The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH REGULATION
Senator Garcia, Chair
Senator Sobel, Vice Chair

MEETING DATE: Wednesday, February 22, 2012
TIME: 3:30 —6:00 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Garcia, Chair; Senator Sobel, Vice Chair; Senators Diaz de la Portilla, Fasano, Gaetz, Jones, and Norman

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SM 1836** Negron (Compare CS/HM 1349)	Medicaid; Urging the United States Secretary of Health and Human Services to approve the requested federal Medicaid waivers in order to expand Florida's Medicaid managed care pilot program statewide, etc. HR 02/22/2012 Fav/1 Amendment	Fav/1 Amendment (441898) Yeas 6 Nays 1
2	**SM 1840** Garcia (Compare CS/HM 1281, SM 1854)	Patient Protection and Affordable Care Act; Urging Congress to defund the health insurance exchanges required by the Patient Protection and Affordable Care Act, etc. HR 02/22/2012 Favorable	Favorable Yeas 4 Nays 1
3	**SM 1854** Garcia (Similar CS/HM 1281, Compare SM 1840)	Patient Protection and Affordable Care Act; Urging Congress to repeal the Patient Protection and Affordable Care Act signed into law by President Obama in 2010, etc. HR 02/22/2012 Favorable	Favorable Yeas 6 Nays 1
4	**SB 624** Richter (Identical H 335, Compare H 333, Link S 626)	Household Pharmaceuticals Collection and Disposal Trust Fund/DEP; Creating the Household Pharmaceuticals Collection and Disposal Trust Fund within the Department of Environmental Protection; providing for sources of funds and purposes; providing for annual carryforward of funds; providing for the future review and termination or re-creation of the trust fund, etc. EP 02/06/2012 Fav/1 Amendment HR 02/22/2012 Favorable BC	Favorable Yeas 7 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
5	**SB 626** Richter (Identical H 333, Compare H 335, Link S 624)	Collection and Disposal of Household Pharmaceuticals; Requiring the Department of Environmental Protection to establish a grant program to reimburse local law enforcement agencies for the expenses associated with the collection and disposal of household pharmaceuticals; providing eligibility requirements; requiring that the court impose an additional surcharge for specified offenses; providing for the proceeds of the surcharge to be deposited into the Household Pharmaceuticals Collection and Disposal Trust Fund; providing for the clerk of the court to retain a service charge, etc. EP 02/06/2012 Fav/1 Amendment HR 02/22/2012 Favorable BC	Favorable Yeas 7 Nays 0
6	**SB 668** Hays (Compare CS/H 511)	Workers' Compensation Medical Services; Revising requirements for determining the amount of a reimbursement for repackaged or relabeled prescription medication; providing limitations, etc. BI 01/19/2012 Fav/1 Amendment HR 02/16/2012 Temporarily Postponed HR 02/22/2012 Fav/1 Amendment BC	Fav/1 Amendment (115316) Yeas 7 Nays 0
7	**SB 1006** Latvala	Prescription Drug Wholesale Regulations; Requiring the Department of Health to issue a permit by endorsement to an out-of-state prescription drug wholesale distributor that meets certain requirements; authorizing out-of-state wholesale distributors holding a valid permit to continue to operate under that permit until its expiration, etc. HR 02/09/2012 Not Considered HR 02/22/2012 Fav/CS CM BC	Fav/CS Yeas 7 Nays 0
8	**SB 1116** Altman (Identical H 1051)	Human Papillomavirus; Requiring that the Department of Health adopt a rule adding the human papillomavirus to the list of communicable diseases for which immunizations are recommended; requiring that schools provide the parents or guardians of certain public school students information regarding the human papillomavirus and the availability of a vaccine; requiring that the Department of Health prescribe the required information, etc. HR 02/22/2012 Fav/CS ED BC	Fav/CS Yeas 7 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
9	**SB 290** Flores (Identical H 277, Compare CS/H 839, H 1151, S 1374)	Abortions; Restricting the circumstances in which an abortion may be performed in the third trimester or after viability; requiring a physician who offers to perform or who performs abortions to complete continuing education related to ethics; providing that an infant born alive subsequent to an attempted abortion is entitled to the same rights, powers, and privileges as are granted by the laws of this state; providing that it is a first-degree misdemeanor to unlawfully advertise how to obtain an abortion; prohibiting a person from establishing, conducting, managing, or operating a clinic in this state without a valid and current license issued by the Agency for Health Care Administration; revising the amount of the fine that the Agency for Health Care Administration may impose for a violation of ch. 390, F.S., relating to abortion, or part II of ch. 408, F.S., relating to licensure, etc. HR 02/16/2012 Temporarily Postponed HR 02/22/2012 Favorable CJ BC	Favorable Yeas 5 Nays 2

Other Related Meeting Materials

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SM 1836

INTRODUCER: Senator Negron

SUBJECT: A Memorial to the United States Secretary of Health and Human Services

DATE: February 20, 2012 REVISED: 02/22/12

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Fav/1 amendment**
2.				
3.				
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	☐	Statement of Substantial Changes
B. AMENDMENTS.....	☐	Technical amendments were recommended
	☐	Amendments were recommended
	☒	Significant amendments were recommended

I. Summary:

Senate Memorial 1836 requests the United States Secretary of Health and Human Services to approve Florida's requested Medicaid waivers so that the Medicaid managed care pilot program can be implemented statewide.

This bill creates a Senate Memorial.

II. Present Situation:

Medicaid

Medicaid is the medical assistance program that provides access to health care for low-income families and individuals. Medicaid also assists aged and disabled people with the costs of nursing facility care and other medical expenses. The Agency for Health Care Administration (AHCA) is responsible for administering the Medicaid program in Florida. Medicaid serves approximately 3.19 million people in Florida, with over half of those being children and adolescents 20 years of age or younger. Estimated Medicaid expenditures for FY 2011-2012 are approximately $20.3 billion.

Medicaid is a joint program between the federal government and state governments. Although each state administers its own Medicaid program, the federal Centers for Medicare and Medicaid Services (CMS) within the United States Department of Health and Human Services monitors the state-run programs and establishes requirements for service delivery, quality, funding, and eligibility standards. Medicaid was created by the Social Security Amendments of 1965 which added Title XIX to the Social Security Act.

Medicaid Managed Care in Florida

Part III of ch. 409, F.S., provides the statutory requirements for the Florida Medicaid program. Sections 409.9121 – 409.9124, F.S., contain provisions relating to managed care in Medicaid.

In 1993, the Legislature passed legislation declaring its intent that the Medicaid program require, to the maximum extent practicable and permitted by federal law, all Medicaid recipients to be enrolled in a managed care program.[1] This intent language was codified in s. 409.9121, F.S., and has remained in effect and unchanged since 1993. Section 409.9122, F.S., which was also created in 1993, set Florida on the path of mandatory enrollment of Medicaid recipients in managed care by providing for the statewide expansion of the primary care case management program known as MediPass and for the growth of health maintenance organizations and prepaid health plans for Medicaid recipients. Section 409.9122, F.S., has been amended almost every year since 1993 to expand the role of managed care in Medicaid as managed care has evolved.

In 2005, the Legislature directed the AHCA to seek federal Medicaid waivers pursuant to s. 1115 of the Social Security Act to create a Medicaid managed care pilot program in five counties in the state. Under the pilot program, most Medicaid recipients have been moved from Medicaid fee-for-service and the MediPass program into capitated managed care systems. As of December 15, 2011, the pilot program waiver was extended for 3 years, through June 30, 2014. This coincides with the implementation schedule of the new statewide Medicaid managed care program established in 2011 and codified in pt. IV of ch. 409, F.S. (s. 409.961 – 409.9841, F.S.).[2]

Part IV of ch. 409, F.S., requires all Medicaid recipients to enroll in a managed care plan unless they are specifically exempted. The statewide Medicaid managed care program includes the long-term care managed care program and the managed medical assistance program. The law directs the AHCA to begin implementation of the long-term care managed care program by July 1, 2012, with full implementation in all regions of the state by October 1, 2013. By January 1, 2013, the AHCA must begin implementation of the managed medical assistance program, with full implementation in all regions of the state by October 1, 2014.

The AHCA is required to separately procure long-term care managed care plans and managed medical assistance plans in each of the 11 regions of the state, which coincide with the existing Medicaid areas. The AHCA is required to select a limited number of eligible plans to participate in the program using Invitations to Negotiate. Each Medicaid recipient must have a choice of

[1] *See* s. 50 of ch. 93-129, L.O.F.
[2] *See* ch. 2011-134, L.O.F.

plans and may select any available plan unless that plan is restricted by contract to a specific population that does not include the recipient.

Medicaid Waiver Requests

Waivers are the means by which states can get approval to waive certain federal Medicaid requirements in order to test new or existing ways to deliver and pay for health care services. There are four primary types of waivers and demonstration projects:[3]

- Section 1115 Research and Demonstration Projects – states can apply for program flexibility to test new or existing approaches to financing and delivering Medicaid;
- Section 1915(b) Managed Care Waivers – states can apply for waivers to provide services through managed care delivery systems or otherwise limit people's choice of providers;
- Section 1915(c) Home and Community-Based Services Waivers – states can apply for waivers to provide long-term care services in home and community settings rather than institutional settings; and
- Concurrent Section 1915(b) and 1915(c) Waivers – states can apply to simultaneously implement two types of waivers to provide a continuum of services to the elderly and people with disabilities, as long as all Federal requirements for both programs are met.

Section 409.964, F.S., requires the AHCA to apply for and implement state plan amendments or waivers of applicable federal laws and regulations necessary to implement the statewide managed care program. The law requires the AHCA to submit any state plan amendments, new waiver requests, or requests for extensions or expansions for existing waivers, needed to implement the statewide Medicaid managed care program by August 1, 2011.

The AHCA had already submitted, on June 30, 2010, a request for extension of the Florida Medicaid Reform 1115 Demonstration waiver. On December 15, 2011, the CMS approved the request, with special terms and conditions. With the approval of the extension, Florida has received approval of many of the authorities required to proceed with the statewide Medicaid managed care program. Also, with federal approval, certain parts of the original demonstration waiver have been dropped.

On August 1, 2011, the AHCA submitted three requests[4] to amend the Florida Medicaid Reform 1115 Demonstration waiver in order to implement the managed medical assistance component of the statewide Medicaid managed care program enacted by the 2011 Legislature. The three requests include requests to:

- Expand the geographic operation of the program statewide and transition certain Medicaid eligibility groups into mandated participation in the statewide managed medical assistance program;
- Require Medicaid recipients who are enrolled in managed care plans operating in the managed medical assistance program , as a condition of Medicaid eligibility, to pay the Medicaid program a premium of $10 per month; and

[3] Medicaid.gov, *Waivers*. Found at: < http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/Waivers.html> (Last visited on February 16, 2012).
[4] Agency for Health Care Administration, *Federal Submission and Authorities*. Found at: <http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#fedsubmiss> (Last visited on February 16, 2012).

- Require Medicaid recipients to pay a $100 copayment for nonemergency services and care furnished in a hospital emergency department.

In a letter dated February 9, 2012,[5] the CMS responded to these requests by rejecting the requests for the $10 per month premium and the $100 copayment. The letter states that the CMS shares the state's goal of promoting cost-effective use of hospital emergency department services and will work with Florida to consider alternative approaches to meeting this goal. The letter also states that the CMS is continuing to review the state's request to expand the demonstration statewide and looks forward to working with Florida on this request.

III. Effect of Proposed Changes:

Senate Memorial 1836 provides a series of Whereas clauses supporting the establishment of Florida's Medicaid program as a statewide, integrated managed care program for all covered services, including long-term care services. The memorial requests the United States Secretary of Health and Human Services to approve Florida's requested Medicaid waivers, which will allow the existing Medicaid managed care pilot project to be implemented statewide.

Copies of the memorial will also be dispatched to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, to the United States Secretary of Health and Human Services, and to each member of the Florida delegation to the United States Congress.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

[5] Letter to Mr. Justin M. Senior, Deputy Secretary for Medicaid, Florida Agency for Health Care Administration from Victoria Wachino, Director, Center for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. Found at: <http://ahca.myflorida.com/medicaid/statewide_mc/fsdocs/Final_signed_FL_amend_02-09-12.pdf> (Last visited on February 16, 2012).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

On lines 5-6 and 56-57, the bill refers to statewide expansion of Florida's managed care pilot program, although lines 11-14 refer to the new statewide, integrated managed care program, including long-term care services. It is unclear whether the request for approval of the Medicaid waivers includes waivers for both the managed medical assistance component and the long-term care managed care component of the new managed care program. The memorial appears to address only the managed medical assistance component of the statewide Medicaid managed care program, not the long-term care managed care component.

VIII. Additional Information:

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

None.

B. Amendments:

Barcode 441898 by Health Regulation on February 22, 2012:
The amendment expands the request to the U.S. Secretary of Health and Human Services to include approval of all waivers needed to implement the new statewide, integrated Medicaid managed care program, not just the waivers needed for the managed medical assistance component. (WITH TITLE AMENDMENT)

441898

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
02/22/2012	.	
	.	
	.	
	.	

The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment (with title amendment)

Delete lines 56 - 57
and insert:
waivers, which will allow the statewide, integrated Medicaid managed care program to be implemented.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete lines 5 - 6
and insert:
allow Florida to implement its statewide, integrated

441898

Medicaid managed care program.

By Senator Negron

28-01466-12 20121836__

Senate Memorial

A memorial to the United States Secretary of Health and Human Services, urging the Secretary to approve the requested federal Medicaid waivers in order to expand Florida's Medicaid managed care pilot program statewide.

WHEREAS, the Legislature believes that Medicaid reform should be pro-patient and pro-taxpayer and Florida's Medicaid managed care pilot program has achieved both conditions, and

WHEREAS, in 2011, the Legislature adopted CS/HB 7107, chapter 2011-134, Laws of Florida, which established the Medicaid program as a statewide, integrated managed care program for all covered services, including long-term care services, and

WHEREAS, Medicaid patients in this state are deserving of more control over their health care than the current system allows, and decisions regarding health care should not be made by politicians and bureaucrats, but by Medicaid patients and their doctors based on each patient's unique health care needs, and

WHEREAS, taxpayers are demanding greater accountability over how their tax dollars are spent, and must be assured that these funds are being used efficiently to support an affordable and sustainable Medicaid safety net that promotes health and wellness, and

WHEREAS, as the cost of maintaining the traditional Medicaid program continues to grow, taxpayers are faced with the threat of tax hikes and service cuts to prop up a failing program, and

28-01466-12 20121836__

WHEREAS, Medicaid patients in counties where the Medicaid managed care pilot program has been implemented are healthier and happier with their health care than patients enrolled in traditional Medicaid managed care and commercial plans from health maintenance organizations, have better health care outcomes, have more plan options to choose from, and have access to health care services that would otherwise not be covered in Florida or any other state, and

WHEREAS, competition within this state's Medicaid managed care pilot program resulted in more customized benefits, expanded coverage, and lower costs for patients, and

WHEREAS, taxpayers in this state have saved up to $118 million annually since 2006, when Florida's five-county Medicaid reform pilot program took effect, and approval of this state's waiver requests will allow taxpayers to save an estimated $901 million annually, and

WHEREAS, approval of Florida's waiver requests will allow all state residents to enjoy the benefits of a well-run Medicaid program that is efficient, affordable, and sustainable, NOW, THEREFORE,

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

That, on behalf of the residents of this state, the Legislature requests the United States Secretary of Health and Human Services to approve this state's requested Medicaid waivers, which will allow the Medicaid managed care pilot program to be implemented statewide.

BE IT FURTHER RESOLVED that copies of this memorial be

dispatched to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, to the United States Secretary of Health and Human Services, and to each member of the Florida delegation to the United States Congress.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR JOE NEGRON
28th District

COMMITTEES:
Budget - Subcommittee on Health and Human Services Appropriations, *Chair*
Budget, *Vice Chair*
Banking and Insurance
Communications, Energy, and Public Utilities
Higher Education
Reapportionment
Rules

SELECT COMMITTEE:
Protecting Florida's Children, *Chair*

JOINT COMMITTEE:
Legislative Budget Commission

January 24, 2012

The Honorable Rene Garcia, Chair
Committee on Health Regulation
530 Knott Building
404 S Monroe Street
Tallahassee, FL 32399-1100

Re: Senate Bill 1836

Dear Chairman Garcia:

I would like to request Senate Bill 1836 relating to a memorial to the United States Secretary of Health and Human Services be placed on the agenda for the next scheduled committee meeting.

Thank you, in advance, for your consideration of this request.

Sincerely yours,

Joe Negron
State Senator
District 28

JN/hd
c: Sandra Stovall, Staff Director ✓

ENTERED

REPLY TO:
❒ 3500 SW Corporate Parkway, Suite 204, Palm City, Florida 34990 (772) 219-1665
❒ 306 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5088

Senate's Website: *www.flsenate.gov*

MIKE HARIDOPOLOS
President of the Senate

MICHAEL S. "MIKE" BENNETT
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

02/22/12
Meeting Date

Topic Medicaid — Bill Number SM 1836 *(if applicable)*

Name Michael Garner — Amendment Barcode *(if applicable)*

Job Title Pres & CEO

Address 200 W. College Ave, Suite 104 — Phone (850) 386-2904
Street

Tallahassee, FL 32301 — E-mail michael@fahp.net
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Association of Health Plans

Appearing at request of Chair: ☐ Yes ☑ No — Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/2012
Meeting Date

Topic _____ Bill Number 1836 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH *Street* Phone 727-897-9291

SAINT PETERSBURG *City* FLORIDA *State* 33705 *Zip* E-mail JUSTICE2JESUS@YAHOO.COM

Speaking: ☐ For ☑ Against ☑ Information

Representing JUSTICE-2-JESUS

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☐ Yes ☑ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SM 1840

INTRODUCER: Senator Garcia

SUBJECT: Health Insurance Exchanges

DATE: February 18, 2012 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Favorable**
2.				
3.				
4.				
5.				
6.				

