for a DSO to support the Statewide Public Guardianship Office within the Department of Elderly Affairs.

- Section 893.055(11), F.S., authorizes the Department of Health to establish a DSO to provide assistance, funding, and promotional support for the activities of the prescription drug monitoring program.

- Section 944.802, F.S., specifies the organizational requirements and duties for a DSO to support the Department of Corrections or individual units of the state correctional system.

[6] Section 683.23, F.S.

- Section 960.002, F.S., permits the Governor to authorize a DSO to assist in addressing the needs of victims of adult and juvenile crime. The DSO must operate under a contract with the Executive Office of the Governor.

- Section 985.672, F.S., specifies the organizational requirements and duties for a DSO to support the Department of Juvenile Justice or the juvenile justice system operated by a county commission or a circuit board.

- Section 1009.983, F.S., authorizes the Florida Prepaid College Board, which administers the Florida College Savings Program, to establish a DSO to make expenditures to or for the benefit of the board, and to administer the Florida Prepaid Tuition Scholarship Program, which provides economically disadvantaged youth with prepaid postsecondary tuition scholarships.[7]

Effect of Bill

The bill creates new reporting and transparency requirements for each CSO and DSO that is created or authorized pursuant to law or executive order and created, approved, or administered by a state agency. The bill requires each CSO and DSO to report information related to its organization, mission, and finances to the agency it was created to support. Specifically, the CSO or DSO must provide:

- The name, mailing address, telephone number, and website address of the organization;
- The statutory authority or executive order that created the CSO or DSO;
- A brief description of the mission of, and results obtained by, the organization;
- A brief description of the organization's plans for the next three fiscal years;
- A copy of the organization's code of ethics; and
- A copy of the organization's most recent federal Internal Revenue Service Return of Organization Exempt from Income Tax form (Form 990).

A contract between an agency and a CSO or DSO entered into on or after July 1, 2014, must require the CSO or DSO to submit the information that must be provided to an agency pursuant to this bill. The contract also must require the agency to terminate the contract if a CSO or DSO fails to submit the required information for two consecutive years. Each agency receiving such information from a CSO or DSO must make the information available on its website, and must provide a link to the CSO's or DSO's website if such a website exists.

The bill requires each agency to report the information provided to the agency by the CSO or DSO by August 30 of each year to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability, and to make a recommendation on whether to continue, terminate, or modify the agency's association with the CSO or DSO.

The bill provides that a law creating or authorizing the creation of a CSO or DSO must state that the creation authorization is repealed on October 1 of the fifth year after enactment, unless reviewed and saved from repeal through reenactment by the Legislature. The bill directs the Legislature to review CSOs and DSOs in existence on the effective date of the bill by July 1, 2019.

The bill provides for the future repeal of certain sections of law establishing, authorizing, or permitting the creation of CSOs or DSOs, or specifying requirements for and duties of a CSO or DSO. The bill does not provide for future repeal of all sections pertaining to a CSO or DSO. For example, the bill excludes university DSOs and the CSO authorized to support the Florida Historic Capitol.

[7] Section 1009.984, F.S.

The bill provides for repeal of the sections provided in the following chart, unless reviewed and saved from repeal by the Legislature:

Bill Section	Statute	Organization	Repealed October 1 of:
5	39.0011	Office of Adoption and Child Protection DSO (Executive Office of the Governor)	2017
7	250.115	Department of Military Affairs DSO	2017
16	292.055	Department of Veterans' Affairs DSO	2017
18	413.0111	Blind Services DSO	2017
19	413.615	Florida Endowment for Vocational Rehabilitation (DSO of Department of Education)	2017
20	430.82	Department of Elderly Affairs DSO	2017
26	893.055	Prescription drug monitoring program DSO	2017
30	1009.983	Florida Prepaid College Board DSO	2017
1	14.29(9)	Florida Commission on Community Service DSO	2018
2	16.616	Council on Social Status of Black Men and Boys DSO	2018
6	39.8298	Guardian Ad Litem DSO	2018
24	683.231	Florida Missing Children's Day CSO	2018
25	744.7082	Statewide Public Guardianship Office DSO	2018
27	944.802	Department of Corrections DSO	2018
28	960.002	DSO to assist victims of crime	2018
29	985.672	Department of Juvenile Justice DSO	2018
4	20.2551	Department of Environmental Protection CSO	2019
8	257.43	Division of Library and Information Services of the Department of State CSO	2019
9	258.015	Division of Recreation and Parks of the Department of Environmental Protection CSOs	2019
10	259.10521	Babcock Ranch CSO	2019
11	265.703	Department of State CSO	2019
12	267.17	Division of Historical Resources of the Department of State CSOs	2019
13	288.1226	Florida Tourism Industry Marketing Corporation (DSO of Enterprise Florida, Inc.) and the Division of Tourism Marketing[8]	2019
14	288.809	Florida Intergovernmental Relations Foundation (DSO of the Executive Office of the Governor)	2019
15	288.923	Duties of the Division of Tourism Marketing	2019
17	379.223	Fish and Wildlife Conservation Commission CSOs	2019
21	570.903	Department of Agriculture and Consumer Services DSO	2019
22	570.9135	Florida Beef Council (DSO of the Department of Agriculture and Consumer Services)	2019
23	626.9895	Motor vehicle insurance fraud DSO	2019
			TOTAL: 29

18 of the organizations listed above have specified in statute what happens to the funds held in the CSO or DSO if the organization ceases to exist. The remaining 11 organizations above have nothing in statute that directs what should be done with the funds held in the CSO or DSO if the organization ceases to exist.

[8] *See* FN 5.

B. SECTION DIRECTORY:

Section 1 amends s. 14.29, F.S.; providing for future review and repeal of provisions authorizing the Florida Commission on Community Service to establish and operate a DSO.

Section 2 amends s. 16.616, F.S.; providing for future review and repeal of the DSO established within the Department of Legal Affairs.

Section 3 creates s. 20.058, F.S.; requiring CSOs and DSOs to annually submit certain information to the agency the organization was created to support; requiring each agency receiving such information to post submissions on the agency's website; requiring each agency receiving such information to annually submit a report to the Governor, the Legislature, and the Office of Program Policy Analysis and Government Accountability; providing report requirements; requiring that a contract entered into between an agency and a CSO or DSO on or after July 1, 2014, contain certain provisions; requiring that each CSO or DSO created or authorized by law be subject to legislative review and repeal; and requiring that CSOs and DSOs in existence as of a certain date be subject to future legislative review.

Section 4 amends s. 20.2551, F.S.; providing for future review and repeal of the CSO established within DEP.

Section 5 amends s. 39.0011, F.S.; providing for future review and repeal of the DSO of the Office of Adoption and Child Protection.

Section 6 amends s. 39.8298, F.S.; providing for future review and repeal of the Statewide Guardian Ad Litem Office's authorization to create a DSO.

Section 7 amends s. 250.115, F.S.; providing for future review and repeal of the DSO of the Department of Military Affairs.

Section 8 amends s. 257.43, F.S.; providing for future review and repeal of the CSO of the Division of Library and Information Services of the Department of State.

Section 9 amends s. 258.015, F.S.; providing for future review and repeal of provisions relating to CSOs under the Division of Recreation and Parks of DEP.

Section 10 amends s. 259.10521, F.S.; providing for future review and repeal of the CSO benefitting the Babcock Ranch Preserve.

Section 11 amends s. 265.703, F.S.; providing for future review and repeal of the CSO of the Division of Cultural Affairs of the Department of State.

Section 12 amends s. 267.17, F.S.; providing for future review and repeal of the CSO of the Division of Historical Resources of the Department of State.

Section 13 amends s. 288.1226, F.S.; providing for future review and repeal of the Florida Tourism Industry Marketing Corporation.

Section 14 amends s. 288.809, F.S.; providing for future review and repeal of the Florida Intergovernmental Relations Foundation.

Section 15 amends s. 288.923, F.S.; providing for future review and repeal of the Division of Tourism Marketing of Enterprise Florida, Inc.

Section 16 amends s. 292.055, F.S.; providing for future review and repeal of the DSO of the Department of Veterans' Affairs.

Section 17 amends s. 379.223, F.S.; providing for future review and repeal of the Fish and Wildlife Conservation Commission's authorization to establish CSOs.

Section 18 amends s. 413.0111, F.S.; providing for future review and repeal of the DSO of the Division of Blind Services of the Department of Education.

Section 19 amends s. 413.615, F.S.; providing for future review and repeal of the Florida Endowment Foundation for Vocational Rehabilitation.

Section 20 amends s. 430.82, F.S.; providing for future review and repeal of the Department of Elderly Affairs' authority to establish a DSO.

Section 21 amends s. 570.903, F.S.; providing for future review and repeal of the Department of Agriculture and Consumer Services' authority to establish a DSO.

Section 22 amends s. 570.9135, F.S.; providing for future review and repeal of Florida Beef Council, Inc.

Section 23 amends s. 626.9895, F.S.; providing for future review and repeal of the Division of Insurance Fraud of the Department of Financial Services' authority to establish a DSO.

Section 24 amends s. 683.231, F.S.; providing for future review and repeal of the Department of Law Enforcement's authority to establish a CSO for Florida Missing Children's Day.

Section 25 amends s. 744.7082, F.S.; providing for future review and repeal of the DSO supporting the Statewide Public Guardianship Office.

Section 26 amends s. 893.055, F.S.; providing for future review and repeal of the Department of Health's authority to establish a DSO supporting the prescription drug monitoring program.

Section 27 amends s. 944.802, F.S.; providing for future review and repeal of the Department of Corrections' authority to establish a DSO.

Section 28 amends s. 960.002, F.S.; providing for future review and repeal of the Governor's authority to authorize a DSO to assist victims of adult and juvenile crime.

Section 29 amends s. 985.672, F.S.; providing for future review and repeal of the Department of Juvenile Justice's DSO.

Section 30 amends s. 1009.983, F.S.; providing for future review and repeal of the Florida Prepaid College Board's authority to establish a DSO.

Section 31 provides that the bill takes effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See FISCAL COMMENTS.

2. Expenditures:

   See FISCAL COMMENTS.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There may be an indeterminate fiscal impact to CSOs and DSOs caused by the reporting requirements in this bill.

D. FISCAL COMMENTS:

If the bill results in the repeal of CSOs or DSOs, the state may experience indeterminate negative and positive fiscal impacts.

An indeterminate negative fiscal impact may result from reduced revenues available to certain public entities that may receive support from CSOs or DSOs.[9]

The bill requires agencies to prepare and submit reports relating to information provided to them by CSOs and DSOs, and to make such information available on agency websites. These reporting and website modification requirements may result in a minimal negative fiscal impact on agencies.

An indeterminate positive fiscal impact on the state might result following the repeal of CSOs or DSOs if the state was previously required to provide financial support to such CSOs or DSOs; for example if the state was required to provide for reimbursement of per diem and travel reimbursements for the board members of such CSOs and DSOs.[10]

11 of the 29 CSOs and DSOs have nothing in statute that directs what should be done with the funds held by the CSO or DSO if the organization ceases to exist. The statutes direct what happens to the funds held by the other 18 organizations. For example, if the Florida Endowment Foundation for Vocational Rehabilitation is repealed and the contract is terminated, the statute states that the funds in the foundation would revert to the state. Another example is if the Automotive Insurance Fraud Strike Force is repealed, the statute directs the funds to revert to the Division of Insurance Fraud of the Department of Financial Services.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

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[9] The Department of Elderly Affairs has indicated that if this bill results in the repeal of the authority for the Foundation for Indigent Guardianship, Inc., a DSO, the department would no longer receive support for its public guardianship programs through the State of Florida Public Guardianship Pooled Special Needs Trust. Agency Bill Analysis for HB 1153 by the Department of Elderly Affairs, March 5, 2014 (on file with the Government Operations Subcommittee).

[10] *See for example* s. 14.29(6), F.S.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill does not appear to create a need for executive branch rulemaking or rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Other Comments: Reporting Requirements for CSOs and DSOs

The bill requires each CSO and DSO to annually submit to the agency that the organization was created to support a copy of the organization's most recent federal Internal Revenue Service Return of Organization Exempt from Income Tax form (Form 990). However, not all CSOs and DSOs are required by law to have federal tax exempt status.[11]

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 31, 2014, the Government Operations Subcommittee adopted a proposed committee substitute for HB 1153 and reported the bill favorably as a committee substitute. The committee substitute:

- Removes certain proposed CSO and DSO annual reporting requirements related to expenditures and capital improvements.
- Revises the proposed annual report date by changing it to August 30 instead of August 1.
- Clarifies that any contract entered into between an agency and a CSO or DSO on or after July 1, 2014, must contain provisions that require the CSO or DSO to submit a report and requires the agency head to terminate the contract if the CSO or DSO fails to do so for two consecutive years.

This analysis is drafted to the committee substitute as passed by the Government Operations Subcommittee.

[11] *See for example* s. 744.7082, F.S.