I. Summary:

Senate Memorial 1840 urges the Congress of the United States to defund planning grants to states for the establishment of health insurance exchanges required by the Patient Protection and Affordable Care Act (PPACA or the Act).

This bill creates a Senate Memorial.

II. Present Situation:

Patient Protection and Affordable Care Act

The PPACA,[1] often referred to as federal health care reform, was signed into law by President Barack Obama on March 23, 2010. The Act is far-reaching and is so broad that it will be years before all of its provisions will be fully implemented and its ramifications fully understood.

Among other objectives, the Act seeks to increase the availability and affordability of health insurance. It seeks to expand access to health insurance coverage by requiring most U.S. citizens and legal residents to have health insurance and providing for the creation of state-based American Health Benefit Exchanges through which individuals can purchase qualifying coverage. Exchanges are new organizations that will be set up to create an organized, competitive market for buying health insurance. They will offer a choice of different health plans, certifying plans that participate and providing information to help consumers better understand their options. They will also be the mechanism through which low and moderate-income individuals receive premium and cost-sharing subsidies to make health coverage more affordable.

States are expected to establish Exchanges – which can be a government agency or a non-profit organization – with the federal government stepping in if a state does not set them up. States can create multiple Exchanges, so long as only one serves each geographic area, and can work together to form regional Exchanges. State exchanges are required to be fully operational by January 1, 2014. The federal government is providing technical assistance to help states set up Exchanges.

Small businesses with fewer than 100 employees will be able to purchase coverage through Small Business Health Options Program (SHOP) Exchanges. These state-based exchanges are intended to allow employers to shop for qualified coverage and more easily compare prices and benefits. The Act places requirements on certain employers to provide coverage, and provides some subsidies to encourage the expansion of employer-based coverage.

Beginning in 2014, Exchanges will serve primarily individuals buying insurance on their own and small businesses with up to 100 employees. In 2017, states will have the option to allow businesses with more than 100 employees to purchase coverage through the SHOP Exchanges.

State Efforts to Establish Exchanges

By December 2011, over $640 million had been distributed to states through federal exchange planning grants, establishment grants, and early innovator grants.[2] Almost every state received some amount of funding to study exchange implementation. Florida received a $1 million grant to plan for an exchange; however, Governor Rick Scott ordered the grant returned.

As of January 2012, 13 states have established exchanges and five more have signaled their plans to establish one.[3] Arkansas and Louisiana have announced plans to stop pursuing a state-based exchange. The majority of states continue to study their options for exchange implementation, making use of federal exchange planning and establishment grant funding.

By January 2013, the federal Department of Health and Human Services will evaluate states to identify those that lack sufficient progress toward establishing an exchange. In states that are not ready or choose not to run an exchange, a federally-facilitated exchange will be implemented. States may also choose to partner with the federal government and assume some exchange functions.

[1] Found at: <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf> (Last visited on February 18, 2012).

[2] The Henry J. Kaiser Family Foundation, *Focus on Health Reform, Establishing Health Insurance Exchanges: A National Overview of State Efforts*. Found at: <http://www.kff.org/healthreform/upload/8213-FS.pdf> (Last visited on February 18, 2012).

[3] *Id.* (The states that have established an exchange are California, Colorado, Connecticut, Hawaii, Maryland, Massachusetts, Nevada, Oregon, Rhode Island, Utah, Vermont, Washington, and West Virginia. The states that plan to establish an exchange are Illinois, Indiana, Mississippi, North Dakota, and Virginia.)

States' Challenge of PPACA

Immediately after the PPACA was signed into law, 13 Attorneys General filed a lawsuit against the U.S. Department of Health and Human Services, U.S. Department of Treasury and the U.S. Department of Labor alleging the Health Care Reform law signed by the President was unconstitutional.[4] The amended complaint currently features 26 state plaintiffs.[5] Additionally, the National Federation of Independent Business (NFIB) joined the lawsuit as a co-plaintiff on behalf of its members nationwide.

The lawsuit, filed in the federal court's Northern District of Florida on March 23, 2010, alleges the PPACA infringes upon the constitutional rights of Floridians and residents of the other states by mandating all citizens and legal residents have qualifying health care coverage or pay a tax penalty. The lawsuit further alleges that by imposing such a mandate, the law exceeds the powers of the United States under Article I of the Constitution. Additionally, the tax penalty required under the law constitutes an unlawful direct tax in violation of Article I, sections 2 and 9 of the Constitution.[6]

The lawsuit further claims the health care reform law infringes on the sovereignty of the states and the Tenth Amendment to the Constitution by imposing onerous new operating rules that Florida must follow as well as requiring the state to spend billions of additional dollars without providing funds or resources to meet the state's cost of implementing the law. This burden comes at a time when Florida faces severe budget cuts to offset shortfalls in an already-strained budget.

On January 31, 2011, Senior United States District Judge Roger Vinson ruled that the PPACA is unconstitutional.[7] The district court granted summary judgment to the federal government on the state plaintiffs' claim that the Act's expansion of Medicaid is unconstitutional and to the plaintiffs on their claim that the Act's individual mandate – that individuals purchase and continuously maintain health insurance from private companies – is unconstitutional. The district court concluded that the individual mandate exceeded congressional authority under Article I of the Constitution because it was not enacted pursuant to Congress's tax power and it exceeded Congress's power under the Commerce Clause and the Necessary and Proper Clause. The district court also concluded that the individual mandate provision was not severable from the rest of the Act and declared the entire Act invalid.

The federal government appealed the district court's ruling that the individual mandate is unconstitutional and its severability holding. The state plaintiffs cross-appealed the district court's ruling on their Medicaid expansion claim. On appeal, the United States Court of Appeals for the Eleventh Circuit ruled, on August 12, 2011, that the individual mandate is severable from

[4] *Florida, et al. v. Department of Health and Human Services, et al.*
[5] The 26 plaintiffs include: Florida, South Carolina, Nebraska, Texas, Utah, Louisiana, Alabama, Colorado, Michigan, Pennsylvania, Washington, Idaho, South Dakota, Indiana, Mississippi, Nevada, Arizona, Georgia, Alaska, North Dakota, Wisconsin, Iowa, Ohio, Kansas, Wyoming, and Maine.
[6] Office of the Attorney General of Florida, *The States' Lawsuit Challenging the Constitutionality of the Health Care Reform Law*. Found at: <http://www.healthcarelawsuit.us/> (Last visited on February 18, 2012).
[7] *State of Florida, by an through Attorney General Pam Bondi, et al. v. United States Department of Health and Human Services, et al.*, United States District Court for the Northern District of Florida Pensacola Division, Case No.: 3:10-cv-91-RV/EMT, January 31, 2011. Found at: < http://myfloridalegal.com/webfiles.nsf/WF/JDAS-8DMNTD/$file/VinsonRuling1312011.pdf> (Last visited on February 18, 2012).

the remainder of the Act. The court also affirmed the district court's grant of summary judgment to the federal government that the Medicaid expansion is constitutional and concluded that the individual mandate exceeds Congress's enumerated commerce power and is unconstitutional. The court concluded that the individual mandate is a civil regulatory penalty and not a tax.[8]

The parties filed petitions for the Supreme Court to review the lower court holdings.

On December 19, 2011, the U.S. Supreme Court agreed to take the case and announced the dates for the oral argument in the States' challenge to the federal health care law. The oral arguments will begin Mach 26, 2012, and continue through March 28, 2012. On March 26, the Court will hear one hour of oral argument on the jurisdictional issue of whether the federal Anti-Injunction Act bars challenges to the individual mandate. On March 27, the Court will hear two hours of oral argument limited to the issue of whether the individual mandate is constitutional. On March 28, the Court will hear 90 minutes of oral argument on the severability argument. Also on March 28, the Court will hear one hour of oral argument on the constitutionality of the law's substantial expansion of Medicaid.

III. Effect of Proposed Changes:

Senate Memorial 1840 urges the Congress of the United States to defund planning grants to states for the establishment of health insurance exchanges required by the PPACA.

Copies of the memorial will also be dispatched to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

[8] *State of Florida, by an through Attorney General Pam Bondi, et al. v. United States Department of Health and Human Services, et al.*, United States Court of Appeals for the Eleventh Circuit, D.C. Docket No. 3:10-cv-00091-RV-EMT. Found at: <http://myfloridalegal.com/webfiles.nsf/WF/JDAS-8KNNU8/$file/HCR_11thCirOpinion8.12.11.pdf> (Last visited on February 18, 2012).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

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

None.

B. Amendments:

None.

By Senator Garcia

40-01470-12 20121840__

Senate Memorial

A memorial to the Congress of the United States, urging Congress to defund the health insurance exchanges required by the Patient Protection and Affordable Care Act.

WHEREAS, on March 23, 2010, President Barack Obama signed into law the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, ostensibly for the purpose of making health insurance more affordable for American citizens, and

WHEREAS, the Patient Protection and Affordable Care Act requires the creation of health insurance exchanges in each state through which health insurance policies that meet certain requirements determined by the Federal Government may be bought and sold, and

WHEREAS, these health insurance exchanges may be established only upon the approval of appointed federal officials, who are granted the authority to establish exchanges in any state that fails to win approval of its state-created exchange, and

WHEREAS, the creation of state health insurance exchanges pursuant to the Patient Protection and Affordable Care Act forces states to cede their resources and sovereignty to the service of the Federal Government and to sacrifice their ability to flexibly serve their own citizens, and

WHEREAS, in a unanimous opinion in *Bond v. United States*, 131 S.Ct. 2355 (2011), the United States Supreme Court found that federalism secures the freedom of the individual, allowing states to respond, through the enactment of positive law, to the

40-01470-12 20121840__

initiative of those who seek a voice in shaping the destiny of their own times and, in doing so, rejected the notion that Americans might be forced to rely upon the political processes that control a "remote central power," and

WHEREAS, in *Florida et al v. United States Department of Health and Human Services*, 648 F.3d 1235 (11th Cir. 2011), now pending appeal before the United States Supreme Court, 26 states, with the support of 22 attorneys general and four governors, brought a constitutional challenge against the Patient Protection and Affordable Care Act on the basis that it creates an unlawful mandate requiring individuals to obtain health insurance coverage, and

WHEREAS, on March 3, 2011, United States District Court Judge Roger Vinson issued an order staying his original decision in that case, which held the Patient Protection and Affordable Care Act unconstitutional, and

WHEREAS, in that order, Judge Vinson noted that the severity of injury from the Patient Protection and Affordable Care Act is undercut by the fact that, irrespective of his ruling, at least eight of the plaintiff states had represented that they would continue to implement and fully comply with the act's requirements while the case was pending on appeal, clearly implying that, as states continue to plan exchanges in preparation for implementation of the act, the perceived harm to states is reduced, making it less likely it will ultimately be declared unconstitutional, and

WHEREAS, in July 2011, the United States Department of Health and Human Services published 61 pages of proposed rules regarding the establishment of health insurance exchanges, which

required 172 pages of commentary and clarification, including numerous references to future rulemaking, bringing into question the proposition that states have any significant flexibility in the establishment of the exchanges, and

WHEREAS, the health insurance exchanges are the cornerstone of the individual mandate that is at the heart of the constitutional challenge, and

WHEREAS, if the Patient Protection and Affordable Care Act is struck down by the high court, states will have wasted millions of dollars of taxpayer funds in planning irrelevant exchanges that fail to serve a public purpose, and

WHEREAS, despite claims by some that states can create health care exchanges that both enjoy the benefits of a free marketplace and comply with the Patient Protection and Affordable Care Act, these exchanges would be, in truth, contrived devices offering insurance products regulated in their essential characteristics by the Federal Government, in effect, eliminating the free market, and

WHEREAS, the health insurance exchanges required by the Patient Protection and Affordable Care Act will continue to be subject to the arbitrary whims of the federal bureaucracy that, with its ongoing rulemaking authority, can render any plan for a state exchange, no matter how rational and well-designed it might be today, obsolete and irrelevant at a later date, and

WHEREAS, while the Patient Protection and Affordable Care Act does not clearly and unequivocally preempt state law, it contains only a vague provision that can be interpreted as stating that federal law will not preempt state laws that preserve free enterprise health care systems, and

WHEREAS, in fact, the Patient Protection and Affordable Care Act mandates the establishment of health insurance exchanges that are required to conform to federal law, forcing states that establish exchanges to actively participate in the preemption of their own laws, and

WHEREAS, states can and should develop and implement state-based health reform solutions that are tailored to the specific needs of their citizens and that are free of the mandates included in the Patient Protection and Affordable Care Act, and

WHEREAS, it is not in the best interest of any state for any official of that state to participate in planning or establishing health insurance exchanges as provided for in the Patient Protection and Affordable Care Act, NOW, THEREFORE,

Be It Resolved by the Senate of the State of Florida:

That the Congress of the United States is urged to defund planning grants to states for the establishment of health insurance exchanges required by the Patient Protection and Affordable Care Act.

BE IT FURTHER RESOLVED that copies of this memorial be dispatched to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke ✓

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/2012
Meeting Date

Topic _____ Bill Number 1840 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH *Street* Phone 727-897-9291

SAINT PETERSBURG *City* FLORIDA *State* 33705 *Zip* E-mail JUSTICE2JESUS@YAHOO.COM

Speaking: ☐ For ☑ Against ☑ Information

Representing JUSTICE-2-JESUS

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☐ Yes ☑ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SM 1854

INTRODUCER: Senator Garcia

SUBJECT: Patient Protection and Affordable Care Act

DATE: February 17, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Davlantes	Stovall	HR	**Favorable**
2.				
3.				
4.				
5.				
6.				

I. Summary:

Senate Memorial 1854 urges the Congress of the United States to repeal the Patient Protection and Affordable Care Act (PPACA or the Act) signed into law by President Obama in 2010.

This bill creates a Senate Memorial.

II. Present Situation:

Patient Protection and Affordable Care Act

The PPACA,[1] often referred to as federal health care reform, was signed into law by President Barack Obama on March 23, 2010. The Act is far-reaching and is so broad that it will be years before all of its provisions will be fully implemented and its ramifications fully understood.

Changes for the Federal Government
The primary changes for the federal government center on Medicare, the establishment of a number of new organizations, and increasing government spending on health care. Medicare will provide more preventative care without co-pays and deductibles, cover more prescription drugs, and test new health care delivery and payment programs. Medicare payments for primary care providers, including general surgeons working in rural areas, will be raised by 10 percent. Certain Medicare beneficiaries will be required to pay higher premiums, depending on their income level.

[1] Found at: <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf> (Last visited on January 31, 2012).

The Act creates a variety of federal institutes and boards to focus on national quality and prevention strategies, greater coordination between health care institutions, comparative effectiveness research, and workforce research.

The federal government will enhance the financial participation initially for Medicaid, subsidize low-income people trying to obtain health insurance through the state exchanges created by the Act, and fund incentives and tax breaks for businesses who exhibit innovation in health care.

Changes for State Governments
Medicaid currently focuses on covering low-income children, pregnant women, and adults who are elderly or have disabilities. The PPACA increases the mandatory population to all adults, regardless of whether they are disabled or elderly, up to 133 percent of the poverty level. The PPACA would finance the expansion by raising the federal match rate for the new groups. States would still have to pay a share for the new groups, but it would be smaller than for existing groups. However, the additional federal match is time-limited.

The costs of PPACA to Florida Medicaid will be significant. Florida is expected to have over 379,000 new enrollees from the expanded PPACA Medicaid population in 2014, at a cost of $1.5 billion (of which $142 million will be paid by the state), bringing the total cost of Medicaid that year to $25 billion. By 2019, Florida Medicaid will have 1.9 million additional enrollees, at an additional cost of over $7.7 billion (of which $1 billion will be paid by the state).[2] In subsequent years, the state share may increase.

The PPACA will create additional costs unrelated to caseload expansion. For example, the law increases the minimum federal rebate for brand drugs from 15.1 percent to 23.1 percent and requires that 100 percent of this portion of rebates be withheld by the federal government rather than the current procedure of sharing rebate revenue with the states. This provision will cost Florida approximately $37 million annually at current levels.[3] The FY 2010-2011 impact was estimated to be a loss in rebate general revenue of $39.8 million. This will be a recurring loss. Additionally, when the federal enhanced payments to primary care providers expire in 2014, it is estimated that continuing the payments will cost the state $247.9 million in 2015.

The Act seeks to expand access to health insurance coverage by requiring most U.S. citizens and legal residents to have health insurance and providing for the creation of state-based American Health Benefit Exchanges (commonly known as health insurance exchanges) through which individuals can purchase qualifying coverage. Exchanges are new organizations that will be set up to create an organized, competitive market for buying health insurance. They will offer a choice of different health plans, certifying plans that participate and providing information to help consumers better understand their options. They will also be the mechanism through which low and moderate-income individuals receive premium and cost-sharing subsidies to make health coverage more affordable.

[2] Agency for Health Care Administration, Overview of Federal Affordable Care Act, August 13, 2010; State of Florida Long-Range Financial Outlook Fiscal Year 2011-12 through 2013-14, Fall 2010 Report.
[3] Agency for Health Care Administration, Patient Protection and Affordable Care Act Overview of Medicaid Prescribed Drug Changes, October 21, 2010.