A bill to be entitled

An act relating to citizen support and direct-support organizations; amending s. 14.29, F.S.; providing for future review and repeal of provisions authorizing the Florida Commission on Community Service to establish and operate a direct-support organization; amending s. 16.616, F.S.; providing for future review and repeal of the direct-support organization established within the Department of Legal Affairs; creating s. 20.058, F.S.; requiring citizen support and direct-support organizations to annually submit certain information to the agency that the organization was created to support; requiring each agency receiving such information to post submissions on the agency's website; requiring each agency receiving such information to annually submit a report to the Governor, the Legislature, and the Office of Program Policy Analysis and Government Accountability; providing report requirements; requiring that a contract entered into between an agency and a citizen support organization or direct-support organization on or after a specified date contain certain provisions; requiring that each citizen support organization or direct-support organization created or authorized by law be subject to legislative review and repeal; requiring that citizen support organizations or

direct-support organizations in existence as of a certain date be subject to future legislative review; amending s. 20.2551, F.S.; providing for future review and repeal of the citizen support organization established within the Department of Environmental Protection; amending s. 39.0011, F.S.; providing for future review and repeal of the direct-support organization of the Office of Adoption and Child Protection; amending s. 39.8298, F.S.; providing for future review and repeal of the Statewide Guardian Ad Litem Office's authorization to create a direct-support organization; amending s. 250.115, F.S.; providing for future review and repeal of the direct-support organization of the Department of Military Affairs; amending s. 257.43, F.S.; providing for future review and repeal of the citizen support organization of the Division of Library and Information Services of the Department of State; amending s. 258.015, F.S.; providing for future review and repeal of provisions relating to citizen support organizations under the Division of Recreation and Parks of the Department of Environmental Protection; amending s. 259.10521, F.S.; providing for future review and repeal of the citizen support organization benefitting the Babcock Ranch Preserve; amending s. 265.703, F.S.; providing for future review and repeal

of the citizen support organization of the Division of Cultural Affairs of the Department of State; amending s. 267.17, F.S.; providing for future review and repeal of the citizen support organization of the Division of Historical Resources of the Department of State; amending s. 288.1226, F.S.; providing for future review and repeal of the Florida Tourism Industry Marketing Corporation; amending s. 288.809, F.S.; providing for future review and repeal of the Florida Intergovernmental Relations Foundation; amending s. 288.923, F.S.; providing for future review and repeal of the Division of Tourism Marketing of Enterprise Florida, Inc.; amending s. 292.055, F.S.; providing for future review and repeal of the direct-support organization of the Department of Veterans' Affairs; amending s. 379.223, F.S.; providing for future review and repeal of the Fish and Wildlife Conservation Commission's authorization to establish citizen support organizations; amending s. 413.0111, F.S.; providing for future review and repeal of the direct-support organization of the Division of Blind Services of the Department of Education; amending s. 413.615, F.S.; providing for future review and repeal of the Florida Endowment Foundation for Vocational Rehabilitation; amending s. 430.82, F.S.; providing for future review and repeal of the Department of

Elderly Affairs' authority to establish a direct-support organization; amending s. 570.903, F.S.; providing for future review and repeal of the Department of Agriculture and Consumer Services' authority to establish a direct-support organization; amending s. 570.9135, F.S.; providing for future review and repeal of Florida Beef Council, Inc.; amending s. 626.9895, F.S.; providing for future review and repeal of the Division of Insurance Fraud of the Department of Financial Services' authority to establish a direct-support organization; amending s. 683.231, F.S.; providing for future review and repeal of the Department of Law Enforcement's authority to establish a citizen support organization for Florida Missing Children's Day; amending s. 744.7082, F.S.; providing for future review and repeal of the direct-support organization supporting the Statewide Public Guardianship Office; amending s. 893.055, F.S.; providing for future review and repeal of the Department of Health's authority to establish a direct-support organization supporting the prescription drug monitoring program; amending s. 944.802, F.S.; providing for future review and repeal of the Department of Corrections' authority to establish a direct-support organization; amending s. 960.002, F.S.; providing for future review and repeal

of the Governor's authority to authorize a direct-support organization to assist victims of adult and juvenile crime; amending s. 985.672, F.S.; providing for future review and repeal of the Department of Juvenile Justice's direct-support organization; amending s. 1009.983, F.S.; providing for future review and repeal of the Florida Prepaid College Board's authority to establish a direct-support organization; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (9), (10), (11), (12), (13), (14), and (15) of section 14.29, Florida Statutes, are amended to read:

14.29 Florida Commission on Community Service.—

(9)(a) The commission may establish a direct-support organization which is:

1.~~(a)~~ A Florida corporation, not for profit, incorporated under the provisions of chapter 617 and approved by the Secretary of State.

2.~~(b)~~ Organized and operated exclusively to receive, hold, invest, and administer property and funds and to make expenditures to or for the benefit of the program.

3.~~(c)~~ An organization which the commission, after review, has certified to be operating in a manner consistent with the

goals of the program and in the best interests of the state.

(b) ~~(10)~~ The direct-support organization shall operate under written contract with the commission. The contract must provide for:

1. ~~(a)~~ Approval of the articles of incorporation and bylaws of the direct-support organization by the commission.

2. ~~(b)~~ Submission of an annual budget for the approval of the commission. The budget must comply with rules adopted by the commission.

3. ~~(c)~~ Certification by the commission that the direct-support organization is complying with the terms of the contract and in a manner consistent with the goals and purposes of the commission and in the best interest of the state. Such certification must be made annually and reported in the official minutes of a meeting of the commission.

4. ~~(d)~~ The reversion to the commission, or the state if the commission ceases to exist, of moneys and property held in trust by the direct-support organization if the direct-support organization is no longer approved to operate for the commission or the commission ceases to exist.

5. ~~(e)~~ The fiscal year of the direct-support organization, to begin July 1 of each year and end June 30 of the following year.

6. ~~(f)~~ The disclosure of material provisions of the contract and the distinction between the board of directors and the direct-support organization to donors of gifts,

contributions, or bequests, as well as on all promotional and fundraising publications.

(c) ~~(11)~~ The members of the direct-support organization's board of directors must include members of the commission.

(d) ~~(12)~~ The commission may authorize a direct-support organization to use its personal services, facilities, and property, ~~(~~except money~~), facilities, and personal services~~, subject to the provisions of this section. A direct-support organization that does not provide equal employment opportunities to all persons regardless of race, color, religion, sex, age, or national origin may not use the property, facilities, or personal services of the commission. For the purposes of this subsection, the term "personal services" includes full-time personnel and part-time personnel as well as payroll processing.

(e) ~~(13)~~ The commission shall adopt rules prescribing the procedures by which the direct-support organization is governed and any conditions with which the direct-support organization must comply to use property, facilities, or personal services of the commission.

(f) ~~(14)~~ Moneys of the direct-support organization may be held in a separate depository account in the name of the direct-support organization and subject to the provisions of the contract with the commission. Such moneys may include membership fees, private donations, income derived from fundraising activities, and grants applied for and received by the direct-

support organization.

(g) ~~(15)~~ The direct-support organization shall provide for an annual financial audit in accordance with s. 215.981.

(h) This subsection is repealed effective October 1, 2018, unless reviewed and saved from repeal by the Legislature.

Section 2. Subsection (7) is added to section 16.616, Florida Statutes, to read:

16.616 Direct-support organization.—

(7) This section is repealed October 1, 2018, unless reviewed and saved from repeal by the Legislature.

Section 3. Section 20.058, Florida Statutes, is created to read:

20.058 Citizen support and direct-support organizations.—

(1) By August 1 of each year, a citizen support organization or direct-support organization created or authorized pursuant to law or executive order and created, approved, or administered by an agency shall submit the following information to the agency that the organization was created to support:

(a) The name, mailing address, telephone number, and website address of the organization.

(b) The statutory authority or executive order that created the organization.

(c) A brief description of the mission of, and results obtained by, the organization.

(d) A brief description of the organization's plans for

the next 3 fiscal years.

(e) A copy of the organization's code of ethics.

(f) A copy of the organization's most recent federal Internal Revenue Service Return of Organization Exempt from Income Tax form (Form 990).

(2) Each agency receiving information from a citizen support organization or direct-support organization pursuant to subsection (1) shall make such information available to the public through the agency's website. In addition, if the organization maintains a website, the agency's website must provide a link to that website.

(3) By August 30 of each year, each agency shall report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability the information provided by each citizen support organization or direct-support organization. The report must also include a recommendation by the agency, with supporting rationale, to continue, terminate, or modify the agency's association with each organization.

(4) Each contract entered into between an agency and a citizen support organization or direct-support organization on or after July 1, 2014, shall contain provisions that require the organization to submit information in compliance with subsection (1) and require the agency to terminate the contract if the organization fails to do so for 2 consecutive years.

(5) A law creating, or authorizing the creation of, a

citizen support organization or a direct-support organization must state that the creation of or authorization for the organization is repealed on October 1 of the 5th year after enactment, unless reviewed and saved from repeal through reenactment by the Legislature. Citizen support organizations and direct-support organizations in existence on July 1, 2014, must be reviewed by the Legislature by July 1, 2019.

Section 4. Subsection (6) is added to section 20.2551, Florida Statutes, to read:

20.2551 Citizen support organizations; use of property; audit; public records; partnerships.—

(6) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 5. Subsection (5) is added to section 39.0011, Florida Statutes, to read:

39.0011 Direct-support organization.—

(5) This section is repealed October 1, 2017, unless reviewed and saved from repeal by the Legislature.

Section 6. Subsection (8) is added to section 39.8298, Florida Statutes, to read:

39.8298 Guardian Ad Litem direct-support organization.—

(8) REPEAL.—This section is repealed October 1, 2018, unless reviewed and saved from repeal by the Legislature.

Section 7. Subsection (8) is added to section 250.115, Florida Statutes, to read:

250.115 Department of Military Affairs direct-support

organization.—

(8) REPEAL.—This section is repealed October 1, 2017, unless reviewed and saved from repeal by the Legislature.

Section 8. Subsection (4) is added to section 257.43, Florida Statutes, to read:

257.43 Citizen support organization; use of state administrative services and property; audit.—

(4) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 9. Subsection (4) is added to section 258.015, Florida Statutes, to read:

258.015 Citizen support organizations; use of property; audit.—

(4) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 10. Subsection (4) is added to section 259.10521, Florida Statutes, to read:

259.10521 Citizen support organization; use of property.—

(4) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 11. Subsection (4) is added to section 265.703, Florida Statutes, to read:

265.703 Citizen support organizations; use of state administrative services and property; audit.—

(4) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 12. Subsection (4) is added to section 267.17, Florida Statutes, to read:

267.17 Citizen support organizations; use of state administrative services and property; audit.—

(4) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 13. Subsections (7) and (8) of section 288.1226, Florida Statutes, are amended, and a new subsection (9) is added to that section, to read:

288.1226 Florida Tourism Industry Marketing Corporation; use of property; board of directors; duties; audit.—

(7) REPORT.—The corporation shall provide a quarterly report to Enterprise Florida, Inc., which shall:

(a) Measure the current vitality of the visitor industry of this state as compared to the vitality of such industry for the year to date and for comparable quarters of past years. Indicators of vitality shall be determined by Enterprise Florida, Inc., and shall include, but not be limited to, estimated visitor count and party size, length of stay, average expenditure per party, and visitor origin and destination.

(b) Provide detailed, unaudited financial statements of sources and uses of public and private funds.

(c) Measure progress towards annual goals and objectives set forth in the 4-year marketing plan.

(d) Review all pertinent research findings.

(e) Provide other measures of accountability as requested

by Enterprise Florida, Inc.

(8) PUBLIC RECORDS EXEMPTION.—The identity of any person who responds to a marketing project or advertising research project conducted by the corporation in the performance of its duties on behalf of Enterprise Florida, Inc., or trade secrets as defined by s. 812.081 obtained pursuant to such activities, are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(9) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 14. Subsection (5) is added to section 288.809, Florida Statutes, to read:

288.809 Florida Intergovernmental Relations Foundation; use of property; board of directors; audit.—

(5) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 15. Subsection (6) is added to section 288.923, Florida Statutes, to read:

288.923 Division of Tourism Marketing; definitions; responsibilities.—

(6) This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 16. Subsection (10) is added to section 292.055, Florida Statutes, to read:

292.055 Direct-support organization.—

(10) REPEAL.—This section is repealed October 1, 2017,

unless reviewed and saved from repeal by the Legislature.

Section 17. Subsection (4) is added to section 379.223, Florida Statutes, to read:

379.223 Citizen support organizations; use of state property; audit.—

(4) This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 18. Subsection (7) is added to section 413.0111, Florida Statutes, to read:

413.0111 Blind services direct-support organization.—

(7) This section is repealed October 1, 2017, unless reviewed and saved from repeal by the Legislature.

Section 19. Subsection (14) is added to section 413.615, Florida Statutes, to read:

413.615 Florida Endowment for Vocational Rehabilitation.—

(14) REPEAL.—This section is repealed October 1, 2017, unless reviewed and saved from repeal by the Legislature.

Section 20. Subsection (9) is added to section 430.82, Florida Statutes, to read:

430.82 Direct-support organization.—

(9) This section is repealed October 1, 2017, unless reviewed and saved from repeal by the Legislature.

Section 21. Subsection (10) is added to section 570.903, Florida Statutes, to read:

570.903 Direct-support organization.—

(10) This section is repealed October 1, 2019, unless

reviewed and saved from repeal by the Legislature.

Section 22. Subsection (14) is added to section 570.9135, Florida Statutes, to read:

570.9135 Beef Market Development Act; definitions; Florida Beef Council, Inc., creation, purposes, governing board, powers, and duties; referendum on assessments imposed on gross receipts from cattle sales; payments to organizations for services; collecting and refunding assessments; vote on continuing the act; council bylaws.—

(14) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 23. Subsection (9) is added to section 626.9895, Florida Statutes, to read:

626.9895 Motor vehicle insurance fraud direct-support organization.—

(9) REPEAL.—This section is repealed October 1, 2019, unless reviewed and saved from repeal by the Legislature.

Section 24. Subsection (8) is added to section 683.231, Florida Statutes, to read:

683.231 Citizen support organization for Florida Missing Children's Day.—

(8) This section is repealed October 1, 2018, unless reviewed and saved from repeal by the Legislature.

Section 25. Subsection (9) is added to section 744.7082, Florida Statutes, to read:

744.7082 Direct-support organization; definition; use of

property; board of directors; audit; dissolution.—

(9) REPEAL.—This section is repealed October 1, 2018, unless reviewed and saved from repeal by the Legislature.

Section 26. Paragraph (k) is added to subsection (11) of section 893.055, Florida Statutes, to read:

893.055 Prescription drug monitoring program.—

(11) The department may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.

(k) This subsection is repealed October 1, 2017, unless reviewed and saved from repeal by the Legislature.

Section 27. Subsection (4) is added to section 944.802, Florida Statutes, to read:

944.802 Direct-support organization; definition; use of property; board of directors; audit.—

(4) REPEAL.—This section is repealed October 1, 2018, unless reviewed and saved from repeal by the Legislature.

Section 28. Subsection (6) is added to section 960.002, Florida Statutes, to read:

960.002 Direct-support organization to assist victims of adult and juvenile crime.—

(6) This section is repealed October 1, 2018, unless reviewed and saved from repeal by the Legislature.

Section 29. Subsections (5) and (6) of section 985.672,

Florida Statutes, are amended, and a new subsection (7) is added to that section, to read:

985.672 Direct-support organization; definition; use of property; board of directors; audit.—

(5) DEPOSIT OF FUNDS.—Any moneys may be held in a separate depository account in the name of the direct-support organization and subject to the provisions of the contract with the department.

(6) AUDIT.—The direct-support organization shall provide for an annual financial audit in accordance with s. 215.981.

(7) REPEAL.—This section is repealed October 1, 2018, unless reviewed and saved from repeal by the Legislature.

Section 30. Subsection (9) is added to section 1009.983, Florida Statutes, to read:

1009.983 Direct-support organization; authority.—

(9) This section is repealed October 1, 2017, unless reviewed and saved from repeal by the Legislature.

Section 31. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1235 Florida Homeowners' Construction Recovery Fund
SPONSOR(S): Business & Professional Regulation Subcommittee; Dudley
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1098

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Business & Professional Regulation Subcommittee	11 Y, 0 N, As CS	Whittier	Luczynski
2) Government Operations Appropriations Subcommittee		Topp	Topp BDT
3) Regulatory Affairs Committee			

SUMMARY ANALYSIS

The Florida Homeowners' Construction Recovery Fund (fund) was created in 1993, after Hurricane Andrew, as a fund of last resort to compensate consumers who contracted for construction, repair or improvement of their Florida residence and who suffered monetary damages due to the financial misconduct, abandonment, or fraudulent statement of the licensed contractor, financially responsible officer, or business organization licensed under ch. 489, F.S. A claimant must be a homeowner and, currently, the damage must have been caused by a Division I contractor, which includes general contractors, building contractors, and residential contractors. The fund is not permitted to compensate consumers who contracted with Division II contractors or to compensate consumers who have suffered damages as a result of payments made in violation of the Florida Construction Lien Law.

Each recovery claim is limited to both a per-claim maximum amount and a total lifetime per-contractor maximum. For contracts entered into prior to July 1, 2004, the fund claims are limited to $25,000 per claim with a total life time aggregate limit of $250,000 per licensee. For contracts entered into after July 1, 2004, the per-claim payment limits are increased to $50,000 with a total life time aggregate of $500,000 per licensee. Claims are paid in the order that they are filed. The fund must be repaid by the contractor in violation or have their license suspended until the repayment is made. The fund is financed by a 1.5% surcharge on all building permit fees associated with the enforcement of the Florida Building Code. The proceeds from the surcharge are allocated equally to fund the Florida Homeowners' Construction Recovery Fund and the operations of the Building Code Administrators and Inspectors Board.

The bill revises the law to include Division II contractors within the parameters of the Florida Homeowners' Construction Recovery Fund. It revises the statutory limits on recovery payments to include Division II contracts beginning January 1, 2015, for any contract entered into after July 1, 2014. The bill limits Division II claims to $15,000 per claim with a $150,000 lifetime maximum per licensee. The bill removes the prohibition against paying consumer claims where the damages resulted from payments made in violation of the Florida Construction Lien Law for contracts entered into after July 1, 2014.

The bill revises language for a notice that contractors must give to homeowners informing them of their rights under the recovery fund, to advise that payments from the fund are up to a limited amount.

This bill will likely result in additional claims being paid from the Florida Homeowners' Construction Recovery Fund. However, the fiscal impact of the bill is indeterminate as the total amount of additional claims to be paid is unknown and the number of eligible claims and the amount of each claim will vary based on the circumstances. The amount of yearly recovery fund payments is limited by the amount of funding received from the 1.5% surcharge. Therefore, the total amount of all claims paid each year will not increase as a result of receiving additional claims. However, the inclusion of additional claims will likely extend the amount of time it takes to pay each individual claim.

The bill has an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida Homeowners' Construction Recovery Fund

The Florida Homeowners' Construction Recovery Fund (fund) is created in s. 489.140, F.S., as a separate account in the Professional Regulation Trust Fund.

According to the Department of Business and Professional Regulation (DBPR), the fund was created in 1993, after Hurricane Andrew, as a fund of last resort to compensate consumers who contracted for construction, repair, or improvement of their Florida residence and who suffered monetary damages due to the financial misconduct, abandonment, or fraudulent statement of the licensed contractor,[1] financially responsible officer, or business organization licensed under ch. 489, F.S.[2]

The fund is financed by a 1.5% surcharge on all building permit fees associated with the enforcement of the Florida Building Code.[3] The proceeds from the surcharge are allocated equally to fund the Florida Homeowners' Construction Recovery Fund and the operations of the Building Code Administrators and Inspectors Board.[4, 5]

A claimant must be a homeowner and the damage must have been caused by a Division I contractor.[6] The fund is not permitted to compensate consumers who contracted with Division II contractors or to compensate consumers who suffered damages as a result of payments made in violation of the Florida Construction Lien Law under part I of ch. 713, F.S.

Division I contractors are listed in s. 489.105(3)(a)-(c), F.S., as:

- General contractors,
- Building contractors, and
- Residential contractors.

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[1] Department of Business and Professional Regulation, Agency Analysis for SB 1098 (March 11, 2014) (on file with the Business & Professional Regulation Subcommittee).
[2] Section 489.1402(1)(g), F.S.
[3] Section 468.631(1), F.S.
[4] *Id.*
[5] In 2013, the Legislature gave the department authority to transfer excess cash to the Florida Homeowners' Construction Recovery Fund if the department determines it is not needed to fund the operation of the Building Code Administrators and Inspectors Board; however, the department may not transfer excess cash that would exceed the amount appropriated in the General Appropriations Act and any amount approved by the Legislative Budget Commission pursuant to s. 216.181, F.S. See sect. 2, ch. 2013-187, Laws of Fla.
[6] Section 489.1402(1)(c), (f), and (d), F.S.

Division II contractors are listed in 489.105(3)(d)-(q), F.S., as:

- Sheet metal contractors,
- Roofing contractors,
- Class A air-conditioning contractors,
- Class B air-conditioning contractors,
- Class C air-conditioning contractors,
- Mechanical contractors,
- Commercial pool/spa contractors,
- Residential pool/spa contractors,
- Swimming pool/spa servicing contractors,
- Plumbing contractors,
- Underground utility and excavation contractors,
- Solar contractors,
- Pollutant storage systems contractors, and
- Specialty contractors.

Decisions regarding the fund are made by the Construction Industry Licensing Board which is housed within the department.

Construction Industry Licensing Board

The Construction Industry Licensing Board (board) consists of 18 members who are responsible for licensing and regulating the construction industry in this state.[7] The board is divided into Division I and Division II members following the definitions of Division I and Division II contractors respectively, jurisdiction falling to each division relative to their scope.[8] Five members constitute a quorum for each division.

The board meets regularly to consider applications for licensure, to review disciplinary cases, and to conduct informal hearings related to licensure and discipline.[9] It engages in rulemaking to implement the provisions set forth in its statutes and conducts other general business, as necessary.[10]

The board, with respect to actions for recovery from the fund, may "intervene, enter an appearance, file an answer, defend the action, or take any action it deems appropriate and may take recourse through any appropriate method of review" on behalf of the state.[11] In accordance with department rules, "The Board shall either authorize payment of the claim in full or in part, or deny the claim in full, by entry of a Final Order in accordance with Section 489.143, F.S. Action by the Board shall be considered final agency action."[12]

Section 489.129, F.S., grants the board the authority to take actions against any certificate holder or registrant if the contractor, financially responsible officer, or business organization for which the contractor is a primary qualifying agent, a financially responsible officer, or a secondary qualifying agent responsible under s. 489.1195, F.S., is found guilty of certain acts, including the acts that may qualify a claim to the fund. Specifically, these acts are financial misconduct, abandonment, or fraudulent statement of the contractor[13] and are described in s. 489.129, F.S.

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[7] Section 489.107, F.S.
[8] Section 489.107(4)(c), F.S.
[9] Florida Department of Business and Professional Regulation, Construction Industry Licensing Board, *available at* http://www.myfloridalicense.com/DBPR/pro/cilb/index.html (Last visited March 18, 2014).
[10] Section 489.108, F.S.
[11] Section 489.142(1), F.S.
[12] Rule 61G4-21.004(7), F.A.C.
[13] Department of Business and Professional Regulation, Agency Analysis for SB 1098 (March 11, 2014) (on file with the Business & Professional Regulation Subcommittee).

Financial Misconduct

Section 489.129(1)(g), F.S., allows disciplinary proceedings for committing mismanagement or misconduct in the practice of contracting that causes financial harm to a customer. Financial mismanagement or misconduct occurs when:

- Valid liens have been recorded against the customer's property by the contractor for supplies or services ordered by the contractor for which the customer has paid the contractor, but the contractor has not removed the liens within 75 days of such liens;
- The contractor has abandoned a job and the percentage of completion is less than the percentage of the contract price received by the contractor, unless the contractor is entitled to retain such funds under the terms of the contract or refunds the excess funds within 30 days after abandonment; or
- The contractor's job has been completed, and the customer has been made to pay more than the original contract price, as adjusted for subsequent change orders, unless such increase in cost was the result of circumstances beyond the contractor's control, was caused by the customer, or was otherwise permitted by the terms of the contract between the contractor and the customer.

Abandonment of the Project

Section 489.129(1)(j), F.S., allows disciplinary proceedings for abandoning a construction project, which is presumed after 90 days if the contractor terminates the project without just cause or without proper notification to the owner, including the reason for termination, or fails to perform work without just cause for 90 consecutive days.

Fraudulent Statement by the Contractor

Section 489.129(1)(k), F.S, allows disciplinary proceedings for signing a statement with respect to a project or contract:

- Falsely indicating that the work is bonded;
- Falsely indicating that payment has been made for all subcontracted work, labor, and materials which results in a financial loss to the owner, purchaser, or contractor; or
- Falsely indicating that workers' compensation and public liability insurance are provided.

Claims

Section 489.129, F.S., allows the board to take the following actions given the circumstances above:

- Place on probation or reprimand the licensee;
- Revoke, suspend, or deny the issuance or renewal of the certificate or registration;
- Require financial restitution to a consumer for financial harm directly related to a violation of a provision of part 1 of ch. 489, F.S.;
- Impose an administrative fine not to exceed $10,000 per violation;
- Require continuing education; or
- Assess costs associated with investigation and prosecution.

If the violation is not expressly based on s. 489.129(1)(g), (j), or (k), F.S., the claimant must demonstrate that the contractor engaged in activity that is described in those subsections.[14]

[14] Rule 61G4-21.003(3), F.A.C.