States are expected to establish Exchanges – which can be a government agency or a non-profit organization – with the federal government stepping in if a state does not set them up. States can create multiple Exchanges, so long as only one serves each geographic area, and can work together to form regional Exchanges. State Exchanges are required to be fully operational by January 1, 2014. The federal government is providing funding and technical assistance to help states set up Exchanges.

Changes for Insurers
Health insurance companies can no longer deny individuals coverage based on pre-existing medical conditions, end coverage when policyholders become ill, or place annual or lifetime limits on the amount they will pay for policyholders. Insurers may not charge higher premiums based on current or projected health status; the only risk factors that may be considered for setting premiums are age, geographic location, family composition, and tobacco use. Children up to age 26 may be covered under their parents' health insurance.

Insurance companies are also required to maintain medical loss ratios (MLR) of 80 percent or 85 percent, depending on their size. This means that 80-85 percent of all revenues of the insurance company must be spent on health care payments for policyholders, rather than on administrative overhead. Tax breaks for certain insurance plans have also been discontinued.

Changes for Employers
Small employers are not required to provide health insurance for their employees, but they receive tax credits if they do, and they will be allowed to purchase insurance through the Exchanges. Large employers are required to offer employee health insurance and are penalized monetarily if they do not. All employers may receive federal grants for establishing wellness programs and may offer incentives to employees for participating in such programs and meeting certain health benchmarks.

Changes for Hospitals
Medicare payments to hospitals will be changed from fee-for-service (providing individual reimbursement for each procedure performed on a patient while admitted) to bundled payments (providing one lump sum for a patient stay, regardless of what procedures were performed). Overall Medicare payments are decreased for certain hospitals, although payments to hospitals serving low-income and uninsured areas will increase, and new quality standards are established for certain hospitals.

Changes for Individuals
All individuals other than undocumented immigrants will be required to have health insurance and will face penalties for not doing so. Individuals may be insured by Medicare or Medicaid, receive insurance through their employers, or purchase it individually from state Exchanges. Federal subsidies for purchasing health insurance are available to certain individuals, and fewer out-of-pocket medical expenses will be tax-deductible. To help pay for the PPACA's expanded health care access, Medicare taxes will increase for individuals making more than $200,000 or couples making more than $250,000 annually.

Other Changes

Additional taxes are created by the Act, including a 10 percent tax on indoor tanning services and taxes on medical device companies and pharmaceutical companies. Certain pharmaceutical companies will be required to offer drug discounts to Medicare beneficiaries, and relationships between pharmaceutical companies, hospital systems, and other health care entities must be more public. Restaurants chains with more than 20 locations will be required to post the caloric content of their food on all menus, with certain exceptions.[4]

States' Challenge of PPACA

Immediately after the PPACA was signed into law, 13 Attorneys General filed a lawsuit against the U.S. Department of Health and Human Services, U.S. Department of Treasury and the U.S. Department of Labor alleging the Health Care Reform law signed by the President was unconstitutional.[5] The amended complaint currently features 26 state plaintiffs.[6] Additionally, the National Federation of Independent Business (NFIB) joined the lawsuit as a co-plaintiff on behalf of its members nationwide.

The lawsuit, filed in the federal court's Northern District of Florida on March 23, 2010, alleges the PPACA infringes upon the constitutional rights of Floridians and residents of the other states by mandating all citizens and legal residents have qualifying health care coverage or pay a tax penalty. By imposing such a mandate, the law exceeds the powers of the United States under Article I of the Constitution. Additionally, the tax penalty required under the law constitutes an unlawful direct tax in violation of Article I, sections 2 and 9 of the Constitution.[7]

The lawsuit further claims the health care reform law infringes on the sovereignty of the states and the Tenth Amendment to the Constitution by imposing onerous new operating rules that Florida must follow as well as requiring the state to spend billions of additional dollars without providing funds or resources to meet the state's cost of implementing the law. This burden comes at a time when Florida faces severe budget cuts to offset shortfalls in an already-strained budget.

On January 31, 2011, Senior United States District Judge Roger Vinson ruled that the PPACA is unconstitutional.[8] The district court granted summary judgment to the government on the state plaintiffs' claim that the Act's expansion of Medicaid is unconstitutional and to the plaintiffs on their claim that the Act's individual mandate – that individuals purchase and continuously maintain health insurance from private companies – is unconstitutional. The district court concluded that the individual mandate exceeded congressional authority under Article I of the Constitution because it was not enacted pursuant to Congress's tax power and it exceeded

[4] Elisabeth Askin and Nathan Moore, *Health Care Handbook: A Guide to the U.S. Health Care System*. A copy is on file with the Senate Health Regulation Committee.
[5] *Florida, et al. v. Department of Health and Human Services, et al.*
[6] The 26 plaintiffs include: Florida, South Carolina, Nebraska, Texas, Utah, Louisiana, Alabama, Colorado, Michigan, Pennsylvania, Washington, Idaho, South Dakota, Indiana, Mississippi, Nevada, Arizona, Georgia, Alaska, North Dakota, Wisconsin, Iowa, Ohio, Kansas, Wyoming, and Maine.
[7] Office of the Attorney General of Florida, *The States' Lawsuit Challenging the Constitutionality of the Health Care Reform Law*. Found at: <http://www.healthcarelawsuit.us/> (Last visited on February 17, 2012).
[8] *State of Florida, by and through Attorney General Pam Bondi, et al. v. United States Department of Health and Human Services, et al.*, United States District Court for the Northern District of Florida Pensacola Division, Case No.: 3:10-cv-91-RV/EMT, January 31, 2011. Found at: < http://myfloridalegal.com/webfiles.nsf/WF/JDAS-8DMNTD/$file/VinsonRuling1312011.pdf> (Last visited on February 17, 2012).

Congress's power under the Commerce Clause and the Necessary and Proper Clause. The district court also concluded that the individual mandate provision was not severable from the rest of the Act and declared the entire Act invalid.

The federal government appealed the district court's ruling that the individual mandate is unconstitutional and its severability holding. The state plaintiffs cross-appeal the district court's ruling on their Medicaid expansion claim. On appeal, the United States Court of Appeals for the Eleventh Circuit ruled, on August 12, 2011, that the individual mandate is severable from the remainder of the Act. The court also affirmed the district court's grant of summary judgment to the federal government that the Medicaid expansion is constitutional and concluded that the individual mandate exceeds Congress's enumerated commerce power and is unconstitutional. The court concluded that the individual mandate is a civil regulatory penalty and not a tax.[9]

The parties have filed petitions for the Supreme Court to review the lower court holdings.

On December 19, 2011, the U.S. Supreme Court announced the dates for the oral argument in the States' challenge to the federal health care law. The oral arguments will begin March 26 and continue through March 28. On March 26, the Court will hear one hour of oral argument on the jurisdictional issue of whether the federal Anti-Injunction Act bars challenges to the individual mandate. On March 27, the Court will hear two hours of oral argument limited to the issue of whether the individual mandate is constitutional. On March 28, the Court will hear 90 minutes of oral argument on the severability argument. Also on March 28, the Court will hear one hour of oral argument on the constitutionality of the law's substantial expansion of Medicaid.

III. Effect of Proposed Changes:

Senate Memorial 1854 urges the Congress of the United States to repeal the Patient Protection and Affordable Care Act (PPACA or the Act) signed into law by President Obama in 2010. Copies of this memorial will be dispatched to the President of the United States, the President of the United States Senate, the Speaker of the House of Representatives, and to each member of the Florida delegation to the United States Congress.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

[9] *State of Florida, by an through Attorney General Pam Bondi, et al. v. United States Department of Health and Human Services, et al.*, United States Court of Appeals for the Eleventh Circuit, D.C. Docket No. 3:10-cv-00091-RV-EMT. Found at: <http://myfloridalegal.com/webfiles.nsf/WF/JDAS-8KNNU8/$file/HCR_11thCirOpinion8.12.11.pdf> (Last visited on February 17, 2012).

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

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

None.

B. Amendments:

None.

By Senator Garcia

40-01369-12 20121854__

Senate Memorial

A memorial to the Congress of the United States, urging Congress to repeal the Patient Protection and Affordable Care Act signed into law by President Obama in 2010.

WHEREAS, the health insurance mandate within the Patient Protection and Affordable Care Act is a form of government interference in the free market and an all-out assault on personal liberties, and

WHEREAS, the mandate for individuals to purchase health insurance exceeds the scope and authority of Congress, and

WHEREAS, as the United States economy continues to struggle and the unemployment rate holds steadfast at alarming percentages, the employer mandate to provide health insurance to employees will raise the cost of hiring new employees and have an adverse effect on the state of our economy, and

WHEREAS, as the cost of employing workers rises, it will become increasingly vital that employers get more production out of their more highly paid employees, which will lead to higher and more sustained unemployment for the lower skilled workforce, NOW, THEREFORE,

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

That the Florida Legislature urges the United States Congress to repeal the Patient Protection and Affordable Care Act signed into law by President Obama in 2010.

BE IT FURTHER RESOLVED that copies of this memorial be

Florida Senate - 2012 **SM 1854**

40-01369-12 20121854__

dispatched to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Spoke ✓

2/22/2012
Meeting Date

Topic _____ Bill Number 1854 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH Phone 727-897-9291
Street

SAINT PETERSBURG FLORIDA 33705 E-mail JUSTICE2JESUS@YAHOO.COM
City *State* *Zip*

Speaking: ☐ For ☑ Against ☑ Information

Representing JUSTICE-2-JESUS

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☐ Yes ☑ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SB 624

INTRODUCER: Senator Richter

SUBJECT: Household Pharmaceuticals Collection and Disposal Trust Fund/DEP

DATE: February 20, 2012 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wiggins	Yeatman	EP	**Fav/1 amendment**
2.	Looke	Stovall	HR	**Favorable**
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	[ ]	Statement of Substantial Changes
B. AMENDMENTS.....	[X]	Technical amendments were recommended
	[ ]	Amendments were recommended
	[ ]	Significant amendments were recommended

I. Summary:

This bill creates the Household Pharmaceuticals Collection and Disposal Trust Fund within the Department of Environmental Protection (DEP) and provides for sources, purposes and management of the funds. This bill is related to SB 626, which creates a grant program for pharmaceutical collection and disposal.

As required by the constitution, the trust fund takes effect July 1, 2012, and is terminated on July 1, 2016, but only if enacted by a three-fifths vote of the membership of each house of the Legislature.

This bill creates section 403.7451, Florida Statutes.

II. Present Situation:

Section 19(f), Art. III of the State Constitution, requires that every trust fund be created by a three-fifths vote of the membership in each house of the Legislature in a separate bill for the sole purpose of creating that trust fund. The Constitution also provides that all newly created trust funds terminate not more than four years after the initial creation unless recreated.

III. Effect of Proposed Changes:

Section 1 creates the Household Pharmaceuticals Collection and Disposal Trust Fund within the DEP. The funds deposited into the trust fund will be used for the grant program established in s. 403.745, F.S., by SB 626 to reimburse local law enforcement agencies for the expenses associated with the collection and disposal of household pharmaceuticals. The trust fund sunsets on July 1, 2016, unless terminated sooner. The trust fund must be reviewed prior to its scheduled termination as provided in ss. 215.3206 (1) and (2), F.S.

Section 2 provides the effective date of July 1, 2012, if SB 626 or similar legislation is adopted and becomes law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

Article III, section 19(f)(1), of the Florida Constitution, provides no trust fund of the state or other public body may be created without three-fifths vote of the membership of each house of the Legislature in a separate bill for that purpose only.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

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

None.

B. Amendments:

Barcode 304776 by Environmental Preservation and Conservation on February 6, 2012:
The amendment clarifies that the Household Pharmaceuticals Collection and Disposal Trust Fund is tied to SB 626.

304776

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
02/06/2012	.	
	.	
	.	
	.	

The Committee on Environmental Preservation and Conservation (Detert) recommended the following:

Senate Amendment

Delete line 37
and insert:
Senate Bill 626 or similar legislation is adopted in the same

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Banking and Insurance, *Chair*
Budget
Budget - Subcommittee on Health and Human Services Appropriations
Community Affairs
Judiciary
Rules
Rules - Subcommittee on Ethics and Elections

JOINT COMMITTEE:
Legislative Budget Commission

SENATOR GARRETT RICHTER
37th District

February 10, 2012

The Honorable Miguel Garcia, Chair
Committee on Health Regulation
530 Knott Building
404 South Monroe Street
Tallahassee, FL 32399

Dear Chairman Garcia:

Senate Bills 626 and the linked trust fund bill, SB 624 relating to Household Prescriptions Collection and Disposal have been referred to the Committee on Health Regulation. They passed unanimously out of Environmental Preservation and Conservation. I would appreciate the placing of these bills on the committee's agenda at your earliest convenience.

Thank you for your consideration.

Garrett Richter

cc: Sandra Stovall, Staff Director

ENTERED

REPLY TO:
❒ 3299 East Tamiami Trail, Suite 203, Naples, Florida 34112 (239) 417-6205
❒ 1039 S.E. 9th Place, Room 310, Cape Coral, Florida 33990 (239) 338-2777
❒ 322 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5124

Senate's Website: *www.flsenate.gov*

MIKE HARIDOPOLOS
President of the Senate

MICHAEL S. "MIKE" BENNETT
President Pro Tempore

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SB 626

INTRODUCER: Senator Richter

SUBJECT: Collection and Disposal of Household Pharmaceuticals

DATE: February 17, 2012 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wiggins	Yeatman	EP	**Fav/1 amendment**
2.	Looke	Stovall	HR	**Favorable**
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	☐	Statement of Substantial Changes
B. AMENDMENTS.....	X	Technical amendments were recommended
	☐	Amendments were recommended
	☐	Significant amendments were recommended

I. Summary:

This bill requires the Department of Environmental Protection (DEP) to establish a grant program to reimburse local law enforcement agencies for the expenses associated with the collection and proper disposal of household pharmaceuticals.

This bill also imposes a new $21 surcharge against persons who violate certain statutes regulating controlled substances in order to pay for the grant program. Of the $21 fine, $20 will fund the grant program, and $1 will be retained by the clerk of the court that imposed the fine.

This bill creates sections 403.745 and 938.16, Florida Statutes.

II. Present Situation:

According to the DEP, there are two main issues related to pharmaceutical disposal, drug diversion and environmental impacts.

Drug Diversion

A recent Florida Department of Law Enforcement report found that legal prescription drugs were found to be the cause of more deaths than illegal drugs[1] and "studies show that a majority of prescription drugs are obtained from family and friends."[2] Section 499.005, F.S., prohibits certain specific acts regarding prescription drugs including, but not limited to, "[t]he sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug…[and the] purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient." Such acts are criminalized and punishable as provided in s. 499.0051, F.S.

Controlled substances with the potential for abuse are regulated under ch. 893, F.S., which sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act, and classifies controlled substances into five categories, known as schedules. The distinguishing factors between the schedule of one substance when compared with another is the potential for abuse, as defined in s. 893.02(2), F.S., and whether there is a currently accepted medical use. These schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances.[3]

- A **Schedule I** substance has a high potential for abuse, currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples: heroin and methaqualone.

- A **Schedule II** substance has a high potential for abuse but also has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of a Schedule II substance may lead to severe psychological or physical dependence. Examples: cocaine and morphine.

- A **Schedule III** substance has less potential for abuse than a Schedule I or II substance and a currently accepted medical use in treatment in the United States. However, abuse of a Schedule III substance may lead to varying degrees of psychological dependence or, in the case of anabolic steroids, to physical damage. Examples: lysergic acid; ketamine; and some anabolic steroids.

- A **Schedule IV** substance has a low potential for abuse relative to the substances in Schedule III and a currently accepted medical use in treatment in the United States. Abuse of a Schedule IV substance may lead to limited physical or psychological dependence. Examples: alprazolam; diazepam; and phenobarbital.

[1] Florida Department of Law Enforcement, *Drugs Identified in Deceased Persons by Medical Examiners*, 2010.
[2] Florida Department of Environmental Protection, *Draft Bill Analysis on SB 626*, 1/20/2012, on file with the Senate Health Regulation Committee.
[3] *See*, s. 893.03, F.S.

- A **Schedule V** substance has a low potential for abuse and a currently accepted medical use in treatment in the United States. Abuse of a Schedule V substance may lead to limited physical or psychological dependence. Examples: low dosage levels of codeine; certain stimulants; and certain narcotic compounds.

Section 893.13, F.S., makes it unlawful for any person to sell, manufacture, deliver, or possess with intent to sell, manufacture, or deliver a controlled substance except as authorized by ch. 893 and 499, F.S.; s. 893.135, F.S., relates to trafficking in controlled substances; and s. 893.1351, F.S., provides that a person may not own or lease a place with the knowledge that it will be used for the purpose of trafficking in a controlled substance. A person who violates ch. 893, F.S., may be found guilty of committing a crime ranging anywhere from a Misdemeanor of the First Degree up to and including a Felony of the First Degree.