The claimant must have obtained a final judgment, arbitration award, or board issued restitution order against the contractor for damages that are a direct result of a compensable violation. A claim for recovery must be made within one year after the conclusion of any civil, criminal, administrative action, or award in arbitration based on the act.[15]

Completed claim forms must be submitted with:

- A copy of the complaint that initiated action against the contractor, a certified copy of the underlying judgment, order of restitution, or award in arbitration, together with the judgment;
- A copy of any contract between the claimant and the contractor, including change orders;
- Proof of payment to the contractor and/or subcontractors;
- Copies of any liens and releases filed against the property, together with the Notice of Claim and Notice to Owner; copies of applicable bonds, sureties, guarantees, warranties, letters of credit and/or policies of insurance; and
- Certified copies of levy and execution documents, and proof of all efforts and inability to collect the judgment or restitution order, and other documentation as may be required by the board to determine causation of injury or specific actual damages.[16]

Pursuant to s. 489.143, F.S., each recovery claim is limited to both a per-claim maximum amount and a total life time per-contractor maximum. For contracts entered prior to July 1, 2004, the fund claims are limited to $25,000 per claim with a total life time aggregate limit of $250,000 per licensee.[17] For contracts entered after July 1, 2004, the per-claim payment limits are increased to $50,000 with a total life time aggregate of $500,000 per licensee.[18] Claims are paid in the order that they are filed.[19]

The board will not compensate claimants from the recovery fund for any of the following reasons.

- The claimant is a licensee who acted as the contractor;
- The claimant is the spouse of the judgment debtor or licensee or a personal representative of such spouse;
- The claim is based upon a construction contract in which the licensee was acting with respect to the property owned or controlled by the licensee;
- The claim is based upon a construction contract in which the contractor did not hold a valid and current license at the time of the construction contract;
- The claimant was associated in a business relationship with the licensee other than the contract at issue;
- When, after notice, the claimant has failed to provide documentation in support of the claims required by rule;
- Where the licensee has reached the aggregate limit; or
- The claimant has contracted for scope of work described in s. 489.105(3)(d)-(q), F.S. [Division II contractors].[20]

The fund is also not permitted to compensate consumers who suffered damages as a result of payments made in violation of Florida Construction Lien Law under part I of ch. 713, F.S.

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[15] Rule 61G4-21.003(5), F.A.C.
[16] Rule 61G4-21.003(2), F.A.C.
[17] Section 489.143(2) and (5), F.S.
[18] *Id.*
[19] Section 489.143(6), F.S.
[20] Rule 61G4-21.004(3), F.A.C.

Duty of Contractor to give Notice of Fund

Any agreement or contract for the repair, restoration, improvement, or construction to residential real property must contain a statutorily mandated notification statement informing the consumer of their rights under the recovery fund, unless the total contract price is less than $2,500.[21]

Effect of Proposed Changes

The bill revises the law to include Division II contractors within the parameters of the Florida Homeowners' Construction Recovery Fund (fund). Specifically, it revises the statutory limits on recovery payments to include Division II contracts beginning January 1, 2015, for any contract entered into after July 1, 2014. The bill limits Division II claims to $15,000 per claim with a $150,000 lifetime maximum per licensee.

The bill removes the prohibition against paying consumer claims where the damages resulted from payments made in violation of the Florida Construction Lien Law for contracts entered into after July 1, 2014.

The bill revises language for the notice that contractors must give to homeowners informing them of their rights under the recovery fund, to advise that payments from the fund are up to a limited amount.

B. SECTION DIRECTORY:

Section 1. Amends s. 489.1401, F.S., revising legislative intent.

Section 2. Amends s. 489.1402, F.S., revising definitions.

Section 3. Amends s. 489.141, F.S., revising conditions under which a claimant is eligible to seek recovery from the recovery fund.

Section 4. Amends s. 489.1425, F.S., revising a form required to be provided by a contractor.

Section 5. Amends s. 489.143, F.S., prohibiting fund disbursements from exceeding a specified amount for each Division I claim and each Division II claim and revising requirements providing caps on payment for certain claims against a licensee.

Section 6. Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   Indeterminate. See Fiscal Comments.

[21] Section 489.1425, F.S.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may increase restitution payments required of licensed Division II contractors against whom a recovery claim is paid. Licensees must repay the Florida Homeowners' Construction Recovery Fund for any amount of recovery paid to a consumer from the fund or have their license suspended until the repayment is made.

D. FISCAL COMMENTS:

This bill will likely result in additional claims being paid from the Florida Homeowners' Construction Recovery Fund. However, the fiscal impact of the bill is indeterminate as the total amount of additional claims to be paid is unknown and the number of eligible claims and the amount of each claim will vary based on the circumstances. During the five fiscal years prior to removal of Division II licensees from the Recovery Fund eligibility (FY 2002 through 2006), Division II contractor claims constituted approximately 23.3% of all claims paid by the Recovery Fund. The average payment amount for each Division II claim was approximately $8,200.00. Applying the percentage of Division II contractor claims paid during FY 2002 to 2006 and the average payment per claim, there is a reasonable estimate of additional claims of $852,800 per year. The total amount of each claim can vary widely based on the circumstances of the contract. In addition, the number of claims received per year can vary widely from year to year.[22]

According to the Department of Business and Professional Regulation, as of March 27, 2014, the Florida Homeowners' Construction Recovery Fund currently has a backlog of 142 completed claims representing $4,345,735.02[23] in anticipated payments, which are awaiting approval by the board. The amount of yearly recovery fund payments is limited by the amount of funding received from the 1.5% surcharge. Therefore, the total amount of all claims paid each year will not increase as a result of receiving additional claims. However, the inclusion of additional claims will likely extend the amount of time it takes to pay each individual claim.[24]

DBPR indicates the bill will increase the workload of staff in the Office of General Counsel to prosecute cases against Division II contractors with revoked licenses. The bill expands the definition of "contractor" for Recovery Fund purposes to include Division II contractors; therefore, the department would continue to prosecute cases against revoked licensees solely for Recovery Fund purposes. However, DBPR states that the additional workload can be accomplished within current staffing and within current departmental resources.[25]

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[22] Department of Business and Professional Regulation, Agency Bill Analysis for HB 1235 (March 20, 2014) on file with the Government Operations Appropriations Subcommittee.

[23] Updated outstanding claims information, email from Department of Business and Professional Regulation to House Government Operation Subcommittee staff (March 27, 2014), on file with the Government Operations Appropriations Subcommittee.

[24] Department of Business and Professional Regulation, Agency Analysis for SB 1098 (March 11, 2014) on file with the Business & Professional Regulation Subcommittee.

[25] Department of Business and Professional Regulation, Agency Bill Analysis for HB 1235 (March 20, 2014) on file with the Government Operations Appropriations Subcommittee.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

On line 232 of the committee substitute, "per claimant" needs to be changed to "per claim." Statutes and the bill provide fiscal limits per licensee and per claim for different categories, but there are not statutory or proposed limits per claimant. This error was not discovered until after the committee substitute had been adopted by the Business & Professional Regulation Subcommittee.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 24, 2014, the Business & Professional Regulation Subcommittee adopted an amendment that did the following and reported the bill favorably with committee substitute:

- Reinserts language that was stricken in the bill that limits claims to a $250,000 lifetime cap per licensee and clarifies that this limitation is for contracts entered into prior to July 1, 2004.

This analysis is drafted to the committee substitute as adopted by the Business & Professional Regulation Subcommittee.

A bill to be entitled

An act relating to the Florida Homeowners' Construction Recovery Fund; amending s. 489.1401, F.S.; revising legislative intent; amending s. 489.1402, F.S.; revising definitions; amending s. 489.141, F.S.; revising conditions under which a claimant is eligible to seek recovery from the recovery fund; amending s. 489.1425, F.S.; revising the form required to be provided by a contractor which explains a consumer's rights under the recovery fund; amending s. 489.143, F.S.; prohibiting fund disbursements from exceeding a specified amount for each Division I claim and each Division II claim; revising requirements providing caps on payment for certain claims against a licensee; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (2) and (3) of section 489.1401, Florida Statutes, are amended to read:

489.1401 Legislative intent.—

(2) It is the intent of the Legislature that the sole purpose of the Florida Homeowners' Construction Recovery Fund is to compensate an ~~any~~ aggrieved claimant who contracted for the construction or improvement of the homeowner's residence located

within this state and who has obtained a final judgment in any court of competent jurisdiction, was awarded restitution by the Construction Industry Licensing Board, or received an award in arbitration against a licensee on grounds of financial mismanagement or misconduct, abandoning a construction project, or making a false statement with respect to a project. Such grievance must arise ~~and arising~~ directly out of a ~~any~~ transaction conducted when the judgment debtor was licensed and must involve an act ~~performed any of the activities~~ enumerated under s. 489.129(1)(g), (j) or (k) ~~on the homeowner's residence~~.

(3) It is the intent of the Legislature that Division I and Division II contractors set apart funds for the specific objective of participating in the fund.

Section 2. Paragraphs (d), (i), (k), and (l) of subsection (1) of section 489.1402, Florida Statutes, are amended to read:

489.1402 Homeowners' Construction Recovery Fund; definitions.—

(1) The following definitions apply to ss. 489.140-489.144:

(d) "Contractor" means a Division I or a Division II contractor performing his or her respective services described in s. 489.105(3)(a)-(q) ~~s. 489.105(3)(a)-(c)~~.

(i) "Residence" means a single-family residence, an individual residential condominium or cooperative unit, or a residential building containing not more than two residential units in which the owner contracting for the improvement is

residing or will reside 6 months or more each calendar year upon completion of the improvement.

(k) "Same transaction" means a contract, or a ~~any~~ series of contracts, between a claimant and a contractor or qualified business, when such contract or contracts involve the same property or contiguous properties and are entered into either at one time or serially.

(l) "Valid and current license," for the purpose of s. 489.141(2)(d), means a ~~any~~ license issued pursuant to this part to a licensee, including a license in an active, inactive, delinquent, or suspended status.

Section 3. Subsections (1) and (2) of section 489.141, Florida Statutes, are amended to read:

489.141 Conditions for recovery; eligibility.—

(1) A ~~Any~~ claimant is eligible to seek recovery from the recovery fund after making ~~having made~~ a claim and exhausting the limits of any available bond, cash bond, surety, guarantee, warranty, letter of credit, or policy of insurance, if ~~provided that~~ each of the following conditions is satisfied:

(a) The claimant has received final judgment in a court of competent jurisdiction in this state or has received an award in arbitration or the Construction Industry Licensing Board has issued a final order directing the licensee to pay restitution to the claimant. The board may waive this requirement if:

1. The claimant is unable to secure a final judgment against the licensee due to the death of the licensee; or

2. The claimant has sought to have assets involving the transaction that gave rise to the claim removed from the bankruptcy proceedings so that the matter might be heard in a court of competent jurisdiction in this state and, after due diligence, the claimant is precluded by action of the bankruptcy court from securing a final judgment against the licensee.

(b) The judgment, award, or restitution is based upon a violation of s. 489.129(1)(g), (j), or (k) or s. 713.35.

(c) The violation was committed by a licensee.

(d) The judgment, award, or restitution order specifies the actual damages suffered as a consequence of such violation.

(e) The contract was executed and the violation occurred on or after July 1, 1993, and provided that:

1. The claimant has caused to be issued a writ of execution upon such judgment, and the officer executing the writ has made a return showing that no personal or real property of the judgment debtor or licensee liable to be levied upon in satisfaction of the judgment can be found or that the amount realized on the sale of the judgment debtor's or licensee's property pursuant to such execution was insufficient to satisfy the judgment;

2. If the claimant is unable to comply with subparagraph 1. for a valid reason to be determined by the board, the claimant has made all reasonable searches and inquiries to ascertain whether the judgment debtor or licensee is possessed of real or personal property or other assets subject to being

sold or applied in satisfaction of the judgment and by his or her search has discovered no property or assets or has discovered property and assets and has taken all necessary action and proceedings for the application thereof to the judgment but the amount thereby realized was insufficient to satisfy the judgment; and

3. The claimant has made a diligent attempt, as defined by board rule, to collect the restitution awarded by the board.

(f) A claim for recovery is made within 1 year after the conclusion of any civil, criminal, or administrative action or award in arbitration based on the act. This paragraph applies to any claim filed with the board after October 1, 1998.

(g) Any amounts recovered by the claimant from the judgment debtor or licensee, or from any other source, have been applied to the damages awarded by the court or the amount of restitution ordered by the board.

(h) The claimant is not a person who is precluded by this act from making a claim for recovery.

(2) A claimant is not qualified to make a claim for recovery from the recovery fund, if:

(a) The claimant is the spouse of the judgment debtor or licensee or a personal representative of such spouse;

(b) The claimant is a licensee who acted as the contractor in the transaction <u>that</u> ~~which~~ is the subject of the claim;

(c) The claim is based upon a construction contract in which the licensee was acting with respect to the property owned

or controlled by the licensee;

(d) The claim is based upon a construction contract in which the contractor did not hold a valid and current license at the time of the construction contract;

(e) The claimant was associated in a business relationship with the licensee other than the contract at issue;

(f) The claimant has suffered damages as the result of making improper payments to a contractor as defined in part I of chapter 713 on contracts entered into before July 1, 2014; or

(g) The claimant has contracted with a licensee to perform a scope of work described in s. 489.105(3)(d)-(p) on contracts entered into before July 1, 2014.