Environmental Impacts

The environmental impacts of improper disposal of pharmaceuticals are harder to demonstrate empirically. Recently, a national study has found certain pharmaceuticals in Florida's waters at concentrations of parts per million, which is on par with many other water bodies across the nation.[4] However, due to widespread use of drugs, such as antibiotics, in agriculture and animal husbandry, and the low metabolism rate of some of these substances in the human body, it is difficult to pinpoint exactly how these pharmaceuticals are being introduced into the water.[5]

Collection Programs

Currently, no standardized collection program for household pharmaceuticals exists for the whole state of Florida and many people, instead of disposing of expired or unused household pharmaceuticals properly, simply throw them out or flush them down the toilet. Local jurisdictions occasionally run such collection programs, though. For example, the Broward County Sherriff's Office runs Operation Medicine Cabinet which sets up locations and times, at least once a month, to allow participants to "drop off prescription drugs with no questions asked and receive a $5 gift card to local stores and pharmacies."[6] Also, other law enforcement agencies periodically collaborate with retail stores to host community events to collect and safely dispose of expired or unused pharmaceuticals. According to the DEP, at a pharmaceutical collection event in Tallahassee held in October of 2011, citizens were polled on how they typically disposed of expired or unused pharmaceuticals assuming a collection event was not available. Of the citizens polled, 26 percent reported that they threw the pharmaceuticals in the trash, 18 percent reported that they flushed them down the toilet, and 54 percent reported that they simply stored them.[7]

[4] Id.
[5] Id.
[6] Broward Sherriff's Office, *Operation Medicine Cabinet*, found at http://sheriff.org/safety/operation_medicine_cabinet/, last viewed on Feb. 20, 2012.
[7] Id.

III. Effect of Proposed Changes:

Section 1 creates s. 403.745, F.S., which establishes a grant program to reimburse local law enforcement agencies for the expenses associated with the collection and disposal of household pharmaceuticals. To be eligible for a grant, a law enforcement agency must conduct the collection and disposal of household pharmaceuticals in a manner consistent with DEP rules and state and federal requirements.

Section 2 creates s. 938.16, F.S., in order to fund the household pharmaceuticals collection and disposal grant program. It provides that, in addition to any sanction imposed for a violation of ss. 893.13, 893.135, or 893.1351, F.S., the court must impose a surcharge of $21. Payment of the surcharge will be a condition of probation, community control, or any other court-ordered supervision. Twenty dollars of the surcharge shall be remitted to the DOR to be deposited into the Household Pharmaceuticals Collection and Disposal Trust Fund established in s. 403.7451, F.S., and the clerk of the court will retain $1 of each surcharge that they collect as a service charge.

Section 3 establishes an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

This bill may provide new opportunities for businesses that provide collection and disposal services of prescription drugs.

This bill will impose an additional $21 fine on persons who violate ss. 893.13, 893.135, or 893.1351, F.S.

C. Government Sector Impact:

This bill will create a grant program within the DEP. The DEP has indicated that they can administer this program with existing resources but would need budget authority to administer the revenues generated by the surcharge. If local law enforcement agencies choose to hold collection events, the costs would be reimbursed through the grant program. It is anticipated that there would be no additional costs to local governments other than the costs associated with managing the grant receipts and processing requests for reimbursement under the grants. However, according to the Florida Association of County Clerks this bill is expected to have an indeterminate fiscal impact on the various offices of the clerks of county courts that process the new fine[8] due to the costs of processing and the $1 surcharge which may offset such costs.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

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

None.

B. Amendments:

Barcode 631912 by Environmental Preservation and Conservation on February 6, 2012:
The amendment clarifies that $20 of the surcharge shall be remitted to the Department of Revenue for deposit into the Household Pharmaceuticals Collection and Disposal Trust Fund. (WITH TITLE AMENDMENT)

[8] Association of County Clerks, *RE: SENATE BILL # 626 Collection and Disposal of Household Pharmaceuticals*, Nov. 8, 2011, on file with the Senate Health Regulation Committee.

By Senator Richter

37-00684-12 2012626__

A bill to be entitled

An act relating to the collection and disposal of household pharmaceuticals; creating s. 403.745, F.S.; requiring the Department of Environmental Protection to establish a grant program to reimburse local law enforcement agencies for the expenses associated with the collection and disposal of household pharmaceuticals; providing eligibility requirements; creating s. 938.16, F.S.; requiring that the court impose an additional surcharge for specified offenses; providing for the proceeds of the surcharge to be deposited into the Household Pharmaceuticals Collection and Disposal Trust Fund; providing for the clerk of the court to retain a service charge; providing an effective date.

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

Section 1. Section 403.745, Florida Statutes, is created to read:

403.745 Household pharmaceuticals collection and disposal grant program.—The department shall establish a grant program to reimburse local law enforcement agencies for the expenses associated with the collection and disposal of household pharmaceuticals. To be eligible for a grant, a law enforcement agency must conduct the collection and disposal of household pharmaceuticals in a manner consistent with applicable rules of the department and applicable state and federal requirements.

Section 2. Section 938.16, Florida Statutes, is created to

37-00684-12 2012626__

read:

938.16 Additional cost to fund the household pharmaceuticals collection and disposal grant program.—In addition to any sanction imposed for a violation of s. 893.13, s. 893.135, or s. 893.1351, the court shall impose a surcharge of $21. Payment of the surcharge shall be a condition of probation, community control, or any other court-ordered supervision. Twenty dollars of the surcharge shall be deposited into the Household Pharmaceuticals Collection and Disposal Trust Fund established in s. 403.7451. The clerk of the court shall retain $1 of each surcharge that the clerk of the court collects as a service charge of the clerk's office.

Section 3. This act shall take effect July 1, 2012.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

631912

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
02/06/2012	.	
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The Committee on Environmental Preservation and Conservation (Detert) recommended the following:

Senate Amendment (with title amendment)

Delete line 37
and insert:
supervision. Twenty dollars of the surcharge shall be remitted to the Department of Revenue for deposit

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 12
and insert:
remitted to the Department of Revenue for deposit into

631912

the Household Pharmaceuticals

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/2012
Meeting Date

Topic _____ Bill Number 626 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH Phone 727-897-9291
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SAINT PETERSBURG FLORIDA 33705 E-mail JUSTICE2JESUS@YAHOO.COM
City *State* *Zip*

Speaking: ☐ For ☐ Against ☑ Information

Representing JUSTICE-2-JESUS

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☐ Yes ☑ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SB 668

INTRODUCER: Senator Hays

SUBJECT: Workers' Compensation Medical Services

DATE: February 14, 2012 REVISED: 02/23/12

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Burgess	BI	**Fav/1 amendment**
2.	Wilson	Stovall	HR	**Fav/1 amendment**
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	[ ]	Statement of Substantial Changes
B. AMENDMENTS.....	[ ]	Technical amendments were recommended
	[ ]	Amendments were recommended
	[X]	Significant amendments were recommended

I. Summary:

Chapter 440, F.S., generally requires employers and carriers to provide medical and indemnity benefits to workers who are injured due to an accident arising out of and during the course of employment. Medical benefits can include, but are not limited to, medically necessary care and treatment, and prescription medications. In Florida, the prescription reimbursement rate for dispensing physicians and pharmacies is the average wholesale price (AWP) plus a $4.18 dispensing fee, or the contracted rate, whichever is lower.

Prescription drug repackagers are licensed by the Department of Business and Professional Regulation. Drug repackagers purchase pharmaceuticals in bulk from the manufacturer and repackage the drugs into individual prescription sizes. The repackaged drugs are assigned a new National Drug Code and can be assigned a new, higher AWP than the original manufacturer's AWP.

The bill revises requirements for determining the amount of reimbursement for prescription medications of workers' compensation claimants by providing that the reimbursement amount is the same for repackaged or relabeled drugs as for non-repackaged drugs. Reimbursement for repackaged or relabeled drugs would be determined by multiplying the number of units of the drug dispensed by the per-unit AWP set by the original manufacturer of the drug (which may not be the manufacturer of the repackaged or relabeled drug), plus a $4.18 dispensing fee, unless the carrier has contracted for a lower amount. The bill expressly prohibits the price of repackaged or relabeled drugs from exceeding the amount that would otherwise be payable had the drug not been repackaged or relabeled.

It is estimated that the bill would reduce workers' compensation costs overall by 2.5 percent.

This bill substantially amends the following section of the Florida Statutes: 440.13.

II. Present Situation:

State and Federal Regulation of Prescription Drugs

Section 510 of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. s. 360, requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. Drug products are identified and reported to the FDA using a unique, three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs. The current edition of the NDC Directory is limited to prescription drugs and insulin products that have been manufactured, prepared, propagated, compounded, or processed by registered establishments for commercial distribution.[1]

The term "repackaged" drugs refers to drugs that have been purchased in bulk by a wholesaler/repackager from a manufacturer, relabeled, and repackaged into individual prescription sizes that can be dispensed directly by physicians or pharmacies to patients. Repackagers of drugs are required to register and list all such drug products repackaged and relabeled with the FDA.

In Florida, the Department of Business and Professional Regulation (DBPR) regulates prescription drug repackagers. A permit as a prescription drug repackager is required for any person that repackages a prescription drug in Florida. The permit authorizes the wholesale distribution of prescription drugs repackaged at the establishment.

Rule 64F-12, F.A.C., defines "repackaging or otherwise changing the container, wrapper, or labeling to further the distribution" to mean:

- Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic. For example, repackaging from bottles of 1,000 to bottles of 100.
- Altering a manufacturer's package for sale under a label different from the manufacturer. For example: a kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D; packaged together and marketed as an immunization kit under a label of manufacturer Z.
- Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product.[2]

[1] *National Drug Code Database Background Information*, U.S. Food and Drug Administration. Found at: <http://www.fda.gov/drugs/developmentapprovalprocess/ucm070829> (Last visited on February 14, 2012).

[2] The Rule provides that repackaging does not include:

Dispensing Practitioners

According to the Workers' Compensation Research Institute, some states, such as Massachusetts, New York, and Texas prohibit physicians from dispensing drugs.3 In Florida, s. 465.0276(1), F.S., authorizes physicians and pharmacies to dispense, as provided below:

> A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

To become a dispensing practitioner in Florida, a practitioner is required to register under s. 465.0276, F.S., with the applicable professional licensing board as a dispensing practitioner and pay a $100 fee.[4] Dispensing practitioners must comply with all laws and rules applicable to pharmacists and pharmacies including undergoing inspections. A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III in s. 893.03, F.S.[5]

Section 458.347, F.S., allows a supervising physician to delegate dispensing authority to his or her physician assistant (PA). No registration is required for a PA to dispense. The PA may prescribe under his or her supervising physician; however, a PA cannot prescribe controlled substances.

According to advocates of physician dispensers, there are some advantages for patients from physicians dispensing drugs. These benefits may include greater compliance by the patient in taking a drug dispensed directly by the physician, more convenience for patients residing in remote areas, and the benefit of prompt treatment.

A health care provider rendering medical treatment and care to an injured employee must be certified pursuant to Rule 69L-29.002, F.A.C., by the Department of Financial Services (DFS) or deemed certified, pursuant to s. 440.13(1)(d), F.S., as a provider within a managed care organization licensed through the Agency for Health Care Administration. Section 440.13(1) (d), F.S., provides that a "certified health care provider" is a provider approved to receive reimbursement through the Florida workers' compensation system. A certified provider may be a physician, a licensed practitioner, or a facility approved by the DFS or a provider who has entered an agreement with a licensed managed care organization to provide treatment to injured employees. Generally, a certified health care provider must receive authorization from the insurer before providing treatment.

a. Selling or transferring an individual unit which is a fully labeled self-contained package that is shipped by the manufacturer in multiple units, or
b. Selling or transferring a fully labeled individual unit, by adding the package insert, by a person authorized to distribute prescription drugs to an institutional pharmacy permit, health care practitioner, or emergency medical service provider for the purpose of administration and not for dispensing or further distribution.

[3] *Prescription Benchmarks for Massachusetts* by the Workers' Compensation Research Institute, March 2010.
[4] If the practitioner is dispensing complimentary packages of medicinal drugs, the practitioner is not required to register.
[5] *See* s. 465.0276(1)(b), F.S.

Section 440.13(14), F.S., provides that fees charged for remedial treatment, care, and attendance, except for independent medical examinations and consensus independent medical examinations, may not exceed the applicable fee schedules adopted under ch. 440, F.S., and department rule. However, if a physician or health care provider specifically agrees in writing to follow identified procedures aimed at providing quality medical care to injured workers at reasonable costs, deviations from established fee schedules are allowed.

Reimbursement for Prescription Drugs in Workers' Compensation

Chapter 440, F.S., is Florida's workers' compensation law. The Division of Workers' Compensation within the Department of Financial Services is responsible for administering ch. 440, F.S. Generally, employers/carriers are required to provide medical and indemnity benefits to a worker who is injured due to an accident arising out of and during the course of employment. For such compensable injuries, an employer/carrier is responsible for providing medical treatment, which includes, but is not limited to, medically necessary care and treatment and prescription drugs.[6]

The reimbursement method for a prescription medication to pharmacies and dispensing physicians is found in s. 440.13(12)(c), F.S. The reimbursement amount is the average wholesale price (AWP) of the drug plus $4.18 for the dispensing fee, unless the carrier has contracted for a lower amount. The AWP is comparable to a wholesaler's suggested price and the term, AWP, is not defined in ch. 440, FS. Current law does not provide caps on reimbursements for repackaged or relabeled prescription drugs.

An NDC is assigned to each drug and used to identify the medication and the manufacturer or repackager of the medication. The original drug manufacturer creates an AWP for each drug. Drug repackagers purchase pharmaceuticals in bulk from the manufacturer, then relabel, and repackage the drugs into individual prescription sizes. Although drug repackagers do not alter the drugs, they do sell them in different quantities. By repackaging a drug, a new NDC is created and a new AWP is assigned to the repackaged drug.

Costs of Prescription Drugs in the Workers' Compensation System

Workers Compensation Research Institute (WCRI) Findings

According to a recent WCRI[7] report, the average payment per claim for prescription drugs in Florida was $536, which was the second highest average prescription cost per claim among the 17 states in the study.[8] [9] Between 2005/2006 and 2007/2008, the average prescription cost per claim increased 14 percent in Florida. Over the same period, prices per pill paid to physicians grew more rapidly than prices paid to pharmacies for the same prescription. In 2007/2008, the

[6] Section 440.13(2)(a), F.S.
[7] The Workers Compensation Research Institute is an independent, not-for-profit research organization providing information about public policy issues involving workers' compensation systems. Organized in late 1983, the WCRI does not take positions on the issues it researches.
[8] *Prescription Benchmarks for Florida, 2ND Edition*, by Workers' Compensation Research Institute, July 2011.
[9] The following states were included in the WCRI study: Florida, California, Tennessee, Indiana, Texas, Louisiana, Michigan, Minnesota, North Carolina, Iowa, Pennsylvania, Illinois, Maryland, Wisconsin, New Jersey, New York, and Massachusetts.

prices paid to physician dispensers for many common drugs were 40-80 percent higher than what was paid to pharmacies for the same drugs. For generic drugs, physicians were paid much higher prices per pill than pharmacies for the same prescription. According to the WCRI, this suggests that if physicians stop dispensing prescription drugs in response to a large price drop, more pharmacies would dispense the same prescriptions at a lower price, resulting in a decline in prescription costs.

National Council on Compensation Insurance

In Florida, the National Council on Compensation Insurance ("NCCI") is the rating and statistical organization that files rates on behalf of worker's compensation insurers in the state. The NCCI is licensed by the Office of Insurance Regulation. The NCCI provided the following data related to drug repackaging costs:[10]

- Markup on Florida repackaged drugs ranges up to 679 percent above the same drug in a non-repackaged format.
- Physician dispensed drugs have grown from 9 percent of the drug costs in 2003 to 50 percent of the drug costs in 2009.
- Florida has the highest rate of physician-dispensed drugs of 46 states studied.
- Most repackaged drugs are dispensed by physicians.

Division of Risk Management, Department of Financial Services

The Division of Risk Management within the Department of Financial Services administers the State of Florida's self-insurance program for property and casualty risk, which includes workers' compensation coverage.[11] The program covers executive, legislative, and judicial branches of Florida government and state universities and is funded by yearly assessments to participating state agencies. In 2011, the division identified medical costs, including pharmacy, as a claims cost driver.[12] A recent study by the division identified total repackaged drug costs of $1.2 million for the 2010 fiscal year.[13]

III. Effect of Proposed Changes:

The bill amends s. 440.13, F.S., to require the same reimbursement rate for repackaged or relabeled drugs that currently exists for non-repackaged drugs in Florida. The bill provides that regardless of the location or the provider of a prescription to a claimant, the reimbursement amount is the average wholesale price, plus the $4.18 for the dispensing fee, unless the carrier has contracted for a lower amount.

If a drug has been repackaged or relabeled, the reimbursement amount is calculated by multiplying the number of units dispensed times the per-unit average wholesale price set by the original manufacturer of the underlying drug, which may not be the manufacturer of the repackaged or relabeled drug, plus a $4.18 dispensing fee, unless the carrier has contracted for a

[10] NCCI presentation to the Three Member Panel, November 16, 2011.
[11] Ch. 284, F.S.
[12] *Florida's Risk Management Program Initiatives to Address Program Cost Drivers,* Presentation by staff of the Department of Financial Services to the House Subcommittee on General Government Appropriations, February 8, 2011.
[13] Fiscal Analysis of SB 910 by the Department of Financial Services, November 21, 2011. (On file with the Senate Banking and Insurance Committee).

lower amount. The bill also provides that the price of the repackaged or relabeled drug may not exceed the amount otherwise payable if the drug had not been repackaged or relabeled.