Section 4. Subsection (1) of section 489.1425, Florida Statutes, is amended to read:

489.1425 Duty of contractor to notify residential property owner of recovery fund.—

(1) An ~~Any~~ agreement or contract for repair, restoration, improvement, or construction to residential real property must contain a written statement explaining the consumer's rights under the recovery fund, except where the value of all labor and materials does not exceed $2,500. The written statement must be substantially in the following form:

FLORIDA HOMEOWNERS' CONSTRUCTION
RECOVERY FUND

PAYMENT, UP TO A LIMITED AMOUNT, MAY BE AVAILABLE FROM THE FLORIDA HOMEOWNERS' CONSTRUCTION RECOVERY FUND IF YOU LOSE MONEY ON A PROJECT PERFORMED UNDER CONTRACT, WHERE THE LOSS RESULTS FROM SPECIFIED VIOLATIONS OF FLORIDA LAW BY A LICENSED CONTRACTOR. FOR INFORMATION ABOUT THE RECOVERY FUND AND FILING A CLAIM, CONTACT THE FLORIDA CONSTRUCTION INDUSTRY LICENSING BOARD AT THE FOLLOWING TELEPHONE NUMBER AND ADDRESS:

The statement must ~~shall~~ be immediately followed by the board's address and telephone number as established by board rule.

Section 5. Section 489.143, Florida Statutes, is amended to read:

489.143 Payment from the fund.—

(1) The fund shall be disbursed as provided in s. 489.141 on a final order of the board.

(2) A ~~Any~~ claimant who meets all of the conditions prescribed in s. 489.141 may apply to the board to cause payment to be made to a claimant from the recovery fund in an amount equal to the judgment, award, or restitution order or $25,000, whichever is less, or an amount equal to the unsatisfied portion of such person's judgment, award, or restitution order, but only to the extent and amount of actual damages suffered by the claimant, and only up to the maximum payment allowed for each respective Division I and Division II claim. Payment from the fund for other costs related to or pursuant to civil proceedings

such as postjudgment interest, attorney ~~attorney's~~ fees, court costs, medical damages, and punitive damages is prohibited. The recovery fund is not obligated to pay a ~~any~~ judgment, an award, or a restitution order, or any portion thereof, which is not expressly based on one of the grounds for recovery set forth in s. 489.141.

(3) Beginning January 1, 2005, for each Division I contract entered into after July 1, 2004, payment from the recovery fund shall be subject to a $50,000 maximum payment for each Division I claim. Beginning January 1, 2015, for each Division II contract entered into on or after July 1, 2014, payment from the recovery fund shall be subject to a $15,000 maximum payment for each Division II claim.

(4) ~~(3)~~ Upon receipt by a claimant under subsection (2) of payment from the recovery fund, the claimant shall assign his or her additional right, title, and interest in the judgment, award, or restitution order, to the extent of such payment, to the board, and thereupon the board shall be subrogated to the right, title, and interest of the claimant; and any amount subsequently recovered on the judgment, award, or restitution order, to the extent of the right, title, and interest of the board therein, shall be for the purpose of reimbursing the recovery fund.

(5) ~~(4)~~ Payments for claims arising out of the same transaction shall be limited, in the aggregate, to the lesser of the judgment, award, or restitution order or the maximum payment

allowed, for a Division I claim or a Division II claim, regardless of the number of claimants involved in the transaction.

(6) ~~(5)~~ For contracts entered into before July 1, 2004, payments for claims against any one licensee may ~~shall~~ not exceed, in the aggregate, $100,000 annually, up to a total aggregate of $250,000. For any claim approved by the board which is in excess of the annual cap, the amount in excess of $100,000 up to the total aggregate cap of $250,000 is eligible for payment in the next and succeeding fiscal years, but only after all claims for the then-current calendar year have been paid. Payments may not exceed the aggregate annual or per claimant limits under law. Beginning January 1, 2005, for each Division I contract entered into after July 1, 2004, payment from the recovery fund is subject only to a total aggregate cap of $500,000 for each Division I licensee. Beginning January 1, 2015, for each Division II contract entered into on or after July 1, 2014, payment from the recovery fund is subject only to a total aggregate cap of $150,000 for each Division II licensee.

(7) ~~(6)~~ Claims shall be paid in the order filed, up to the aggregate limits for each transaction and licensee and to the limits of the amount appropriated to pay claims against the fund ~~for the fiscal year in which the claims were filed~~. Payments may not exceed the total aggregate cap per licensee or per claimant limits under this section.

(8) ~~(7)~~ If the annual appropriation is exhausted with

claims pending, such claims shall be carried forward to the next fiscal year. Any moneys in excess of pending claims remaining in the recovery fund at the end of the fiscal year shall be paid as provided in s. 468.631.

(9) ~~(8)~~ Upon the payment of any amount from the recovery fund in settlement of a claim in satisfaction of a judgment, award, or restitution order against a licensee as described in s. 489.141, the license of such licensee shall be automatically suspended, without further administrative action, upon the date of payment from the fund. The license of such licensee may ~~shall~~ not be reinstated until he or she has repaid in full, plus interest, the amount paid from the fund. A discharge of bankruptcy does not relieve a person from the penalties and disabilities provided in this section.

(10) ~~(9)~~ A ~~Any~~ firm, a corporation, a partnership, or an association, or a ~~any~~ person acting in his or her individual capacity, who aids, abets, solicits, or conspires with another ~~any~~ person to knowingly present or cause to be presented a ~~any~~ false or fraudulent claim for the payment of a loss under this act is guilty of a third-degree felony, punishable as provided in s. 775.082 or s. 775.084 and by a fine of up to ~~not exceeding~~ $30,000~~,~~ unless the value of the fraud exceeds that amount, ~~$30,000~~ in which event the fine may not exceed double the value of the fraud.

(11) ~~(10)~~ ~~All~~ Payments and disbursements from the recovery fund shall be made by the Chief Financial Officer upon a voucher

signed by the secretary of the department or the secretary's designee.

Section 6. This act shall take effect July 1, 2014.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 7001 PCB RORS 14-01 Administrative Procedures
SPONSOR(S): Government Operations Subcommittee; Rulemaking Oversight & Repeal Subcommittee; Santiago
TIED BILLS: **IDEN./SIM. BILLS:** SB 1708

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Rulemaking Oversight & Repeal Subcommittee	12 Y, 0 N	Miller	Rubottom
1) Government Operations Subcommittee	10 Y, 0 N, As CS	Harrington	Williamson
2) Government Operations Appropriations Subcommittee		White CCW	Topp BDT
3) Rules & Calendar Committee			

SUMMARY ANALYSIS

Agencies must review their existing rules to identify and correct deficiencies, improve efficiencies, reduce paperwork and costs, clarify and simplify text, and revise or delete rules that become obsolete, unnecessary, or are redundant of statute. Biennially, each agency head is required to file a report with the Speaker of the House of Representatives, President of the Senate, and the Legislature's Joint Administrative Procedures Committee (JAPC) summarizing the results of this review and revision, suggesting certain legislative changes, and addressing the economic impact of the rules on small business. In 2011, the Legislature suspended biennial reporting for that year and required all agencies to review and report on the economic effect of all then-existing rules by the end of 2013. In the same act, the Legislature required agencies to file a separate annual "regulatory plan" outlining all rulemaking the agency intended to implement in the next fiscal year, except emergency rulemaking.

When a newly-enacted law requires an agency to adopt new or amend current administrative rules for proper implementation, current law requires the agency charged with enforcing that law to formally propose such rules within 180 days of the effective date of the law. While agencies generally comply with this deadline, there are numerous examples of agencies failing to act within 180 days or interpreting the new law as not requiring rulemaking for proper implementation. In some instances this delay or inaction persists for several years.

The bill replaces the biennial summary reporting requirement with an expanded, annual regulatory plan. It requires each agency to determine whether each new law creating or affecting the agency's authority will require new or amended rules. If so, the agency must initiate rulemaking by a specific time. If not, the agency must state concisely why the law may be implemented without additional rulemaking. The regulatory plan also must state each existing law on which the agency will initiate rulemaking in the current fiscal year. The plan must be certified by the agency head and general counsel and published on the agency's internet website, with a copy of the certification filed with JAPC. The existing 180-day requirement is revised to coincide with the specific publishing requirements.

The bill compels adherence with the new reporting requirements and action deadlines by suspending the rulemaking authority of an agency that fails to comply with specific requirements until that agency completes the required action or the end of the next regular legislative session, whichever is earlier. The bill repeals the retrospective economic review of existing rules and repeals the law pertaining to the online survey.

The bill may have an insignificant fiscal impact on state agencies.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Agency Rulemaking and Reporting Requirements

A rule is an agency statement of general applicability which interprets, implements, or prescribes law or policy, including the procedure and practice requirements of an agency, as well as certain types of forms.[1] The effect of an agency statement determines whether it meets the statutory definition of a rule, regardless of how the agency characterizes the statement.[2] If an agency statement generally requires compliance, creates certain rights while adversely affecting others, or otherwise has the direct and consistent effect of law, it is a rule.[3]

Rulemaking authority is delegated by the Legislature[4] by law authorizing an agency to "adopt, develop, establish, or otherwise create"[5] a rule. Agencies do not have discretion whether to engage in rulemaking.[6] To adopt a rule an agency must have an express grant of authority to implement a specific law by rulemaking.[7] The grant of rulemaking authority itself need not be detailed.[8] The particular statute being interpreted or implemented through rulemaking must provide specific standards and guidelines to preclude the agency from exercising unbridled discretion in creating policy or applying the law.[9] A delegation of authority to an administrative agency by a law that is vague, uncertain, or so broad as to give no notice of what actions would violate the law, may unconstitutionally allow the agency to make the law.[10] Because of this constitutional limitation on delegated rulemaking, the Legislature must provide minimal standards and guidelines in the law creating a program to provide for its proper administration by the agency. As such, the Legislature may delegate rulemaking authority to agencies but not the authority to determine what should be the law.

Section 120.54(1)(b), F.S.: The "180 Day" Requirement

An agency may not delay implementation of a statute pending adoption of specific rules unless there is an express provision prohibiting application of the statute before the implementing rules are adopted.[11] If a law is enacted that requires agency rulemaking for proper implementation, "such rules shall be drafted and formally proposed as provided in [s. 120.54, F.S.] within 180 days after the effective date of the act, unless the act provides otherwise."[12] This "180-day requirement" predates the 1996 revisions.[13]

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[1] Section 120.52(16), F.S.; *Florida Dept. of Financial Services v. Capital Collateral Regional Counsel-Middle Region*, 969 So. 2d 527, 530 (Fla. 1st DCA 2007).

[2] *Dept. of Administration v. Harvey*, 356 So. 2d 323, 325 (Fla. 1st DCA 1977).

[3] *McDonald v. Dept. of Banking & Fin.*, 346 So.2d 569, 581 (Fla. 1st DCA 1977), articulated this principle subsequently cited in numerous cases. *See State of Florida, Dept. of Administration v. Stevens*, 344 So. 2d 290 (Fla. 1st DCA 1977); *Dept. of Administration v. Harvey*, 356 So. 2d 323 (Fla. 1st DCA 1977); *Balsam v. Dept. of Health and Rehabilitative Services*, 452 So.2d 976, 977–978 (Fla. 1st DCA 1984); *Dept. of Transp. v. Blackhawk Quarry Co.*, 528 So. 2d 447, 450 (Fla. 5th DCA 1988), rev. den. 536 So.2d 243 (Fla.1988); *Dept. of Natural Resources v. Wingfield*, 581 So. 2d 193, 196 (Fla. 1st DCA 1991); *Dept. of Revenue v. Vanjaria Enterprises, Inc.*, 675 So. 2d 252, 255 (Fla. 5th DCA 1996); *Volusia County School Board v. Volusia Homes Builders Association, Inc.*, 946 So. 2d 1084 (Fla. 5th DCA 2007); *Florida Dept. of Financial Services v. Capital Collateral Regional Counsel*, 969 So. 2d 527 (Fla. 1st DCA 2007); *Coventry First, LLC v. State of Florida, Office of Insurance Regulation*, 38 So. 3d 200 (Fla. 1st DCA 2010).

[4] *Southwest Florida Water Management District v. Save the Manatee Club, Inc.*, 773 So. 2d 594 (Fla. 1st DCA 2000).

[5] Section 120.52(17), F.S.

[6] Section 120.54(1)(a), F.S.

[7] Sections 120.52(8) & 120.536(1), F.S. In 1996, the Legislature extensively revised agency rulemaking under the Administrative Procedure Act to require both the express grant of rulemaking authority and a specific law to be implemented by rule. Chapter 96-159, L.O.F.

[8] *Save the Manatee Club, Inc.*, supra at 599.

[9] *Sloban v. Florida Board of Pharmacy*, 982 So. 2d 26, 29-30 (Fla. 1st DCA 2008); *Board of Trustees of the Internal Improvement Trust Fund v. Day Cruise Association, Inc.*, 794 So. 2d 696, 704 (Fla. 1st DCA 2001).