The act takes effect July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The NCCI estimates that the implementation of SB 668 would result in an impact of minus 2.5 percent, or approximately $62 million in savings, on the overall workers' compensation costs in Florida. In order to estimate the cost impact of this proposal, the NCCI compared the cost of repackaged or relabeled drugs to the cost of drugs dispensed in its original packaging from the manufacturer (not repackaged or relabeled). A repackaged or relabeled indicator field from First Databank's *National Drug Data FileTM (NDDF), Descriptive and Pricing Data*, was used to distinguish repackaged or relabeled drugs from the drugs dispensed in its original packaging from the manufacturer within the Florida Workers' Compensation Data licensed to NCCI.

The NCCI looked at generic and non-generic drugs separately. As an example, acetaminophen is the generic medication for the brand name drug Tylenol. The NCCI looked at the reimbursement amounts for acetaminophen in physician's offices and in pharmacies, and determined the average markup for acetaminophen. Then, the NCCI looked at the reimbursement amounts for Tylenol in physicians' offices and in pharmacies, and determined the average markup for Tylenol.

If the bill were enacted, the NCCI estimated percentage reduction in physician dispensed drugs would be 57 percent. According to the 2011 Annual Report of the Division of Workers' Compensation, physician dispensed drug costs were $63.2 million for service year 2010. Using the $63.2 million figure provided by the division, the total dollar savings in physician dispensed drugs would be $36 million ($63.2 million x -57 percent). In the Florida January 1, 2012 workers' compensation rate filing, total benefit costs represented 57.8 percent of the premium dollar. Therefore, the reduction in physician dispensed drugs would result in a premium savings of $62 million ($36 million/.578).

The overall decrease in costs attributable to the reduction in the costs of repackaged and relabeled drugs would benefit employers securing workers' compensation coverage. The Office of Insurance Regulation anticipates issuing a rate reduction order prospectively from the effective date of the new law, July 1, 2012.

The bill would continue to allow the repackaging of prescription drugs, but it would limit and reduce the reimbursement amount to the AWP of the original manufacturer, plus the $4.18 dispensing fee.

C. Government Sector Impact:

According to the Division of Risk Management of the Department of Financial Services, implementation of this bill would result in an estimated recurring cost savings of $1 million per fiscal year for the state.

The bill would also result in an indeterminate amount of annual savings to local governments.

VI. Technical Deficiencies:

None.

VII. Related Issues:

In 2010, HB 5603 was vetoed by Governor Crist. That bill would have continued to allow the repackaging and relabeling of drugs, but it would have limited the reimbursement amount to the AWP of the original manufacturer, plus the $4.18 dispensing fee.

VIII. Additional Information:

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

None.

B. Amendments:

Barcode 666350 by Banking and Insurance on January 19, 2012:
The amendment provides that a sick or injured employee is entitled to the choice in the selection of a dispensing practitioner to fill prescriptions for medicines required under

ch. 440, F.S. Current law provides that a sick or injured employee has a choice in the selection of the pharmacy or pharmacist. (WITH TITLE AMENDMENT)

Barcode 115316 by Health Regulation on February 22, 2012:
The amendment prohibits an employer or carrier from refusing to authorize a physician to treat an injured employee solely because the physician is a dispensing practitioner. If a physician who is a dispensing practitioner receives authorization from an employer or carrier to treat a claimant, the physician may dispense and fill prescriptions for medicines under ch. 440, F.S. For purposes of dispensing and filling prescriptions, the department, the employer, or the carrier, or their agents are prohibited from selecting the pharmacy, pharmacist, or dispensing practitioner that the claimant must use.

The amendment repeals the existing statutory paragraph dealing with reimbursement for a prescription medication, which is being amended in the bill, and creates a new subsection dealing with reimbursement for prescription medication, which provides that:

- The reimbursement amount for prescription medication is the average wholesale price plus a $4.18 dispensing fee, unless the provider and the carrier have contracted for a lower reimbursement amount. (Existing statutory language regarding the reimbursement amount in situations where the employee elects to obtain pharmaceuticals and pharmaceutical services from a provider not a party to the contract is not included.)
- If a prescription has been repackaged or relabeled, the provider must give a $15 credit to the insurance carrier or self-insured employer for each prescription that costs more than $25, unless the carrier and provider have contracted for a lower reimbursement amount.
- A physician or the physician's assignee may not hold an ownership interest in a licensed pharmaceutical repackaging entity and may not set a repackaged pharmaceutical average wholesale price.

The amendment provides penalties against insurance carriers or self-insured employers that improperly deny or delay payment of a valid claim for reimbursement of a prescription medication. The amendment also requires an insurance carrier or self-insured employer to clearly state on the face of the final Explanation of Bill Review when the 30-day period for filing a petition for dispute resolution with the department commences.

The amendment requires the Office of Insurance Regulation, effective July 1, 2012, to reduce the rates of workers' compensation and employer liability insurance carriers by 2.5 percent.

The amendment also requires the Office of Insurance Regulation, between the time the bill becomes a law and July 1, 2012, to conduct a retrospective review of any workers' compensation or employer's liability insurance carrier's rate filing during the previous 12 months which resulted in a rate increase. The review must determine whether the rate filing included cost information demonstrating that 2.5 percent of the overall approved rate increase was directly attributable to the costs of repackaging prescription medications. If the office determines that such information was not included in the rate filing, the office must immediately reduce the rates of workers' compensation and

employer liability insurance carriers by 2.5 percent. The office must make its review available to the Legislature by October 1, 2012. (WITH TITLE AMENDMENT)

766998

LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
02/23/2012	.	
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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (a) of subsection (3) and paragraph (c) of subsection (12) of section 440.13, Florida Statutes, are amended, and paragraph (k) is added to subsection (3) of that section, to read:

440.13 Medical services and supplies; penalty for violations; limitations.—

(3) PROVIDER ELIGIBILITY; AUTHORIZATION.—

(a) As a condition for ~~to~~ eligibility for payment under

766998

this chapter, a health care provider who renders services must be a certified health care provider and must receive authorization from the carrier before providing treatment. This paragraph does not apply to emergency care. An employer or a carrier may not refuse to authorize a physician to treat an injured employee solely because the physician is a dispensing practitioner, as defined in s. 465.0276. The department shall adopt rules to implement the certification of health care providers.

(k) If a physician who is a dispensing practitioner as defined in s. 465.0276 receives authorization from an employer or a carrier to treat a claimant pursuant to paragraph (a), the physician may dispense and fill prescriptions for medicines under this chapter. For the purposes of dispensing and filling prescriptions for medicines, the department, the employer or carrier, or an agent or representative of the department, the employer, or the carrier may not select the pharmacy, pharmacist, or dispensing practitioner, as defined in s. 465.0276, that the claimant must use.

(12) CREATION OF THREE-MEMBER PANEL; GUIDES OF MAXIMUM REIMBURSEMENT ALLOWANCES.—

(c) As to reimbursement for a prescription medication, regardless of the location from which or the provider from whom the claimant receives the prescription medication, the reimbursement amount ~~for a prescription~~ shall be the average wholesale price plus $4.18 for the dispensing fee, unless ~~except where~~ the carrier has contracted for a lower amount. If the drug has been repackaged or relabeled, the reimbursement amount is calculated by multiplying the number of units dispensed times

766998

the per-unit average wholesale price set by the original manufacturer of the underlying drug, which may not be the manufacturer of the repackaged or relabeled drug, plus a $4.18 dispensing fee, unless the carrier has contracted for a lower amount. The repackaged or relabeled drug price may not exceed the amount otherwise payable had the drug not been repackaged or relabeled. Fees for pharmaceuticals and pharmaceutical services shall be reimbursable at the applicable fee schedule amount. If ~~Where~~ the employer or carrier has contracted for such services and the employee elects to obtain them through a provider not a party to the contract, the carrier must ~~shall~~ reimburse at the schedule, negotiated, or contract price, whichever is lower. However, if the employee elects to fill a prescription for medicines with a dispensing practitioner as defined in s. 465.0276 who is not a party to such contract, reimbursement shall be at the applicable fee schedule amount. ~~No~~ Such contract may not ~~shall~~ rely on a provider that is not reasonably accessible to the employee.

Section 2. This act shall take effect July 1, 2012.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to workers' compensation; amending s. 440.13, F.S.; authorizing an authorized physician who is also a dispensing physician to dispense and fill prescriptions; prohibiting the Department of Financial Services, an employer, or a carrier from selecting the pharmacy, pharmacist, or dispensing practitioner a claimant must use in certain circumstances; revising requirements for determining the amount of a reimbursement for repackaged or relabeled prescription medication; providing limitations; providing an effective date.

Florida Senate - 2012 COMMITTEE AMENDMENT
Bill No. SB 668

766998

671414

LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
02/23/2012	.	
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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment to Amendment (766998) (with title amendment)

Between lines 59 and 60
insert:
Section 2. Effective July 1, 2012, the Office of Insurance Regulation shall reduce the rates of workers' compensation and employer liability insurance carriers by 2.5 percent.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 76

671414

and insert:
medication; providing limitations; requiring the Office of Insurance Regulation to reduce rates for workers' compensation and employer liability insurance by a specified amount; providing an

279032

LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
02/23/2012	.	
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The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment to Amendment (766998) (with title amendment)

Delete line 60
and insert:
Section 2. Effective upon this act becoming a law and before July 1, 2012, the Office of Insurance Regulation shall conduct a retrospective review of any rate filing submitted by a rating organization on behalf of workers' compensation or employer's liability insurance carriers during the previous 12 months which resulted in a rate increase. The office's review must determine whether the information, data, and documentation

279032

included in the rate filings include cost information demonstrating that 2.5 percent of the overall rate increase that was subsequently approved was directly attributable to the costs of repackaging prescription medications. If the office determines that such documentation or information was not included in the rate filing, the office shall immediately reduce the rates of workers' compensation and employer liability insurance carriers by 2.5 percent. The office shall also make its review available to the Senate and the House of Representatives by October 1, 2012.

Section 3. 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, 2012.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete lines 76 - 77
and insert:
medication; providing limitations; requiring the Office of Insurance Regulation to conduct a retrospective review of certain rate filings to determine if the filings were supported by documentation demonstrating that a certain portion of the approved rate increase was attributable to the costs of repackaging prescription medications and to reduce rates if not so supported; providing effective dates.

409686

LEGISLATIVE ACTION

Senate	.	House
Comm: RE	.	
02/23/2012	.	
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The Committee on Health Regulation (Garcia) recommended the following:

Senate Substitute for Amendment (766998) (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (a) of subsection (3) and paragraph (c) of subsection (12) of section 440.13, Florida Statutes, are amended, paragraph (k) is added to subsection (3), paragraphs (d) and (e) of subsection (12) are redesignated as paragraphs (c) and (d), respectively, present subsections (15) through (17) are renumbered as subsections (16) through (18), respectively, and a new subsection (15) is added to that section, to read:

409686

440.13 Medical services and supplies; penalty for violations; limitations.—

(3) PROVIDER ELIGIBILITY; AUTHORIZATION.—

(a) As a condition for ~~to~~ eligibility for payment under this chapter, a health care provider who renders services must be a certified health care provider and must receive authorization from the carrier before providing treatment. This paragraph does not apply to emergency care. An employer or a carrier may not refuse to authorize a physician to treat an injured employee solely because the physician is a dispensing practitioner, as defined in s. 465.0276. The department shall adopt rules to administer ~~implement~~ the certification of health care providers.

(k) If a physician who is a dispensing practitioner as defined in s. 465.0276 receives authorization from an employer or a carrier to treat a claimant pursuant to paragraph (a), the physician may dispense and fill prescriptions for medicines under this chapter. For purposes of dispensing and filling prescriptions for medicines, the department, employer, or carrier, or an agent or representative of the department, employer, or carrier, may not select the pharmacy, pharmacist, or dispensing practitioner that the claimant must use.

(12) CREATION OF THREE-MEMBER PANEL; GUIDES OF MAXIMUM REIMBURSEMENT ALLOWANCES.—

~~(c) As to reimbursement for a prescription medication, the reimbursement amount for a prescription shall be the average wholesale price plus $4.18 for the dispensing fee, except where the carrier has contracted for a lower amount. Fees for pharmaceuticals and pharmaceutical services shall be~~

409686

~~reimbursable at the applicable fee schedule amount. Where the employer or carrier has contracted for such services and the employee elects to obtain them through a provider not a party to the contract, the carrier shall reimburse at the schedule, negotiated, or contract price, whichever is lower. No such contract shall rely on a provider that is not reasonably accessible to the employee.~~

(15) REIMBURSEMENT FOR PRESCRIPTION MEDICATION.—The reimbursement amount for prescription medication shall be the average wholesale price plus $4.18 for the dispensing fee, unless the carrier and the provider seeking reimbursement have directly contracted with each other for a lower reimbursement amount.

(a) If a prescription has been repackaged or relabeled, the provider shall give a $15 credit to the insurance carrier or self-insured employer for each prescription that costs more than $25. The credit shall be reflected in the Explanation of Bill Review provided by the carrier or employer. The credit does not apply if the carrier and the provider seeking reimbursement have directly contracted with each other for a lower reimbursement amount.

(b) A physician or the physician's assignee may not hold an ownership interest in a licensed pharmaceutical repackaging entity and may not set or cause to be set a repackaged pharmaceutical average wholesale price.

(c) An insurance carrier or self-insured employer that improperly denies or delays payment of a valid claim for reimbursement of a prescription medication is subject to an administrative fine of $250 per instance of improper

409686

reimbursement. If the department determines that a carrier or employer has improperly denied or delayed reimbursement claims more than 15 times in any one calendar year, the administrative penalty increases to $1,000 per instance of improper reimbursement. If the department determines that a carrier or employer has improperly denied or delayed reimbursement claims more than 100 times in any one calendar year, the insurer or employer must show cause to the department as to why its certificate of authority to underwrite workers' compensation insurance should not be revoked or suspended. The penalties in this paragraph are not exclusive and are in addition to remedies provided under part IX of chapter 626.

(d) Pursuant to subsection (7), a provider may challenge a disallowance, denial, or adjustment of payment by filing a petition for dispute resolution with the department within 30 days after receiving the final Explanation of Bill Review issued by the insurance carrier or self-insured employer. The carrier or self-insured employer must clearly state on the face of the final Explanation of Bill Review when the 30-day period for filing a petition for dispute resolution with the department commences.

Section 2. This act shall take effect July 1, 2012.

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to workers' compensation medical

409686

services; amending s. 440.13, F.S.; prohibiting an employer or carrier from refusing to authorize a physician who is a prescribing physician; prohibiting the Department of Financial Services, the employer, or the carrier from selecting a claimant's pharmacy; revising requirements for determining the amount of a reimbursement for prescription medications; prohibiting a physician from having an ownership interest in a pharmacy repackaging entity or setting pharmaceutical wholesale prices; providing penalties for an employer or carrier's improper delay or denial of payment and procedures for a provider to challenge a disallowance, denial, or adjustment of payment; providing an effective date.

433796

LEGISLATIVE ACTION

Senate	.	House
Comm: RE	.	
02/23/2012	.	
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The Committee on Health Regulation (Norman) recommended the following:

Senate Amendment to Amendment (409686)

Delete line 62
and insert:
amount. Any credit to a self-insured employer shall be directly deposited to the self-insurance fund of the entity.

912394

LEGISLATIVE ACTION

Senate	.	House
Comm: RE	.	
02/23/2012	.	
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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment to Amendment (409686) (with title amendment)

Between lines 91 and 92
insert:
Section 2. Effective July 1, 2012, the Office of Insurance Regulation shall reduce the rates of workers' compensation and employer liability insurance carriers by 2.5 percent.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:
Between lines 112 and 113
insert:

912394

requiring the Office of Insurance Regulation to reduce rates for workers' compensation and employer liability insurance by a specified amount;

695294

LEGISLATIVE ACTION

Senate	.	House
Comm: RE	.	
02/23/2012	.	
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The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment to Amendment (409686) (with title amendment)

Delete line 92
and insert:
Section 2. Effective upon this act becoming a law and before July 1, 2012, the Office of Insurance Regulation shall conduct a retrospective review of any rate filing submitted by a rating organization on behalf of workers' compensation or employer's liability insurance carriers during the previous 12 months which resulted in a rate increase. The office's review must determine whether the information, data, and documentation

695294

included in the rate filings include cost information demonstrating that 2.5 percent of the overall rate increase that was subsequently approved was directly attributable to the costs of repackaging prescription medications. If the office determines that such documentation or information was not included in the rate filing, the office shall immediately reduce the rates of workers' compensation and employer liability insurance carriers by 2.5 percent. The office shall also make its review available to the Senate and the House of Representatives by October 1, 2012.

Section 3. 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, 2012.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 113
and insert:
requiring the Office of Insurance Regulation to conduct a retrospective review of certain rate filings to determine if the filings were supported by documentation demonstrating that a certain portion of the approved rate increase was attributable to the costs of repackaging prescription medications and to reduce rates if not so supported; providing effective dates.

115316

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
02/23/2012	.	
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The Committee on Health Regulation (Garcia) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (a) of subsection (3) and paragraph (c) of subsection (12) of section 440.13, Florida Statutes, are amended, paragraph (k) is added to subsection (3), paragraphs (d) and (e) of subsection (12) are redesignated as paragraphs (c) and (d), respectively, present subsections (15) through (17) are renumbered as subsections (16) through (18), respectively, and a new subsection (15) is added to that section, to read:

440.13 Medical services and supplies; penalty for violations; limitations.—

(3) PROVIDER ELIGIBILITY; AUTHORIZATION.—

(a) As a condition for ~~to~~ eligibility for payment under this chapter, a health care provider who renders services must be a certified health care provider and must receive authorization from the carrier before providing treatment. This paragraph does not apply to emergency care. An employer or a carrier may not refuse to authorize a physician to treat an injured employee solely because the physician is a dispensing practitioner, as defined in s. 465.0276. The department shall adopt rules to administer ~~implement~~ the certification of health care providers.