[10] *Conner v. Joe Hatton, Inc.*, 216 So. 2d 209 (Fla.1968).

[11] Section 120.54(1)(c), F.S.

[12] Section 120.54(1)(b), F.S.

The statute does not require complete adoption of rules within 180 days. An agency may comply with the statute merely by publishing a notice of proposed rule.[14] Proposed rules can be repeatedly, substantially revised based on public input and may also be withdrawn. Consequently, the 180-day requirement does not ensure prompt rulemaking.

JAPC Monitoring and Agency Compliance

The Joint Administrative Procedures Committee (JAPC) monitors agency compliance with the 180-day requirement in furtherance of its rulemaking oversight duties.[15] JAPC staff reviews legislation enacted each session to identify new or changed laws that appear to require the adoption of new rules or the amendment or repeal of existing rules. Where the law appears to mandate new rulemaking[16] or restates an existing mandate for rulemaking, JAPC sends a letter reminding the agency of the 180-day requirement. If the text of proposed rules is not published, at least as part of a notice of rule development, within the 180-days, JAPC will follow with an inquiry as to when the agency will initiate public rulemaking on that issue.

Agencies generally comply with the 180-day requirement as a matter of maintaining an effective working relationship between the executive and legislative offices even though JAPC has no power to compel compliance. JAPC identified several agencies that had not proposed rules within 180 days of the enactment of laws appearing to mandate new rulemaking during the period of 2007-2011. At its meeting on February 18, 2013, JAPC heard presentations from 13 different agencies on whether rulemaking was necessary to implement particular laws and, if so, explanations for the lack of progress. Some members of JAPC asked whether these agencies treated the statute as a "suggestion" instead of a mandatory rulemaking requirement.

"Directive" vs. "Mandate"

Courts generally interpret words in statutes such as "shall" or "must" as mandating a particular action where the alternative to the action is a possible deprivation of some right. However, use of such otherwise-mandatory terms where there is no effective consequence for the failure to act renders them *directory*, not compulsory.[17] A person regulated by an agency or having a substantial interest in an agency rule may petition that agency to adopt, amend, or repeal a rule,[18] including when the agency does not act within the 180-day requirement. The Administrative Procedure Act (APA) provides no other process to enforce the 180-day requirement, nor the authority for any specific entity to compel compliance.

Section 120.74, F.S.: Biennial Reporting

1996 Reporting Requirement

As part of the comprehensive revision of the APA in 1996, agencies were required to review all rules adopted before October 1, 1996, identify those exceeding the rulemaking authority permitted under the revised APA, and report the results to JAPC. JAPC would prepare and submit a combined report of all agency reviews to the President of the Senate and Speaker of the House of Representatives for legislative consideration.[19]

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[13] The 180 requirement was enacted as chapter 85-104, s. 7, L.O.F.

[14] Section 120.54(3)(a), F.S. This is the common interpretation of the 180 day requirement. An alternative interpretation would be that a notice of rule development published under s. 120.54(2), F.S., including a *preliminary* draft of proposed rules, may be sufficient to comply.

[15] Joint Rule 4.6.

[16] Such as stating that the agency "shall adopt rules" or "shall establish" or "must establish" a particular standard or policy.

[17] *S.R. v. State,* 346 So.2d 1018, 1019 (Fla. 1977); *Reid v. Southern Development Co.*, 42 So. 206, 208, 52 Fla. 595, 603 (Fla. 1906); *Ellsworth v. State*, 89 So.3d 1076, 1079 (Fla. 2d DCA 2012); *Kinder v. State*, 779 So.2d 512, 514 (Fla. 2d DCA 2000).

[18] Section 120.54(7)(a), F.S. If the agency denies the petition, the requesting party may seek judicial review of that decision. Sections 120.52(2) and 120.68, F.S.

[19] Chapter 96-159, s. 9(2), L.O.F.

Another 1996 revision required ongoing agency rulemaking review, revision, and reporting.[20] Under that law, as amended, each agency must review its rules every two years and amend or repeal rules as necessary to comply with specific requirements.[21] Biennially, the agency head must report the results and other required information to the President of the Senate, Speaker of the House of Representatives, JAPC, and "each appropriate standing committee of the Legislature" on October 1.[22]

Limited Utility of s. 120.74, F.S., Reports

Agencies as defined in the APA,[23] including school districts, comply with the requirements of s. 120.74, F.S., typically by filing summary reports that verify the agency performed the required reviews, list rules identified in the review for amendment or repeal, and state a finding of no undue economic impact on small businesses (a required subject of the report). For example, a 2009 report from a school district identified the following changes to the student code of conduct:

> The Code of Student Conduct is reviewed and revised annually and serves as the School Board's policies and procedures for governing student behavior on school grounds, at school activities, and while being transported to and from school. The majority of the recommended changes for 2008-09 are minor revisions in punctuation, spelling, language, or order of paragraphs.[24]

The 2013 report for the same school district states the following as "what & why the policy changed" for the student code of conduct:

> The Code of Student Conduct is reviewed and revised annually and serves as the School Board's policies and procedures for governing student behavior on school grounds, at school activities, and while being transported to and from school.[25]

A different school district submitted substantially the same reports for 2009 and 2013, commenting only on that district's review and management of forms. That district's reports included no information on whether any rules were identified as requiring revision or repeal due to changes in law.[26]

Reports by state agencies have reflected inconsistent application of the requirement for the report to "specify any changes made to [the agency's] rules as a result of the review. . ."[27] One agency's 2009 report identified each rule requiring repeal or amendment and new rules required by program changes, including a brief explanation of the reason for the amendment or adoption.[28] In contrast, a different agency simply identified obsolete rules for repeal, without stating why the rules were obsolete, and listed a rule for amendment to update documents incorporated by reference, without identifying the documents so referenced.[29] Some agencies provided lengthy lists of rules identified for amendment or

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[20] Chapter 96-399, s. 46, L.O.F, codified as s. 120.74, F.S. In both 2006 and 2008, the Legislature added substantive provisions to this section. Chapters 2006-82, s. 9, and 2008-149, s. 8, L.O.F.

[21] Identify and correct deficiencies; clarify and simply its rules; delete rules that are obsolete, unnecessary, or merely repeat statutory language; improve efficiency, reduce paperwork, decrease costs to private sector and government; coordinate rules with agencies having concurrent or overlapping jurisdiction. Section 120.74(1), F.S.

[22] Section 120.74(2), F.S.

[23] Section 120.52(1), F.S.

[24] School Board of Manatee County, "Section 120.74 Report" (Sept. 29, 2009), received by JAPC on Nov. 3, 2009 (on file with the Rulemaking Oversight and Repeal Subcommittee).

[25] School Board of Manatee County, "Section 120.74 Report" (Sept. 24, 2013), received by the House on Oct. 3, 2013 (on file with the Rulemaking Oversight and Repeal Subcommittee).

[26] School Board of Santa Rosa County, 2009 Report received by JAPC on Sept. 30, 2009, and 2013 Report received by the House on Aug. 26, 2013 (on file with the Rulemaking Oversight and Repeal Subcommittee).

[27] Section 120.74(2), F.S.

[28] Dept. of Children and Families, "Biennial rule review report required by section 120.74, Florida Statutes" (Oct. 1, 2009), received by JAPC on Oct. 7, 2009.

[29] Dept. of Agriculture and Consumer Services, "August 20, 2009 Memorandum regarding §120.74, Florida Statutes, Rule Review" (Oct. 1, 2009), received by JAPC on Oct. 1, 2009.

repeal with little explanation other than repeating the terms of the review statute as to the reason for such proposed action.[30]

Regulatory Plans
In 2011, the reporting requirements were amended to require that each agency file an annual regulatory plan in addition to the biennial reports.[31] The regulatory plan identifies those rules the agency intends to adopt, amend, or repeal during the next fiscal year. These reports have not proven any more substantive than the biennial reports described above.

Effect of the Bill
The bill retains the requirement that agencies identify and proceed with rulemaking necessitated by changes in newly-enacted law, but revises the deadlines, method for compliance, and reporting requirements in the APA.

The bill replaces the biennial reporting with an expanded annual regulatory plan. The regulatory plan requires each agency to identify those laws enacted or amended during the previous 12 months that created or modified the duties or authority of the agency. The plan may exclude any law affecting all or most agencies, if the law is identified as such by letter to JAPC from the Governor or the Attorney General. The plan also must identify whether rulemaking is necessary to implement the newly-enacted provisions.

For each law identified in the regulatory plan as requiring rulemaking, the agency must state whether a notice of rule development has been published, and the date by which the agency expects to publish the notice of proposed rule.

The bill imposes specific deadlines for the agency to publish the Notice of Rule Development and Notice of Proposed Rule. Specifically, the bill requires agencies to publish a Notice of Rule Development by November 1 for each law identified in the regulatory plan for which rulemaking is necessary to implement.

The bill requires an agency to move forward with rulemaking by publishing a Notice of Proposed Rule by April 1 of the year after the submission of the regulatory plan. If the agency is unable to publish the notice by April 1, the agency may extend the deadline to the following October 1, which is the deadline for the next regulatory plan. The Notice of Extension must be published in the Florida Administrative Register (FAR) and reference the published Notice of Rule Development. If the agency needs additional time, the agency must re-list the law on the next regulatory plan. Re-listing the law on a subsequent regulatory plan further extends the deadline for the Notice of Proposed Rule.

If the agency states rulemaking is not necessary to implement the new law, the regulatory plan must contain a concise written explanation supporting that conclusion. An agency also is required to identify all other laws the agency expects to implement by rulemaking, except emergency rulemaking, before the end of that fiscal year. For each law listed, the agency must indicate whether the rulemaking is intended to simplify, clarify, increase efficiency, improve coordination with other agencies, reduce regulatory costs, or delete obsolete, unnecessary, or redundant rules.

The regulatory plan must verify that the agency continuously reviews and revises its rules to maintain conformity with applicable law. The regulatory plan must be certified by both the agency head and the agency's primary lawyer. Copies of the certification will be delivered to JAPC and included with the agency's annual legislative budget request filed with the House of Representatives, Senate, and Executive Office of the Governor.

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[30] Dept. of Business & Professional Regulation, "Section 120.74, Florida Statutes Biennial Report to the Legislature" (Oct. 1, 2009), received by JAPC on Oct. 5, 2009; Dept. of Environmental Protection, 2009 Report received by JAPC on Oct. 2, 2009.
[31] Chapter 2011-225, s. 4, L.O.F. The bill also suspended reporting in 2011 and 2013 under ss. 120.74(1) and (2), F.S., to avoid duplication with the economic reviews and reports under s. 120.745, F.S.

The agency is responsible for publishing its regulatory plan on its website or another state website established for publication of administrative law records. The agency must publish notice of publication in the FAR along with a hyperlink to the regulatory plan, and deliver a copy of the certification to JAPC.

The bill further requires an agency to file with JAPC a certification of compliance with the publishing requirement for the Notice of Rule Development and for each Notice of Extension or regulatory plan correction filed.

By October 15 of each year:

- The Department of Business and Professional Regulation must file with JAPC a certification that it has reviewed the regulatory plan for each board established under s. 20.165(4), F.S., and any other board or commission receiving administrative support from the department.
- The Department of Health must file with JAPC a certification that the department has reviewed the regulatory plan for each board established under s. 20.43(3), F.S.

A certification by the Department of Business and Professional Regulation or the Department of Health may relate to more than one board.

An agency is required to supplement its regulatory plan if a law enacted during a special session affects the agency's duties or authority. The supplement must be completed within 30 days after a bill becomes a law if the law is enacted before the next regular legislative session and the law modifies the agency's specifically legislated duties.

To ensure compliance with the law, the rulemaking authority of an agency that fails to comply with any of the following requirements of the bill is suspended until the agency completes the required action or until the end of the subsequent regular legislative session, whichever occurs first:

- By October 1, the agency must publish the annual regulatory plan on its website, deliver a copy to JAPC, and publish a notice in the FAR.
- The agency must publish a Notice of Proposed Rule by April 1, or must file a Notice of Extension, which extends the period to the next October 1.

During the suspension, the agency may complete any rulemaking actions required by the revised statute, including publishing Notices of Rule Development and Notices of Proposed Rules, and may conduct any public hearings that were noticed prior to the period of suspension. The suspension does not authorize an agency to promulgate or apply a statement defined as a rule, unless the statement was filed for adoption prior to the suspension. The suspension tolls the time for filing any already-pending rules for adoption; time resumes running when the agency meets the statutory requirements to remove the suspension. An agency's ability to adopt emergency rules or rules necessary to comply with federal law would not be suspended.

Educational entities, such as school districts, are exempted entirely from the requirements in the bill.

Retrospective Economic Review of Rules

Background

In November 2010, the Legislature enacted HB 1565 (2010)[32] overriding a gubernatorial veto. The law created a new limitation on agency rulemaking: any rule adopted after the date of the act, whether a new or amended rule, that may likely have a significant economic impact, could not go into effect unless first ratified by the Legislature.[33] The law requires an agency to prepare a full Statement of Estimated Regulatory Costs (SERC) if the proposed rule either will have an adverse impact on small businesses or if the rule is likely to directly or indirectly increase regulatory costs in excess of $200,000

[32] Chapter 2010-279, L.O.F.

[33] Section 120.541(3), F.S.

in the aggregate in the first year after the rule is implemented.[34] Additionally, the SERC must include an economic analysis addressing whether the rule is likely to have one of three specific impacts, directly or indirectly, in excess of $1 million in the aggregate within 5 years of going into effect.[35]

The requirements of chapter 2010-279, L.O.F., applied only to rules which had not become effective as of November 17, 2010, or were proposed for adoption after that date. Existing rules were not subject to the ratification requirement. In 2011 the Legislature passed CS/CS/CS/HB 993 & HB 7239, including a provision requiring a retrospective economic analysis of those existing rules.[36] All agencies required to publish their rules in the Florida Administrative Code (F.A.C.)[37] were required to review their rules, identify those potentially having one of the impacts described in s. 120.541(2)(a), F.S., over a five year period, complete a comprehensive economic review of such rules, and publicly publish the results and certify their compliance with the statute to JAPC. In 2011, all agencies were to publish the results of their initial reviews and identify existing rules likely to have significant economic impacts.[38] At the agency's discretion, the agency may submit the compliance economic reviews in two approximately equal groups: Group 1 reviews were to be published by December 1, 2012, and the remaining reviews in Group 2 were to be published by December 1, 2013.[39]

Concurrently with the development of HB 993 and HB 7239, the Governor directed a review of all existing agency rules through the newly-created Office of Fiscal Accountability and Regulatory Reform (OFARR).[40] Because most agencies participated in this review, and many of the elements were similar to the retrospective economic reviews contemplated by the Legislature, the bill exempted those agencies participating in the Governor's review from most of the new law's requirements. These "exempt" agencies were required to publish their initial determination of those rules requiring compliance economic reviews in 2011[41] and all final reviews by December 31, 2013.[42]

All agencies complied with the required retrospective review and publication of reports. Of those agencies not participating in the OFARR review process, only five[43] identified rules requiring compliance economic reviews.[44] Of the 161 compliance economic reviews published by these five agencies in 2012, only 72 reviews showed the subject rule as having a specific impact exceeding $1 million over the 5 year period from July 1, 2011 to July 1, 2016.

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[34] Sections 120.54(3)(b)1. and 120.541(1)(b), F.S.

[35] Section 120.541(2)(a), F.S. The three impacts are whether the rule will have 1) an adverse impact on economic growth, private sector job creation or employment, or private sector employment; 2) an adverse impact on business competitiveness, including competition with interstate firms, productivity, or innovation; or 3) an increase in regulatory costs, including transactional costs as defined by s. 120.541(2)(d), F.S.

[36] Chapter 2011-225, s. 5, L.O.F, codified as s. 120.745, F.S.

[37] A provision in the act designed specifically to *de facto* exclude educational units (defined in s. 120.52(6), F.S.) which do not publish their rules in the F.A.C. pursuant to s. 120.55(1)(a)2., F.S. Certain other publication requirements also do not apply to educational units. Section 120.81(1), F.S.

[38] Section 120.745(2), F.S. The statute required each agency to publish the number of its rules implementing or affecting state revenues (revenue rules), requiring submission of information or data by third parties (data collection rules), rules to be repealed, rules to be amended to reduce economic impacts, and those rules that would be reported in Groups 1 or 2.

[39] Section 120.745(5), F.S.

[40] Executive Order 11-01, subsequently revised by Executive Order 11-72 and replaced by Executive Order 11-211.

[41] As required by the statute, exempt agencies published the number of identified revenue rules (2,078), data collection rules (3,529), rules to be repealed (1,852), rules to be amended to reduce economic impacts (1,441), and rules requiring compliance economic reviews (3,056). At https://www.myfloridalicense.com/rulereview/Rule-Review-Reports.html (last accessed February 4, 2014).

[42] Section 120.745(9), F.S.

[43] Dept. of Agriculture and Consumer Services, Dept. of Citrus, Dept. of Financial Services, Office of Financial Regulation, and Public Service Commission.

[44] As required by the statute, "non-exempt" agencies published the number of identified revenue rules (508), data collection rules (1,169), rules to be repealed (482), rules to be amended to reduce economic impacts (189), and rules requiring compliance economic reviews to be reported in Group 1 (161) and Group 2 (182).

Effect of the Bill
In December 2013, the retrospective economic reviews of all agency rules were completed with the publication of the required compliance economic reviews. Accordingly, the bill repeals s. 120.745, F.S., effective upon the bill becoming law.

Your Voice Survey

Background
As part of the increased oversight of agency rulemaking enacted in 2011, the Legislature sought public participation and input about the effect of agency rules through use of an online survey. Those wanting to comment on any rule could log in to the survey form,[45] respond to a series of questions intended to identify the particular rule and the context of the comment, and provide as much information as the participant thought necessary. Access to the online form was directed primarily through the website of the Florida House of Representatives and was known as the "Your Voice Survey."

To encourage public participation and obtain as wide a variety of comments as possible during the period of July 1, 2011 through July 1, 2014, s. 120.7455, F.S.,[46] was enacted to provide certain limited protections from enforcement actions based on any response to the survey. Specifically, a person reporting or providing information solicited by the Legislature in conformity with the law is immune from any enforcement action or prosecution based on such reporting.[47] If a person was subject to a penalty in excess of the minimum provided by law or rule, and such person proved the enforcement action was in retaliation for providing or withholding any information in response to the survey, the penalty would be limited to the minimum provided for each separate violation.[48]

The survey was initiated in October 2011, and received 2,723 responses through October 22, 2013. No response appeared to place the participant in jeopardy of prosecution or administrative enforcement. However, the survey responses were of limited value. Many respondents voiced support or disapproval for issues outside the scope of the survey, such as federal laws, regulations or policies, unrelated state statutes, or local ordinances. Fewer than 200 respondents directly addressed a particular agency rule, and of those, no more than 40 respondents provided information about the economic or policy impacts of the rule. Because the limited protection in the statute proved to be unnecessary, no apparent purpose is served by continuing the statute.

Effect of the Bill
The bill repeals s. 120.7455, F.S., effective upon the bill becoming law.

B. SECTION DIRECTORY:

Section 1: Amends s. 120.54, F.S., revising the deadline to propose rules implementing new laws.

Section 2: Amends s. 120.74, F.S., revising requirements for the annual review of agency rules; providing procedures for preparing and publishing regulatory plans; specifying requirements for such plans; requiring publication by specified dates of notices of rule development and of proposed rules necessary to implement new laws; providing for applicability; providing for suspension of an agency's rulemaking authority under certain circumstances.

Section 3: Repeals ss. 120.745 and 120.7455, F.S., relating to legislative review of agency rules in effect on or before a specified date and an Internet-based public survey of regulatory impacts, respectively; providing for rescission of the suspension of rulemaking authority under such repealed provisions.

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[45] At http://www.surveymonkey.com/s/FloridaRegReformSurvey (last accessed February 4, 2014).
[46] Chapter 2011-225, s. 6, L.O.F.
[47] Section 120.7455(3), F.S. The protection also extends to the non-reporting of such information or the use of information provided in response to the survey.
[48] Section 120.7455(4), F.S.

Section 4: Provides an effective date of July 1, 2014, except as otherwise provided in this act.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See FISCAL COMMENTS.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill requires agencies to publish in the FAR a notice identifying the date of publication along with a hyperlink to the regulatory plan, which has an associated cost. There is an increased workload on state agencies to adhere to the annual reporting requirements and action deadlines prescribed in the bill. The additional publication requirements and increased workload will have an insignificant fiscal impact on agencies and can be handled within existing resources. Regulatory plans have been published for the past two years without significant costs incurred.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   The bill does not appear to require counties or municipalities to take any action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill requires no additional rulemaking by any agency. The main analysis discusses particular changes to the accountability of agencies exercising rulemaking authority and to rulemaking to implement new laws.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Drafting Issues: Extension of Time by Listing a Law on a Regulatory Plan
The bill provides that listing a law on a subsequent annual regulatory plan may further extend the rulemaking proceeding; however, the bill does not indicate a time period for such extension. It is unclear if the extension expires on the following April 1 or the following October 1, at which time the agency would appear to be required to either publish a Notice of Extension or re-list the law in the next regulatory plan.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

Rulemaking Oversight & Repeal Subcommittee
On November 5, 2013, the Rulemaking Oversight & Repeal Subcommittee adopted four amendments to the draft PCB and approved PCB RORS 14-01 as amended.

- Amendment 1 revised notice and compliance requirements in section 2 of the bill. Agencies will be required to certify with JAPC their compliance with reporting, filing, and publication requirements. Paragraph (8)(d) was added to exclude emergency rulemaking and rulemaking necessary to comply with federal law from any suspension under this subsection.
- Amendment 2 revised publication requirements, clarifying the agency is responsible for publishing certain notices in the Florida Administrative Register together with a hyperlink providing direct access to the regulatory plan or supplement.
- Amendment 3 added a reference to the statute mandating the filing of annual budget requests by each agency.
- Amendment 4 provided agencies the ability to extend the time for publishing a notice of proposed rule required as a result of this statutory review for up to 180 days.

The final engrossment of the PCB and amendments resulted in changes to some of the internal subsections of the text, a necessary reference to s. 216.351, F.S., and renumbering some of the bill sections.

Government Operations Subcommittee
On March 25, 2014, the Government Operations Subcommittee adopted one strike-all amendment and reported the bill favorably with a committee substitute. The strike-all amendment:

- Clarified the requirements for an annual regulatory plan, including when a law may be excluded from the plan, and allowing for an agency to list a law on a subsequent plan;
- Removed the requirement that the persons certifying the regulatory plan certify the accuracy of the plan;
- Extended the deadline for the notice of proposed rule to April 1; and
- Limited the sanctions for noncompliant agencies to an agency failure to file the regulatory plan, notice of proposed rule, or notice of extension by the applicable deadlines.

This analysis is drawn to the committee substitute as passed by the Government Operations Subcommittee.

A bill to be entitled

An act relating to administrative procedures; amending s. 120.54, F.S.; revising the deadline to propose rules implementing new laws; amending s. 120.74, F.S.; revising requirements for the annual review of agency rules; providing procedures for preparing and publishing regulatory plans; specifying requirements for such plans; requiring publication by specified dates of notices of rule development and of proposed rules necessary to implement new laws; providing for applicability; providing for suspension of an agency's rulemaking authority under certain circumstances; repealing s. 120.745 F.S., relating to legislative review of agency rules in effect on or before a specified date; repealing s. 120.7455,F.S., relating to an Internet-based public survey of regulatory impacts; providing for rescission of the suspension of rulemaking authority under such repealed provisions; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (b) of subsection (1) of section 120.54, Florida Statutes, is amended to read:

120.54 Rulemaking.—

(1) GENERAL PROVISIONS APPLICABLE TO ALL RULES OTHER THAN

EMERGENCY RULES.—

(b) Whenever an act of the Legislature is enacted which requires implementation of the act by rules of an agency within the executive branch of state government, such rules shall be drafted and formally proposed as provided in this section within the times provided in s. 120.74(5) and (6) ~~180 days after the effective date of the act, unless the act provides otherwise~~.

Section 2. Section 120.74, Florida Statutes, is amended to read:

(Substantial rewording of section. See s. 120.74, F.S., for present text.)

120.74 Agency annual rulemaking and regulatory plans; reports.—

(1) REGULATORY PLAN.—By October 1 of each year, each agency shall prepare an implementation and rulemaking plan.

(a) The plan must include a listing of each law enacted or amended during the previous 12 months that creates or modifies the duties or authority of the agency. If the Governor or the Attorney General provides a letter to the committee stating that a law affects all or most agencies, the agency may exclude the law from its plan. For each law listed by an agency under this paragraph, the plan must state:

1. Whether the agency must adopt rules to implement the law.

2. If rulemaking is necessary to implement the law:

a. Whether a notice of rule development has been

published, and if so, the Florida Administrative Register citation for such notice.

b. The date by which the agency expects to publish the notice of proposed rule under s. 120.54(3)(a).

3. If rulemaking is not necessary to implement the law, a concise written explanation of the reasons why the law may be implemented without rulemaking.

(b) The plan must also include a listing of each law not otherwise listed pursuant to paragraph (a) that the agency expects to implement by rulemaking, except emergency rulemaking, before the end of the current fiscal year. For each law listed under this paragraph, the plan must state whether the rulemaking is intended to simplify, clarify, increase efficiency, improve coordination with other agencies, reduce regulatory costs, or delete obsolete, unnecessary, or redundant rules.

(c) The plan must include any desired update to the prior year's regulatory plan or supplement published pursuant to subsection (8). If in a prior year a law was identified under this paragraph or under subparagraph (1)(a)1. as a law requiring rulemaking to implement but a notice of proposed rule has not been published:

1. The agency may identify and again list such law, noting the applicable notice of rule development by citation to the Florida Administrative Register; or

2. If the agency has subsequently determined that rulemaking is not necessary to implement the law, the agency may

identify such law, note the applicable notice of rule development by citation to the Florida Administrative Register, and provide a concise written explanation of the reason why the law may be implemented without rulemaking.