(k) If a physician who is a dispensing practitioner as defined in s. 465.0276 receives authorization from an employer or a carrier to treat a claimant pursuant to paragraph (a), the physician may dispense and fill prescriptions for medicines under this chapter. For purposes of dispensing and filling prescriptions for medicines, the department, employer, or carrier, or an agent or representative of the department, employer, or carrier, may not select the pharmacy, pharmacist, or dispensing practitioner that the claimant must use.

(12) CREATION OF THREE-MEMBER PANEL; GUIDES OF MAXIMUM REIMBURSEMENT ALLOWANCES.—

~~(c) As to reimbursement for a prescription medication, the reimbursement amount for a prescription shall be the average wholesale price plus $4.18 for the dispensing fee, except where the carrier has contracted for a lower amount. Fees for pharmaceuticals and pharmaceutical services shall be reimbursable at the applicable fee schedule amount. Where the~~

115316

~~employer or carrier has contracted for such services and the employee elects to obtain them through a provider not a party to the contract, the carrier shall reimburse at the schedule, negotiated, or contract price, whichever is lower. No such contract shall rely on a provider that is not reasonably accessible to the employee.~~

(15) REIMBURSEMENT FOR PRESCRIPTION MEDICATION.—The reimbursement amount for prescription medication shall be the average wholesale price plus $4.18 for the dispensing fee, unless the carrier and the provider seeking reimbursement have directly contracted with each other for a lower reimbursement amount.

(a) If a prescription has been repackaged or relabeled, the provider shall give a $15 credit to the insurance carrier or self-insured employer for each prescription that costs more than $25. The credit shall be reflected in the Explanation of Bill Review provided by the carrier or employer. The credit does not apply if the carrier and the provider seeking reimbursement have directly contracted with each other for a lower reimbursement amount. Any credit to a self-insured employer shall be directly deposited to the self-insurance fund of the entity.

(b) A physician or the physician's assignee may not hold an ownership interest in a licensed pharmaceutical repackaging entity and may not set or cause to be set a repackaged pharmaceutical average wholesale price.

(c) An insurance carrier or self-insured employer that improperly denies or delays payment of a valid claim for reimbursement of a prescription medication is subject to an administrative fine of $250 per instance of improper

115316

reimbursement. If the department determines that a carrier or employer has improperly denied or delayed reimbursement claims more than 15 times in any one calendar year, the administrative penalty increases to $1,000 per instance of improper reimbursement. If the department determines that a carrier or employer has improperly denied or delayed reimbursement claims more than 100 times in any one calendar year, the insurer or employer must show cause to the department as to why its certificate of authority to underwrite workers' compensation insurance should not be revoked or suspended. The penalties in this paragraph are not exclusive and are in addition to remedies provided under part IX of chapter 626.

(d) Pursuant to subsection (7), a provider may challenge a disallowance, denial, or adjustment of payment by filing a petition for dispute resolution with the department within 30 days after receiving the final Explanation of Bill Review issued by the insurance carrier or self-insured employer. The carrier or self-insured employer must clearly state on the face of the final Explanation of Bill Review when the 30-day period for filing a petition for dispute resolution with the department commences.

Section 2. Effective July 1, 2012, the Office of Insurance Regulation shall reduce the rates of workers' compensation and employer liability insurance carriers by 2.5 percent.

Section 3. Effective upon this act becoming a law and before July 1, 2012, the Office of Insurance Regulation shall conduct a retrospective review of any rate filing submitted by a rating organization on behalf of workers' compensation or employer's liability insurance carriers during the previous 12

115316

months which resulted in a rate increase. The office's review must determine whether the information, data, and documentation included in the rate filings include cost information demonstrating that 2.5 percent of the overall rate increase that was subsequently approved was directly attributable to the costs of repackaging prescription medications. If the office determines that such documentation or information was not included in the rate filing, the office shall immediately reduce the rates of workers' compensation and employer liability insurance carriers by 2.5 percent. The office shall also make its review available to the Senate and the House of Representatives by October 1, 2012.

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, 2012.

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to workers' compensation medical services; amending s. 440.13, F.S.; prohibiting an employer or carrier from refusing to authorize a physician who is a prescribing physician; prohibiting the Department of Financial Services, the employer, or the carrier from selecting a claimant's pharmacy; revising requirements for determining the amount of a

115316

reimbursement for prescription medications; prohibiting a physician from having an ownership interest in a pharmacy repackaging entity or setting pharmaceutical wholesale prices; providing penalties for an employer or carrier's improper delay or denial of payment and procedures for a provider to challenge a disallowance, denial, or adjustment of payment; requiring the Office of Insurance Regulation to reduce rates for workers' compensation and employer liability insurance by a specified amount; requiring the Office of Insurance Regulation to conduct a retrospective review of certain rate filings to determine if the filings were supported by documentation demonstrating that a certain portion of the approved rate increase was attributable to the costs of repackaging prescription medications and to reduce rates if not so supported; providing effective dates.

928020

LEGISLATIVE ACTION

Senate . House

. . . . . .

The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment (with title amendment)

Delete line 39
and insert:
Section 2. Effective upon this act becoming a law and before July 1, 2012, the Department of Financial Services shall conduct a retrospective review of any rate filing submitted by a rating organization on behalf of workers' compensation or employer's liability insurance carriers during the previous 12 months which resulted in a rate increase. The department's review must determine whether the information, data, and documentation included in the rate filings includes cost

928020

information demonstrating that 2.5 percent of the overall rate increase that was subsequently approved was directly attributable to the costs of repackaging prescription medications. If the department determines that such documentation or information was not included in the rate filing, the department shall report such information to the Office of Insurance Regulation. The office shall immediately reduce the rates of workers' compensation and employer liability insurance carriers by 2.5 percent. The department shall also make its review available to the Senate and the House of Representatives by October 1, 2012.

Section 3. 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, 2012.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete lines 6 - 7
and insert:
medication; providing limitations; requiring the Department of Financial Services to conduct a retrospective review of certain rate filings to determine if the filings were supported by documentation demonstrating that a certain portion of the approved rate increase was attributable to the costs of repackaging prescription medications; providing effective dates.

By Senator Hays

20-00558-12 2012668__

A bill to be entitled

An act relating to workers' compensation medical services; amending s. 440.13, F.S.; revising requirements for determining the amount of a reimbursement for repackaged or relabeled prescription medication; providing limitations; providing an effective date.

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

Section 1. Paragraph (c) of subsection (12) of section 440.13, Florida Statutes, is amended to read:

440.13 Medical services and supplies; penalty for violations; limitations.—

(12) CREATION OF THREE-MEMBER PANEL; GUIDES OF MAXIMUM REIMBURSEMENT ALLOWANCES.—

(c) As to reimbursement for a prescription medication, regardless of the location or provider from whom the claimant receives the prescription medication, the reimbursement amount ~~for a prescription~~ shall be the average wholesale price plus $4.18 for the dispensing fee, unless ~~except where~~ the carrier has contracted for a lower amount. If the drug has been repackaged or relabeled, the reimbursement amount shall be calculated by multiplying the number of units dispensed times the per-unit average wholesale price set by the original manufacturer of the underlying drug, which may not be the manufacturer of the repackaged or relabeled drug, plus a $4.18 dispensing fee, unless the carrier has contracted for a lower amount. The repackaged or relabeled drug price may not exceed

20-00558-12 2012668__

the amount otherwise payable if the drug had not been repackaged or relabeled. Fees for pharmaceuticals and pharmaceutical services shall be reimbursable at the applicable fee schedule amount. If ~~Where~~ the employer or carrier has contracted for such services and the employee elects to obtain them through a provider not a party to the contract, the carrier shall reimburse at the schedule, negotiated, or contract price, whichever is lower. ~~No~~ Such contract may not ~~shall~~ rely on a provider that is not reasonably accessible to the employee.

Section 2. This act shall take effect July 1, 2012.

666350

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
01/19/2012	.	
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The Committee on Banking and Insurance (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete lines 11 - 14
and insert:
Section 1. Paragraph (j) of subsection (3) and paragraph (c) of subsection (12) of section 440.13, Florida Statutes, are amended to read:
440.13 Medical services and supplies; penalty for violations; limitations.—
(3) PROVIDER ELIGIBILITY; AUTHORIZATION.—
(j) Notwithstanding any other provision of ~~anything in~~ this chapter ~~to the contrary~~, a sick or injured employee is ~~shall be~~

666350

entitled, at all times, to free, full, and absolute choice in the selection of the pharmacy, ~~or~~ pharmacist, or dispensing practitioner to dispense and fill ~~dispensing and filling~~ prescriptions for medicines required under this chapter. ~~It is expressly forbidden for~~ The department, an employer, or a carrier, or any agent or representative of the department, an employer, or a carrier, may not ~~to~~ select the pharmacy, ~~or~~ pharmacist, or dispensing practitioner that ~~which~~ the sick or injured employee must use; condition coverage or payment on the basis of the pharmacy, ~~or~~ pharmacist, or dispensing practitioner used ~~utilized~~; or to otherwise interfere in the selection by the sick or injured employee of a pharmacy, ~~or~~ pharmacist, or dispensing practitioner.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 3
and insert:
services; amending s. 440.13, F.S.; providing that a sick or injured employee is free to select a dispensing practitioner to fill prescriptions as well as a pharmacy or pharmacist; revising

NCCI Comments Regarding Garcia Amendment # 409686 to SB 668

- Currently, carriers and self-insured employers apply negotiated discounts from the fee schedule (AWP +$4.18) to any provider seeking reimbursement for dispensing drugs. Deletion of the language allowing reimbursement at contract prices to providers not a party to the contract (lines 42-46) and a new requirement for privity of contract between the carrier and provider (lines 52-54) eliminates one of the ways in which carriers and self-insured employers currently control total drug costs. This language impacts payments for drugs dispensed out of a pharmacy as well as dispensed out of a physician's office. This is further exacerbated by the fact that carriers and self-insured employers may not select the pharmacy, pharmacist, or dispensing practitioner. As a result, this would put upward pressure on rates because carriers and self-insured employers would have to pay at the fee schedule for drugs dispensed from providers where there is no contract. This may be mitigated somewhat in the long run to the extent that carriers and self-insured employers are able to put contracts in place with providers. If we assume the average contract discount for drugs is 20%, and the average contract discount goes to 10%, this is an increase in total drug costs of +12.5% {= [(1- 0.10)/(1-0.20)-1] x 100}. Since drug cost represents 16% of medical and medical represent 68.3% of overall benefit costs, this is a 2% (= 12.5% x 0.16) increase in medical or **a 1.4% increase in overall costs (= 2.0% x .683)**.

- The $15 credit is not going to make a difference in the calculation of workers compensation rates because there is no control on the markup of repackaged drugs, or in other words, the final charged amount. As long as the AWP language is not limited to original manufacturer's AWP, then repackagers can simply generate a higher AWP, or in other words, raise the final charged amount, to cover the cost of the credit or more than cover the cost of the credit. So NCCI would not attribute any savings to the credit language and would expect continued upward pressure on workers compensation rates to the extent that more doctors begin dispensing repackaged drugs in Florida and to the extent that the AWP's for repackaged drugs increase, or in other words, the final charged amounts for repackaged drugs increase.

- The penalties in lines 67-82 appear to be in conflict with the following sections of current law which apply to payments to providers for pharmaceuticals:

  - S. 440.20(6)(b) sets out the performance standard for timely payment of medical bills including pharmaceutical bills. The carrier must either pay, disallow, or deny within 45 days of receipt of the medical bill. 95% compliance is required. A carrier falling below the 95% standard is fined $25 for each untimely bill and if the carrier falls below 90% compliance, the carrier is charged $50 for each untimely bill. In contrast, the Garcia amendment has for pharmaceutical bills only effectively a 100% compliance threshold and fines of $250-$1000 per instance. The 2011 annual report of the Division of Workers Compensation shows that 98% of medical bills are timely paid and that this statistic has ranged from 98% to 99% for each of the last four fiscal years.
  - S. 440.13(7)(f) provides penalties for a carrier that engages in a pattern or practice of arbitrarily or unreasonably disallowing or reducing payments to health care providers.
  - S. 440.525 also gives the Division the authority to issue willful and non-willful penalties for patterns or practices related to timeliness and accuracy of payments under S. 440.13 etc.

  The Garcia amendment states that the penalties in lines 67-82 are in addition to penalties in Chapter 626 but the amendment does not reference the above sections in Chapter 440. As a result, it is unclear whether the penalties in lines 67-82 or the penalties in the above sections in Chapter 440 would apply to payments to providers for pharmaceuticals.

- Penalties are excluded from ratemaking but assuming the more severe penalty language in the Garcia amendment described above would apply to the payment of pharmaceutical bills in the future, it will likely cause a change in behavior in carriers that will put upward pressure on workers compensation rates. Even though not all bills for reimbursement of pharmaceuticals are likely to be valid, it is probable that carriers will be less likely to challenge such bills in order to avoid penalties, particularly given the increased severity of the penalties in lines 67-82 relative to other sections of Chapter 440. If carriers do not challenge questionable bills, then bills that perhaps should not be paid will get paid increasing system costs. This expected change in carrier behavior will put upward pressure on workers compensation rates, however, NCCI is not able to attribute a number to this behavioral change.

All in all, we would price this amendment as an increase on Florida workers compensation system costs of at least +1.4%. The other impacts would be expected to flow through the data and be reflected in future workers compensation rate filings. Please note that if this amendment becomes the bill, then the impact of the bill is at least +1.4% and if passed, workers compensation rates would be increased by 1.4%. The +1.4% associated with this amendment is not an offset to the estimated savings of 2.5% associated with other versions of the bill.

Lori Lovgren/NCCI
561-893-3337
Lori_Lovgren@ncci.com

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke ✓

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/2012
Meeting Date

Topic Workers Compensation — Bill Number SB 668 *(if applicable)*

Name Tammy Perdue — Amendment Barcode 706998 *(if applicable)*

Job Title General Counsel

Address 516 N. Adams St *Street* — Phone 850-224-7173

Tallahassee *City* FL *State* 32301 *Zip* — E-mail tperdue@aif.com

Speaking: ☐ For ☑ Against Amendment ☐ Information

Representing Associated Industries of Florida

Appearing at request of Chair: ☐ Yes ☑ No — Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke ✓

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

Topic SB 668 Drug Repackaging

Bill Number 668 *(if applicable)*

Name LORI LOVGREN

Amendment Barcode *(if applicable)*

Job Title State Relations Exec

Address 901 Peninsula Corporate Circle *Street*

Boca Raton FL 33487 *City State Zip*

Phone 5612518333

E-mail LORI_LOVGREN @NCCI.com

Speaking: ☐ For ☐ Against ☒ Information

Representing NCCI

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke ✓

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-22-12

Meeting Date

Topic Workers Comp

Bill Number 668 *(if applicable)*

Name Tom Panza

Amendment Barcode *(if applicable)*

Job Title

Address 3600 North Federal Highway *Street*

Fort Lauderdale, FL 33308 *City State Zip*

Phone (954) 390-0100

E-mail tpanza@panzamaurer.com

Speaking: ☑ For ☐ Against ☐ Information

Garcia & Fasano Amendments

Representing Automated Health Care Solutions

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke ✓

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-22-12
Meeting Date

Topic Workers Comp
Bill Number 668 *(if applicable)*

Name Dr. Gary Kelman
Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 350 North Pine Island Road *Street*
Phone (954) 476-8800

Plantation, FL 33324 *City State Zip*
E-mail kelmang@aol.com

Speaking: ☒ For ☐ Against ☐ Information ✗ Garcia + Fasano amendments

Representing self

Appearing at request of Chair: ☐ Yes ☒ No
Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/20/11)

Spoke on Garcia amend.

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22
Meeting Date

Topic _____
Bill Number 668 *(if applicable)*

Name Gerald C Wester
Amendment Barcode 912394 *(if applicable)*

Job Title _____

Address 101 E College Av *Street*
Phone 850 222 9075

Tallahassee FL 32301 *City State Zip*
E-mail [redacted]

Amendment # 912394
Speaking: ☐ For ☒ Against ☐ Information

Representing American Insurance Association

Appearing at request of Chair: ☐ Yes ☒ No
Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke Garcia Amend

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Workers Comp — Bill Number 668 *(if applicable)*

Name Sally West — Amendment Barcode _____ *(if applicable)*

Job Title Director, Government Affairs

Address _____ *Street* — Phone 850-222-4082

_____ *City* _____ *State* _____ *Zip* — E-mail sally@frf.org

Speaking: [X] For [X] Against [ ] Information

Representing Florida Retail Federation

Appearing at request of Chair: [ ] Yes [X] No — Lobbyist registered with Legislature: [X] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/20/11)

Spoke on Garcia amendment

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Workers Comp/Drug Regulations — Bill Number SB 668 *(if applicable)*

Name Jim Snyder — Amendment Barcode 766998 *(if applicable)*

Job Title Public Policy Associates, Inc

Address PO Box 10615 *Street* — Phone 850-224-2777

Tallahassee *City* FL *State* 32302 *Zip* — E-mail jsnyder@publicpolicyassociates.com

Speaking: [ ] For [X] Against Amendment 766998 [ ] Information

Representing American Fire Sprinkler Assoc + FL Fire Equipment Dealers Assoc

Appearing at request of Chair: [ ] Yes [ ] No — Lobbyist registered with Legislature: [X] Yes [ ] No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke ✓

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

Topic _____ Bill Number 0668 *(if applicable)*

Name Gary Guzzo Amendment Barcode ~~962394~~ 912394 *(if applicable)*

Job Title Lobbyist

Address 108 S. Monroe St Suite 200 Phone _____
Street

Tallahassee, Fla 32301 E-mail ggguzzo@flapartners.com
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

Representing Florida Insurance Council

Appearing at request of Chair: ☐ Yes ☒ No Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

2-22-12

Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Topic Worker's Comp Bill Number 668 *(if applicable)*

Name Monte Stevens Amendment Barcode _____ *(if applicable)*

Job Title Dir. of Government Affairs

Address 200 E. Gaines St. Phone 413-2571
Street

Tally FL E-mail monte.stevens@floir.com
City *State* *Zip*

Speaking: ☑ For ☐ Against ☑ Information

Representing Office of Insurance Regulation

Appearing at request of Chair: ☐ Yes ☒ No Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-22-12
Meeting Date

Topic Workers Comp Bill Number 668 *(if applicable)*

Name Tom Panza Amendment Barcode *(if applicable)*

Job Title

Address 3600 North Federal Highway *Street* Phone (954)390-0100

Fort Lauderdale, FL 33308 *City State Zip* E-mail tpanza@panzamaurer.com

Speaking: ☐ For ☒ Against ☐ Information

Representing Automated Health Care Solutions

Appearing at request of Chair: ☐ Yes ☒ No Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-22-12
Meeting Date

Topic Workers Comp Bill Number 668 *(if applicable)*

Name Dr. Gary Kelman Amendment Barcode *(if applicable)*

Job Title

Address 350 North Pine Island Road *Street* Phone (954)476-8800

Plantation, FL 33324 *City State Zip* E-mail kelmang@aausa.com.

Speaking: ☐ For ☒ Against ☐ Information

Representing Self

Appearing at request of Chair: ☐ Yes ☒ No Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-22-12
Meeting Date

Topic Work Comp

Bill Number 68 *(if applicable)*

Name Steve Johnson

Amendment Barcode *(if applicable)*

Job Title Citrus Harvester

Address P.O. Box 277 *Street*

Phone 863-773-3026

Wauchula, FL 33873 *City State Zip*

E-mail sjohnson@johnsonharvest.com

Speaking: [X] For [ ] Against [ ] Information

Representing Business People of Hardee County

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [ ] Yes [X] No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-22-2012
Meeting Date

Topic SB 1668 - Workers Comp Drug Repeal

Bill Number 1688 *(if applicable)*

Name Steven Southwell

Amendment Barcode *(if applicable)*

Job Title Attorney

Address 502 W Main Street *Street*

Phone 863 773 4449

Wauchula Florida 33873 *City State Zip*

E-mail SSouthwell@morrellpa.com

Speaking: [X] For [ ] Against [ ] Information

Representing

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [ ] Yes [X] No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Workers Comp

Bill Number 668 *(if applicable)*

Name Mike Hill

Amendment Barcode *(if applicable)*

Job Title NFIB Leadership Council Member

Address 611 New Warrington Rd.
Street
Pensacola Fl. 32506
City *State* *Zip*

Phone 850-456 2886

E-mail mikehill0602@cox.net

Speaking: ☑ For ☐ Against ☐ Information

Representing National Federation of Independent Business

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/20/11)

Spoke

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Workers Comp

Bill Number 668 *(if applicable)*

Name Pablo Diaz

Amendment Barcode *(if applicable)*

Job Title Legislative Director

Address 110 E. Jefferson St.
Street
Tallahassee Fl. 32301
City *State* *Zip*

Phone 850-681-0184

E-mail pablo.diaz@nfib.org

Speaking: ☑ For ☐ Against ☐ Information

Representing National Federation of Independent Business

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Repackaging

Bill Number 668 *(if applicable)*

Name Rebecca O'Hara

Amendment Barcode 766998 (Gaetz) *(if applicable)*

Job Title VP Govt Affairs

Address 113 E College Ave
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 339 6211

E-mail rohara@flmedical.org

Speaking: [X] For [ ] Against [ ] Information

Representing Fla Medical Association

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [X] Yes [ ] No

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S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: CS/SB 1006

INTRODUCER: Health Regulation Committee and Senator Latvala

SUBJECT: Health Care

DATE: February 24, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Fav/CS**
2.			CM	
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill requires licensed hospitals and birth centers that provide maternity and newborn care to screen all newborns, prior to discharge, for Critical Congenital Heart Disease (CCHD). For home births, the health care provider in attendance is responsible for the screening. A parent or legal guardian may object to the screening, in which case the screening must not be completed. The bill defines "screening" and requires hospitals and birth centers to designate certain licensed practitioners to be responsible for programmatic oversight of the screening and to ensure that appropriate referrals are completed.

The bill modifies several definitions used in part I of chapter 499, F.S., the Florida Drug and Cosmetic Act (the Act), and organizes various exceptions to the permit requirements into a single subsection. It eases existing restrictions on the limited distribution of active pharmaceutical ingredients to Florida permitted prescription drug manufacturers and restrictions on prescription drug distributions to permitted prescription drug manufacturers and researchers.

The bill authorizes dentists to purchase prescription drugs through a professional corporation or limited liability company composed of dentists and still be exempt from the requirement to obtain a health care clinic establishment permit. The bill provides an exemption from the prescription drug repackager permit requirement and the product registration requirements for a restricted prescription drug distributor permitholder that is a health care entity that repackages prescription drugs in this state for its own use or distributes prescription drugs to a hospital or other health care entity in the state for its own use if it meets certain conditions.

This bill substantially amends the following sections of the Florida Statutes: 499.003 and 499.01. The bill creates s. 383.146, F.S.

II. Present Situation:

Congenital Heart Disease

Congenital Heart Disease (CHD) is a term that embraces a variety of defects that are present in the structure of the heart at birth. These congenital defects change the normal flow of blood through the heart, leading to a range of conditions and symptoms. CHD affects about 7 to 9 of every 1,000 live births in the United States and Europe and is the most common cause of death in the first year of life, with defects accounting for 3 percent of all infant deaths and more than 40 percent of all deaths due to congenital malformations.[1]

Current methods for detecting CHD generally include prenatal ultrasound screening and careful and repeated clinical examinations, both in the hospital nursery and as part of routine well-child care. CHD is often missed by hospital discharge and post-discharge clinical exams of infants. Pulse oximetry screening can identify some newborns with CHD. A pulse oximeter is a medical device that measures the percentage of hemoglobin in the blood that is saturated with oxygen. The device indirectly monitors the oxygen saturation of a patient's blood without the need to take a blood sample. It is estimated that one quarter of congenital heart defects could be detected and potentially treated by measuring blood oxygen saturation.[2]

Neonates with abnormal pulse oximetry screening results need confirmatory testing for the cause of the low oxygen saturation, and immediate intervention, often involving a surgical procedure. Any infant with a positive screen should have a diagnostic echocardiogram. The infant's pediatrician should be notified immediately and the infant might need to be seen by a cardiologist for follow-up.[3]

---

[1] Letter dated October 15, 2010, to The Honorable Kathleen Sebelius, Secretary of Health and Human Services, from R. Rodney Howell, M.D., Chairperson of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. Found at: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/criticalcongenital.pdf> (Last visited on January 23, 2012).

[2] Letter dated September 21, 2011, to R. Rodney Howell, M.D., Chairperson of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, from The Honorable Kathleen Sebelius, Secretary of Health and Human Services. Found at: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/cyanoticheartsecre09212011.pdf> (Last visited on January 23, 2012).

[3] *Pulse Oximetry Screening for Critical Congenital Heart Defects*, Centers for Disease Control and Prevention. Found at: <http://www.cdc.gov/ncbddd/pediatricgenetics/pulse.html> (Last visited on January 23, 2012).

Newborn Screening

All babies born in the United States are checked for certain medical conditions soon after birth. This is called newborn screening. Over 4 million infants are screened each year. Newborn screening identifies conditions that can affect a child's long-term health or survival. Early detection, diagnosis, and intervention can prevent death or disability and enable children to reach their full potential. All babies are screened, even if they look healthy, because some medical conditions cannot be seen by just looking at the baby. Each state runs its own newborn screening program.

Newborn screening usually takes place before a newborn leaves the hospital. Most tests use a few drops of blood from pricking the baby's heel. The blood specimen is placed on a special filter paper and, in Florida, the specimen card is sent to the Department of Health (DOH) Newborn Screening Laboratory in Jacksonville for testing. The laboratory receives about 250,000 specimens annually from babies born in Florida. The majority of the test results are reported within 24-48 hours. The DOH Children's Medical Services program provides the follow-up for all abnormal screening results.

Section 383.14, F.S., requires the Florida DOH to promote the screening of all newborns born in Florida for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, *as screening programs accepted by current medical practice become available and practical in the judgment of the department*.

Most states screen for a standard number of conditions, but some states may screen for more conditions. Florida currently screens for 35 disorders, including hearing impairment, but does not screen for CHD.[4] The National Newborn Screening and Genetics Resource Center provides a current list of conditions included in each state's newborn screening program. As of December 19, 2011, only one state (New Jersey) requires screening of all newborns for CHD, but the requirement has not yet been implemented.[5]

Adding Conditions to Required Screening

The DOH is required, after consultation with the Genetics and Newborn Screening Advisory Council, to adopt rules requiring every newborn in this state, prior to becoming 1 week of age, to be subjected to a test for phenylketonuria and, at the appropriate age, to be tested for other metabolic diseases and hereditary or congenital disorders *as the department deems necessary*.[6]

At the national level, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children advises the Secretary, U.S. Department of Health and Human Services, on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards. The advisory committee recommends conditions that should be added to the Recommended Uniform Screening Panel.

[4] *See* Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 1052 – on file with the Senate Health Regulation Committee.
[5] National Newborn Screening Status Report, updated 11/21/11. Found at: <http://genes-r-us.uthscsa.edu/nbsdisorders.pdf> (Last visited on January 23, 2012).
[6] s. 383.14(2), F.S.

On September 17, 2010, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children recommended that Critical Congenital *Cyanotic* Heart Disease be added to the Recommended Uniform Screening Panel.[7] Secretary Sebelius accepted the committee's recommendation on September 21, 2011, and Critical CHD screening was added to the Recommended Uniform Screening Panel as a core condition.[8]

On January 20, 2012, the Florida Genetics and Newborn Screening Advisory Council recommended that CHD be added to the panel of disorders screened in the Florida Newborn Screening Program.

Hospital, Birth Center, and Home Deliveries

In 2010 there were 214,519 resident live births in Florida.[9] Of these births, 211,485 (98.6 percent) occurred in hospitals and physicians attended 88.5 percent of the hospital births.[10] Midwives attended 10.9 percent of live births in hospitals. Birth centers accounted for 1,377 births (0.64 percent of live births) and midwives attended 96.9 percent of birth center births. Physicians attended 2.8 percent of birth center births. In 2010, there were 1,508 births in an identified place other than a hospital or birth center and 149 births where the place of delivery was unknown.[11]

Hospitals are licensed and regulated under ch. 395, F.S., and part II of ch. 408, F.S. Birth centers are licensed and regulated under ss. 383.30-383.335, F.S., and part II of ch. 408, F.S. There are 23 licensed birth centers in Florida.

Health Insurance

Section 627.6416, F.S., requires individual health insurance policies that provide coverage on an expense-incurred basis, which provide coverage for a member of a family of the insured or subscriber, to include, for children, coverage for child health supervision services. These services are covered from the moment of birth to age 16 years. The term "child health supervision services" means physician-delivered or physician-supervised services that include, at a minimum, periodic visits including a history, a physical examination, a developmental assessment and anticipatory guidance, and appropriate immunizations and laboratory tests. These services must be provided in accordance with prevailing medical standards consistent with the Recommendations for Preventive Pediatric Health Care of the American Academy of Pediatrics. The recommendations currently include newborn metabolic and hemoglobin screening.

The same child health supervision requirements applicable to individual health insurance policies are also applied to group, blanket, and franchise health insurance policies under s. 627.6579, F.S., and to health maintenance organization contracts under s. 641.31(30), F.S.

[7] Supra, fn 1.
[8] Supra, fn 2.
[9] Department of Health, *2010 Florida Vital Statistics Annual Report – Live Births*. Found at: <http://www.flpublichealth.com/VSBOOK/pdf/2010/Births.pdf> (Last visited on January 23, 2012).
[10] *Id.*
[11] *Id.*

Insurance Mandates

Pursuant to s. 624.215, F.S., every person or organization seeking consideration of a legislative proposal which would mandate a health coverage or the offering of a health coverage by an insurance carrier, health care service contractor, or health maintenance organization as a component of individual or group policies, must submit to the Agency for Health Care Administration (Agency) and the legislative committee having jurisdiction a report which assesses the social and financial impacts of the proposed coverage.

Medicaid

Medicaid is the medical assistance program that provides access to health care for low-income families and individuals. Medicaid also assists aged and disabled people with the costs of nursing facility care and other medical expenses. The Agency is responsible for Medicaid. Medicaid serves approximately 3.19 million people in Florida, with over half of those being children and adolescents 20 years of age or younger. Estimated Medicaid expenditures for FY 2011-2012 are approximately $20.3 billion.

The total number of live births paid for by Medicaid through fee for service and health maintenance organizations during FY 2010-2011 was 130,989.[12]

Under s. 383.145(3)(j), F.S., which establishes the requirements for newborn and infant hearing screening, the Medicaid program must cover the initial procedure for screening the hearing of newborns or infants and any medically necessary follow-up reevaluations leading to diagnosis. These services are reimbursable under Medicaid as an expense compensated supplemental to the per diem rate for Medicaid patients enrolled in MediPass or Medicaid patients covered by a fee for service program. For Medicaid patients who are enrolled in a health maintenance organization, Medicaid must reimburse providers directly at the Medicaid rate. These services may not be considered a covered service for the purposes of establishing the payment rate for Medicaid health maintenance organizations. Nonhospital-based providers are eligible to bill Medicaid for the professional and technical component of each procedure code.

Medicaid pays hospitals a per diem rate for hospital inpatient services based on hospital cost reports. Cost reports are submitted annually and rates are adjusted as appropriate. Standard testing of a patient's vital signs is included in the per diem rate regardless of the Medicaid recipient's age. Measuring blood oxygen saturation using pulse oximetry is considered a standard part of testing a patient's vital signs. A separate screening for newborns for congenital heart disease is not currently reimbursed by Medicaid other than as a part of the hospital per diem rate. Medicaid currently does not reimburse separately for the screening of newborns for congenital heart disease in any other setting either.

[12] See Agency for Health Care Administration 2012 Bill Analysis and Economic Impact Statement for SB 1052 – on file with the Senate Health Regulation Committee.

Florida Drug and Cosmetic Act

One purpose of the Act is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. Another purpose of the Act is to promote uniformity between state and federal laws and their administration and enforcement, throughout the United States.

In 2003, the Legislature enacted the Prescription Drug Protection Act,[13]which put in place additional safeguards for the distribution of prescription drugs in, into, and from this state. This legislation was predicated on the findings and recommendations of the report of the Seventeenth Statewide Grand Jury in its First Interim Report to the Legislature.[14] That grand jury was called to examine, among other matters, the safety of prescription drugs in Florida. In particular, they examined the situation concerning the sale and re-sale of prescription drugs in the wholesale market.

Section 499.003, F.S., defines terms that are used in the Act. The bill amends the following terms in s. 499.003, F.S.: "distribute" or "distribution," "drug," "establishment," "prescription drug," and "wholesale distribution."

Section 499.01, F.S., requires a variety of manufacturers, distributors, and other business entities involved in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics to obtain a permit prior to operating. Permits that are addressed in the bill include:

- *Nonresident prescription drug manufacturer permit*, which 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;
- *Out-of-state prescription drug wholesale distributor permit*, which is required for a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state; and
- *Health care clinic establishment permit*, which is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number.

Section 499.012(8), F.S., sets forth the application requirements for an out-of-state prescription drug wholesale distributor. Generally, the applicant must identify the business (name and trade names, address, and telephone number); and provide information about the ownership, operations and affiliated groups,[15] including the name and address of each shareholder of a corporation that owns 5 percent or more of the corporation; a background statement and

[13] *See* ch. 2003-155, L.O.F.
[14] The report is available at: <http://myfloridalegal.com/pages.nsf/Main/09558F82389E020785256CDA006DB01A> (Last visited on February 6, 2012).
[15] "Affiliated group" is defined in s. 499.003(2), F.S., to mean an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.

fingerprint card for affiliated persons;[16] the estimated or actual annual dollar volume of certain activities pertaining to prescription drugs by the applicant; a copy of the deed or lease for the business property; a list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or posses prescription drugs; and documentation of the credentialing policies and procedures for customers if the applicant intends to sell Schedule II or Schedule III controlled substances to physicians in Florida.[17]

Effective October 1, 2011, all of the statutory powers, duties, and functions, records, personnel, property, and unexpended balances of appropriations, allocations, or other funds for the administration of ch. 499, F.S., relating to drugs, devices, cosmetics, and household products were transferred from the Department of Health to the Department of Business and Professional Regulation (DBPR).[18]

III. Effect of Proposed Changes:

Section 1 creates s. 383.146, F.S., to require each licensed hospital and birth center that provides maternity and newborn care services to screen all newborns, prior to discharge, for CCHD. This requirement must be implemented by October 1, 2012. For home births, the health care provider in attendance is responsible for the screening. The bill defines screening to mean measuring blood oxygen saturation using pulse oximetry to determine whether the newborn needs additional diagnostic evaluation for CCHD.