(d) The plan shall include a certification executed on behalf of the agency by both the agency head or, if the agency head is a collegial body, the chair or equivalent presiding officer, and the agency general counsel or, if the agency does not have a general counsel, the individual acting as principal legal advisor to the agency head. The certification must:

1. Verify that the persons executing the certification have reviewed the plan.

2. Verify that the agency regularly reviews all of its rules and identify the period during which all rules have most recently been reviewed to determine if the rules remain consistent with the agency's rulemaking authority and the laws implemented.

(2) PUBLICATION AND DELIVERY TO THE COMMITTEE.—

(a) By October 1 of each year, each agency shall:

1. Publish its regulatory plan on its website or on another state website established for publication of administrative law records. A clearly labeled hyperlink to the current plan must be included on the agency's primary website homepage.

2. Deliver by electronic communication to the committee a copy of the certification required in paragraph (1)(d).

3. Publish in the Florida Administrative Register a notice identifying the date of publication of the agency's regulatory plan. The notice shall include a hyperlink or website address providing direct access to the published plan.

(b) To satisfy the requirements of paragraph (a), each board established by s. 20.165(4), and any other board or commission receiving administrative support from the Department of Business and Professional Regulation, may coordinate with the Department of Business and Professional Regulation, and each board established by s. 20.43(3)(g) may coordinate with the Department of Health, for inclusion of the board's or commission's plan and notice of publication in the coordinating department's plan and notice and for the delivery of the required documentation to the committee.

(c) A regulatory plan prepared under subsection (1) and any regulatory plan published under this chapter before July 1, 2014, shall be maintained at an active website for 10 years after the date of initial publication on the agency's website or another state website.

(3) INCLUSION IN LEGISLATIVE BUDGET REQUEST.—In addition to the requirements of s. 216.023 and pursuant to s. 216.351, a copy of the most recent certification executed under paragraph (1)(d), clearly designated as such, shall be included as part of the agency's legislative budget request.

(4) DEPARTMENT REVIEW OF BOARD PLAN.—By October 15 of each year:

(a) For each board established under s. 20.165(4) and any other board or commission receiving administrative support from the Department of Business and Professional Regulation, the Department of Business and Professional Regulation shall file with the committee a certification that the department has reviewed each board's regulatory plan. A certification may relate to more than one board.

(b) For each board established under s. 20.43(3), the Department of Health shall file with the committee a certification that the department has reviewed the board's regulatory plan. A certification may relate to more than one board.

(5) DEADLINE FOR RULE DEVELOPMENT.—By November 1 of each year, each agency shall publish a notice of rule development under s. 120.54(2) for each law identified in the agency's regulatory plan pursuant to subparagraph (1)(a)1. for which rulemaking is necessary to implement but for which the agency did not report the publication of a notice of rule development under subparagraph (1)(a)2.

(6) DEADLINE TO PUBLISH PROPOSED RULE.—For each law for which implementing rulemaking is necessary as identified in the agency's plan pursuant to subparagraph(1)(a)1. or subparagraph (1)(c)1., the agency shall publish a notice of proposed rule pursuant to s. 120.54(3)(a) by April 1 of the year following the deadline for the regulatory plan. This deadline may be extended if the agency publishes a notice of extension in the Florida

Administrative Register identifying each rulemaking proceeding for which an extension is being noticed by citation to the applicable notice of rule development as published in the Florida Administrative Register. An extension shall expire on October 1 after the April 1 deadline, provided that the regulatory plan due on such date may further extend the rulemaking proceeding by identification pursuant to subparagraph (1)(c)1. or conclude the rulemaking proceeding by identification pursuant to subparagraph (1)(c)2. A published regulatory plan may be corrected at any time to accomplish the purpose of extending or concluding an affected rulemaking proceeding and is deemed corrected as of the October 1 due date. Upon publication of a correction, the agency shall publish in the Florida Administrative Register a notice of the date of the correction identifying the affected rulemaking proceeding by applicable citation to the Florida Administrative Register.

(7) CERTIFICATIONS.—Each agency shall file a certification with the committee upon compliance with subsection (5), upon filing a notice under subsection (6) of a deadline extension or a regulatory plan correction, and upon the completion of an act that terminates a suspension under subsection (9). A certification may relate to more than one notice or contemporaneous act. The date or dates of compliance shall be noted in each certification.

(8) SUPPLEMENTING THE REGULATORY PLAN.—After publication of the regulatory plan, the agency shall supplement the plan

within 30 days after a bill becomes a law, if the law is enacted before the next regular session of the Legislature and the law substantively modifies the agency's specifically delegated legal duties, unless the law affects all or most state agencies as identified by letter to the committee from the Governor or the Attorney General. The supplement shall include the information required in paragraph (1)(a) and shall be published as required in subsection (2), but no certification or delivery to the committee is required. The agency shall publish in the Florida Administrative Register notice of publication of the supplement, and include a hyperlink or web address for direct access to the published supplement. For each law reported in the supplement, if rulemaking is necessary to implement the law, the agency shall publish a notice of rule development by the later of the date provided in subsection (5) or 60 days after the bill becomes a law, and a notice of proposed rule shall be published by the later of the date provided in subsection (6) or 120 days after the bill becomes a law. The proposed rule deadline may be extended to the following October 1 by notice as provided in subsection (6). If such proposed rule has not been filed by October 1, a law included in a supplement shall also be included in the next annual plan pursuant to subsection (1).

(9) FAILURE TO COMPLY.—If an agency fails to comply with a requirement of paragraph (2)(a) or subsection (6), the entire rulemaking authority delegated to the agency by the Legislature under any statute or law shall be suspended automatically as of

the due date of the required action and shall remain suspended until the date the agency completes the required act or until the end of the next regular session of the Legislature, whichever occurs first.

(a) During a period of suspension under this subsection, the agency has no authority to file rules for adoption under s. 120.54, but may complete any action required by this section and may conduct public hearings that were noticed before the period of suspension.

(b) A suspension under this subsection does not authorize an agency to promulgate or apply a statement defined as a rule under s. 120.52(16) unless the statement was filed for adoption under s. 120.54(3) before the suspension.

(c) A suspension under this subsection tolls the time requirements under s. 120.54 for filing a rule for adoption in a rulemaking proceeding initiated by the agency before the date of the suspension. The time requirements shall resume on the date the suspension ends.

(d) This subsection does not suspend the adoption of emergency rules under s. 120.54(4) or rulemaking necessary to ensure the state's compliance with federal law.

(10) EDUCATIONAL UNITS.—This section does not apply to educational units.

Section 3. Effective upon this act becoming a law:

(1) Sections 120.745 and 120.7455, Florida Statutes, are repealed.

(2) Any suspension of rulemaking authority under s. 120.745, Florida Statutes, or s. 120.7455, Florida Statutes, is rescinded. This subsection does not affect any restriction, suspension, or prohibition of rulemaking authority under any other provision of law.

(3) This section serves no other purpose and shall not be codified in the Florida Statutes.

Section 4. Except as otherwise expressly provided in this act and except for this section, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2014.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION		
ADOPTED	____	(Y/N)
ADOPTED AS AMENDED	____	(Y/N)
ADOPTED W/O OBJECTION	____	(Y/N)
FAILED TO ADOPT	____	(Y/N)
WITHDRAWN	____	(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Government Operations Appropriations Subcommittee

Representative Santiago offered the following:

Amendment

Remove lines 51-180 and insert:

2. If rulemaking is necessary to implement the law:

a. Whether a notice of rule development has been published, and if so, the citation to such notice in the Florida Administrative Register.

b. The date by which the agency expects to publish the notice of proposed rule under s. 120.54(3)(a).

3. If rulemaking is not necessary to implement the law, a concise written explanation of the reasons why the law may be implemented without rulemaking.

(b) The plan must also include a listing of each law not otherwise listed pursuant to paragraph (a) that the agency

expects to implement by rulemaking before the following July 1, except emergency rulemaking. For each law listed under this paragraph, the plan must state whether the rulemaking is intended to simplify, clarify, increase efficiency, improve coordination with other agencies, reduce regulatory costs, or delete obsolete, unnecessary, or redundant rules.

(c) The plan must include any desired update to the prior year's regulatory plan or supplement published pursuant to subsection (8). If in a prior year a law was identified under this paragraph or under subparagraph (1)(a)1. as a law requiring rulemaking to implement but a notice of proposed rule has not been published:

1. The agency may identify and again list such law, noting the applicable notice of rule development by citation to the Florida Administrative Register; or

2. If the agency has subsequently determined that rulemaking is not necessary to implement the law, the agency may identify such law, reference the citation to the applicable notice of rule development in the Florida Administrative Register, and provide a concise written explanation of the reason why the law may be implemented without rulemaking.

(d) The plan shall include a certification executed on behalf of the agency by both the agency head or, if the agency head is a collegial body, the chair or equivalent presiding officer, and the agency general counsel or, if the agency does

not have a general counsel, the individual acting as principal legal advisor to the agency head. The certification must:

1. Verify that the persons executing the certification have reviewed the plan.

2. Verify that the agency regularly reviews all of its rules and identify the period during which all rules have most recently been reviewed to determine if the rules remain consistent with the agency's rulemaking authority and the laws implemented.

(2) PUBLICATION AND DELIVERY TO THE COMMITTEE.—

(a) By October 1 of each year, each agency shall:

1. Publish its regulatory plan on its website or on another state website established for publication of administrative law records. A clearly labeled hyperlink to the current plan must be included on the agency's primary website homepage.

2. Deliver by electronic communication to the committee a copy of the certification required in paragraph (1)(d).

3. Publish in the Florida Administrative Register a notice identifying the date of publication of the agency's regulatory plan. The notice shall include a hyperlink or website address providing direct access to the published plan.

(b) To satisfy the requirements of paragraph (a), each board established by s. 20.165(4), and any other board or commission receiving administrative support from the Department of Business and Professional Regulation, may coordinate with the

Department of Business and Professional Regulation, and each board established by s. 20.43(3)(g) may coordinate with the Department of Health, for inclusion of the board's or commission's plan and notice of publication in the coordinating department's plan and notice and for the delivery of the required documentation to the committee.

(c) A regulatory plan prepared under subsection (1) and any regulatory plan published under this chapter before July 1, 2014, shall be maintained at an active website for 10 years after the date of initial publication on the agency's website or another state website.

(3) INCLUSION IN LEGISLATIVE BUDGET REQUEST.—In addition to the requirements of s. 216.023 and pursuant to s. 216.351, a copy of the most recent certification executed under paragraph (1)(d), clearly designated as such, shall be included as part of the agency's legislative budget request.

(4) DEPARTMENT REVIEW OF BOARD PLAN.—By October 15 of each year:

(a) For each board established under s. 20.165(4) and any other board or commission receiving administrative support from the Department of Business and Professional Regulation, the Department of Business and Professional Regulation shall file with the committee a certification that the department has reviewed each board's regulatory plan. A certification may relate to more than one board.

(b) For each board established under s. 20.43(3), the Department of Health shall file with the committee a certification that the department has reviewed the board's regulatory plan. A certification may relate to more than one board.

(5) DEADLINE FOR RULE DEVELOPMENT.—By November 1 of each year, each agency shall publish a notice of rule development under s. 120.54(2) for each law identified in the agency's regulatory plan pursuant to subparagraph (1)(a)1. for which rulemaking is necessary to implement but for which the agency did not report the publication of a notice of rule development under subparagraph (1)(a)2.

(6) DEADLINE TO PUBLISH PROPOSED RULE.—For each law for which implementing rulemaking is necessary as identified in the agency's plan pursuant to subparagraph (1)(a)1. or subparagraph (1)(c)1., the agency shall publish a notice of proposed rule pursuant to s. 120.54(3)(a) by April 1 of the year following the deadline for the regulatory plan. This deadline may be extended if the agency publishes a notice of extension in the Florida Administrative Register identifying each rulemaking proceeding for which an extension is being noticed by citation to the applicable notice of rule development as published in the Florida Administrative Register. An extension shall expire on October 1 after the April 1 deadline, provided that the regulatory plan due on October 1 may further extend the rulemaking proceeding by identification pursuant to subparagraph

(1)(c)1. or conclude the rulemaking proceeding by identification pursuant to subparagraph (1)(c)2. A published regulatory plan may be corrected at any time to accomplish the purpose of extending or concluding an affected rulemaking proceeding and is deemed corrected as of the October 1 due date. Upon publication of a correction, the agency shall publish in the Florida Administrative Register a notice of the date of the correction identifying the affected rulemaking proceeding by applicable citation to the Florida Administrative Register.

(7) CERTIFICATIONS.—Each agency shall file a certification with the committee upon compliance with subsection (5), upon filing a notice under subsection (6) of either a deadline extension or a regulatory plan correction, and upon the completion of an act that terminates a suspension under subsection (9). A certification may relate to more than one notice or contemporaneous act. The date or dates of compliance shall be noted in each certification.