A parent or legal guardian may object to the screening by providing a signed written objection, in which case the screening must not be completed. The physician, midwife, or other person who is attending the newborn is required to maintain a record that the screening has not been performed and attach the written objection.

Appropriate documentation of the screening completion, results, interpretation, and recommendations must be placed in the medical record within 24 hours after completion of the screening procedure.

The bill requires each hospital to formally designate a lead physician to be responsible for programmatic oversight of the newborn CCHD screening and to ensure that the appropriate referrals are being completed following a positive screening test result. The bill requires each birth center to designate a licensed health care provider to be responsible for programmatic oversight and to ensure that the appropriate referrals are being completed.

The DOH is provided with specific rulemaking authority. The bill requires the department to administer and provide services pursuant to this newly created section of law and specifically to:

[16] "Affiliated party" is defined in s. 499.003(3), F.S. In summary, it means a director, officer, trustee, partner, or committee member or a subsidiary or service corporation of the permittee or applicant; a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant; and the five largest natural shareholders that own at least five percent of the permittee or applicant.
[17] The specific application requirement is for documentation of the credentialing policies and procedures requirements by s. 499.0121(14), F.S., However, that subsection addresses reporting requirements. Subsection (15) addresses credentialing requirements for physician-customers for certain controlled substances.
[18] *See* s. 27, ch. 2010-161, L.O.F.

- Furnish all physicians, county health departments, perinatal centers, birthing centers, and hospitals forms on which the results of tests for CCHD are to be reported to the department.
- Charge and collect fees sufficient to administer the newborn screening program for CCHD.

Section 2 amends s. 499.003, F.S., which provides definitions for the Act.

The bill amends the definition of "*distribute*" or "*distribution*" to specify that the term does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction. Under s. 499.003(54), F.S., "wholesale distribution" is defined as "distribution of prescription drugs to persons other than a consumer or patient," with certain specified exceptions. References in the law that require wholesale distributions to be backed up using documents that show each transaction from the manufacture of the drug through each distribution may conflict with the change in the definition of "distribution."

Specifically, s 499.0121(6), F.S., requires wholesale distributors to establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition. One component of the required records is any financial documentation supporting the transaction.[19] The change in the definition of "distribution" appears to have the effect of no longer requiring wholesale distributors to comply with the requirement to keep financial documentation available for inspection by the department.

Also, s. 499.01212, F.S., requires each person engaged in the wholesale distribution of a prescription drug to provide a pedigree paper to the person receiving the drug prior to or simultaneous with the distribution. The wholesale distributor must also maintain and make available to the department, upon request, the invoice numbers from the manufacturer. Pedigrees have to be authenticated in accordance with Rule 64F-12.013(5)(d), F.A.C., using invoices and shipping documents. If a wholesale distribution does not include billing and invoicing activities, the pedigrees, which have to be authenticated using shipping documents and invoices, cannot be authenticated.

The bill amends the definition of "*drug*" to specifically include active pharmaceutical ingredient as a component of a drug. The bill defines "active pharmaceutical ingredient," for purposes of the definition of "drug," to include any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

The definition of "*establishment*" is amended to modify the meaning of "one physical location," at which the place of business is located, to clarify that the location may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous

[19] *See* s. 499.0121(6)(a)5., F.S.

nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

The bill amends the definition of "*prescription drug*" to specify 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 Florida are also prescription drugs. The U.S. Food and Drug Administration determines the classification of drugs, whether prescription or not, and this definition may not be consistent with the federal classification.

The exception from the definition of "*wholesale distribution*" for the sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or entity that is eligible to purchase prescription drugs at public health services prices to a contract provider or its subcontractor for eligible patients of the agency or entity is amended to no longer require a contract provider or subcontractor to maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.

Section 3 amends s. 499.01, F.S., to modify the exemption from the requirement to obtain a health care clinic establishment permit for a licensed practitioner who purchases a prescription drug under his or her license, so that a professional corporation or limited liability company composed of dentists may pay for prescription drugs obtained by a licensed dentist and the licensed dentist is deemed the purchaser and owner of the prescription drugs.

Section 499.01, F.S., is further amended to repeal the exemption from obtaining a nonresident prescription drug manufacturer permit for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than authorized clinical trials and biostudies authorized and regulated by federal law.

The bill also repeals the exemption from obtaining an out-of-state prescription drug wholesale distributor permit for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in Florida, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name.

The bill creates a new subsection (3) to provide exemptions from the required permits. A permit is not required:

- To distribute prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment that is located in Florida and permitted as a prescription drug manufacturer under the following conditions.
  - The active pharmaceutical ingredient is for use by the prescription drug manufacturer in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in Florida where the product is received.
  - The manufacturing must be under an approved and otherwise valid New Drug Approval, Abbreviated New Drug Approval, New Animal Drug Approval, or Therapeutic Biologic Application.

  - The application, active pharmaceutical ingredient, or finished dosage form must not have been withdrawn or removed from the U.S. market for public health reasons.
  - The distributor claiming an exemption must maintain a license, permit or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.
  - The distributor claiming an exemption and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient must comply with recordkeeping requirements, but not the pedigree paper requirements.

- To distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state that is permitted as a prescription drug manufacturer for research and development or to a holder of a letter of exemption issued by the department for research, teaching, or testing.
  - The department must define "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.
  - The distributor claiming an exemption must maintain a license, permit or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.
  - All purchasers and recipients of any prescription drugs under this exemption must ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.
  - The distributor claiming an exemption and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient must comply with recordkeeping requirements, but not the pedigree paper requirements.
  - The immediate package or container of any active pharmaceutical ingredient distributed into the state intended for teaching, testing, research, and development must bear a label prominently displaying the statement "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale."

- For an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in Florida.
  - Both wholesale distributors must conduct wholesale distributions of prescription drugs under the same business name.
  - The recordkeeping requirements and the pedigree paper requirements must be followed for such transactions.

The bill requires persons who receive prescription drugs from a source claimed to be exempt from permitting to maintain on file the following information for all distributors and establishments from whom they purchase or receive prescription drugs under an exemption:

- A record of the FDA establishment registration number, if any;
- The resident state prescription drug wholesale distribution license, permit, or registration number; and
- A copy of the most recent resident state or FDA inspection report.

All persons claiming an exemption from the permitting requirements of the Act who engage in the distribution of prescription drugs in or into Florida are subject to the Act. They must make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under an exemption, regardless of the location where the records are stored.

The bill requires a person who purchases or receives a prescription drug from a person claimed to be exempt from the permitting requirements to report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

The bill authorizes the department to adopt rules to administer the exemption provisions in the bill. The bill declares that the failure to comply with the requirements of the exemption provisions, or rules adopted by the department to administer these provisions is a violation of:

- Section 499.005(14), F.S., which makes the purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient an unlawful act; and
- For knowing failure, s. 499.0051(4), F.S., which states that a person who knowingly purchases or receives a prescription drug in a wholesale distribution transaction from a person not authorized to distribute prescription drugs commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, F.S.

The exemption provisions in the bill do not relieve any persons from any requirement prescribed by law with respect to controlled substances.

The bill provides an exemption from the prescription drug repackager permit requirement for a restricted prescription drug distributor permitholder that is a health care entity that repackages prescription drugs in this state for its own use or distributes prescription drugs to a hospital or other health care entity in the state for its own use if it meets certain conditions. The restricted prescription drug distributor is also exempt from product registration requirements for the drugs it repackages and distributes.

Section 4 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

The requirement in the bill that the objection to screening must contain the parent's or guardian's signature may violate the right of privacy under the Florida Constitution, Article I, Section 23.

The bill may impair existing contracts since the requirement for health insurers and health maintenance organizations to cover screening CCHD takes effect on October 1, 2012, and does not provide an exemption for existing contracts.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The DOH currently collects a maximum hospital fee of $15 per live birth, as authorized in s. 383.14(3)(g), F.S., to cover the cost of newborn screening. Adding CCHD to the list of newborn screenings could require an increase in the hospital fee from $15 to $15.78 per live birth.

B. Private Sector Impact:

Hospitals, birth centers, and health care practitioners attending home births will have additional screening and reporting requirements.

Early detection with prompt early treatment may lead to a better outcome for babies born with severe heart disease. Detection prior to hospital discharge may also prevent unexpected events such as death or an emergency health crisis in the home setting.

An unknown, but probably small, number of specialty distributors providing a narrow category of products to Florida customers would be exempt from permitting fees.

C. Government Sector Impact:

The DOH will need to create and implement a system to track CCHD test results within the existing program structure. The CCHD screening is similar to newborn hearing screening in that the birthing facility conducts the actual testing and the DOH tracks the results and provides surveillance activities for infants who fail the screening test.

The main costs of adding CCHD to the Florida Newborn Screening Program are related to the necessary modifications of the current data system to add the screening results and staff time to track infants who fail the screening test. Follow-up actions would include communicating with physicians and parents regarding the outcome of the confirmatory

testing and obtaining the final diagnosis and outcome. The department estimates its expenditures to be $166,191 in FY 2012-2013 and $154,922 in FY 2013-2014.

Funding for the program could come from surplus revenue generated from billing for other disorders tested in the Newborn Screening program. The department must be provided budget authority to spend the surplus funding for this purpose. As of November 22, 2011, the Newborn Screening program had a surplus of revenue in FY 2010-2011 totaling $2,110,778.[20]

The DBPR estimates that the potential reduction in license fees as a result of the exemptions in the bill would be minimal, if any. The bill may require changes to the inspection application and the associated violation codes, but this can be done with existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The requirement for a written signature for objecting to screening by a parent or guardian at lines 57 and 58 is more prescriptive than a similar requirement under s. 383.14(4), F.S., which does not require a signature.

Section 624.215, F.S., requires every person or organization seeking consideration of a legislative proposal mandating health coverage to submit to the Agency for Health Care Administration and the appropriate legislative committees having jurisdiction a report assessing the social and financial impacts of the proposed coverage. Neither the Committee on Health Regulation nor the Committee on Banking and Insurance received a report analyzing newborn screening for CCHD as created by the bill.

Section 499.0121(6)(c), F.S., requires that the records wholesale distributors are required to maintain be readily available for authorized inspection. The modified definition of "establishment," with no requirement to designate in the permit application the location where the records will be kept, could create conflicts with the requirement that records be readily available.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on February 22, 2012:
Instead of establishing a permit by endorsement for certain out-of-state prescription drug wholesale distributors, the CS:

[20] *See* Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 1052 – on file with the Senate Health Regulation Committee.

- Establishes a newborn screening requirement for critical congenital heart disease;
- Amends definitions in the Florida Drug and Cosmetic Act; and
- Provides certain exemptions from the permitting requirements of the Act.

B. Amendments:

None.

416374

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/23/2012	.	
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The Committee on Health Regulation (Norman) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsections (17), (19), (20), and (43) of section 499.003, Florida Statutes, are amended to read:

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

(17) "Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the

416374

billing and invoicing activities that commonly follow a wholesale distribution transaction.

(19) "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their components, parts, or accessories. For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

(20) "Establishment" means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and

416374

control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

(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 (11), subsection (46), or subsection (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.

Section 2. Paragraphs (c) and (e) of subsection (2) of section 499.01, Florida Statutes, are amended, and subsection (3) is added to that section, to read:

499.01 Permits.—

(2) The following permits are established:

(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.

416374

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(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.

~~3. A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subparagraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The~~

~~prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The department shall specify by rule the allowable number of transactions within a given period of time and the amount of active pharmaceutical ingredients that qualify as limited quantities for purposes of this exemption. The failure to comply with the requirements of this subparagraph, or rules adopted by the department to administer this subparagraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14).~~

(e) *Out-of-state prescription drug wholesale distributor permit.*—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the

department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

~~1.~~ The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

~~2. An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.~~

(3)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in

this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

(b) A permit issued under this part is not required to distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. The department shall define "limited quantities" by rule and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale."

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss.

416374

499.0121(6) and 499.01212 must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1. A record of the FDA establishment registration number, if any;

2. The resident state prescription drug wholesale distribution license, permit, or registration number; and

3. A copy of the most recent resident state or FDA inspection report, for all distributors and establishments whom they purchase or receive prescription drugs under this subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity,

416374

potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

Section 3. This act shall take effect July 1, 2012.

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to prescription drug wholesale regulations; amending s. 499.003, F.S.; revising the definitions of the terms "distribute" or "distribution," "drug," "establishment," and "prescription drug"; amending s. 499.01, F.S.; deleting provisions relating to an exemption from nonresident prescription drug manufacturer permit requirements; deleting provisions relating to an exemption from out-of-state prescription drug wholesale distributor permit requirements for

intracompany sale or transfer of prescription drugs; providing an exemption from permit requirements for the distribution into this state of prescription drug active pharmaceutical ingredients for incorporation into prescription drugs in finished dosage form; requiring a distributor claiming such exemption to maintain a valid license, permit, or registration in the state from which the prescription drug was distributed; requiring compliance with certain recordkeeping requirements; exempting compliance with pedigree paper requirements; providing an exemption from permit requirements for distribution into this state of limited quantities of a prescription drug that has not been repackaged, for research and development or to a holder of a letter of exemption issued by the Department of Business and Professional Regulation for research, teaching, or testing; granting the department authority to define "limited quantities" by rule and limit therein the number of transactions and amount of prescription drugs distributed into the state; requiring a distributor claiming such exemption to maintain a valid license, permit, or registration in the state from which the prescription drug was distributed; requiring all purchasers and recipients of such prescription drugs to ensure the products are not resold or used on humans except in lawful clinical trials and biostudies; requiring compliance with certain recordkeeping requirements; exempting compliance from

pedigree paper requirements; providing labeling requirements for active pharmaceutical ingredients distributed within the state for teaching, testing, research, and development; exempting from out-of-state prescription drug wholesale distributor permit requirements intracompany transactions or the sale of prescription drugs from an out-of-state distributor to a distributor in this state if both distributors conduct wholesale distributions under the same business name; requiring compliance with recordkeeping and pedigree paper requirements; allowing distributors and recipients of prescription drugs claiming exemption from certain permitting requirements to maintain on file their FDA registration number, resident state distributor license or permit number, and most recent resident state or FDA inspection report; providing that persons claiming such exemptions are subject to part I of chapter 499, F.S., the Florida Drug and Cosmetic Act; requiring persons claiming such exemptions to make all records regarding prescription drug distribution available to the department, upon request, within 48 hours; requiring submission of a report of mishandled or adulterated prescription drugs within 14 days after receipt of such drugs; authorizing the department to adopt rules; providing that failure to comply with requirements or rules governing such exemptions constitutes unlawful purchase or receipt of a prescription drug from a person not authorized to distribute prescription drugs

416374

to that purchaser or recipient; providing that knowing failure to comply with such requirements constitutes unlawful sale, distribution, purchase, trade, holding, or offering of a drug; providing penalties; providing construction with respect to federal and state laws relating to controlled substances; providing an effective date.

732876

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/23/2012	.	
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment to Amendment (416374) (with title amendment)

Between lines 4 and 5
insert:
Section 1. Section 383.146, Florida Statutes, is created to read:
383.146 Newborn screening for critical congenital heart disease.—
(1) DEFINITIONS.—As used in this section, the term:
(a) "Department" means the Department of Health.
(b) "Newborn" means an age range from birth through 29

732876

days.

(c) "Screening" means measuring blood oxygen saturation using pulse oximetry to determine whether a newborn needs additional diagnostic evaluation for critical congenital heart disease.

(2) REQUIREMENTS FOR SCREENING OF NEWBORNS; REFERRAL FOR ONGOING SERVICES.—

(a) Each licensed hospital that provides maternity and newborn care services shall ensure that, prior to discharge, all newborns are screened for the detection of critical congenital heart disease.

(b) Each licensed birth center that provides maternity and newborn care services shall ensure that, prior to discharge, all newborns are screened for the detection of critical congenital heart disease.

(c) If the parent or legal guardian of the newborn objects to the screening, the screening must not be completed, notwithstanding any other provision of this section. In such case, the physician, midwife, or other person who is attending the newborn shall maintain a record that the screening has not been performed and attach a written objection that must be signed by the parent or guardian.

(d) For home births, the health care provider in attendance is responsible for the screening.

(e) Appropriate documentation of the screening completion, results, interpretation, and recommendations must be placed in the medical record within 24 hours after completion of the screening procedure.

(f) Each hospital shall formally designate a lead physician

732876

who is responsible for programmatic oversight of newborn congenital heart disease screening. Each licensed birth center shall designate a licensed health care provider to provide such programmatic oversight. Such physician or health care provider shall ensure that the appropriate referrals are completed following a positive screening test result.

(g) By October 1, 2012, screening for critical congenital heart disease must be conducted on all newborns in hospitals and birth centers in this state following birth admission.

(3) RULES.—After consultation with the Genetics and Newborn Screening Advisory Council, the department shall adopt and enforce rules requiring that every newborn in this state be screened for critical congenital heart disease. The department shall adopt such additional rules as are necessary for the administration of this section, including rules providing definitions of terms, rules relating to the methods used and time or times for testing as accepted medical practice indicates, rules relating to charging and collecting fees for the administration of the newborn screening program required by this section, rules for processing requests and releasing test and screening results, and rules requiring mandatory reporting of the results of tests and screenings for this condition to the department.

(4) POWERS AND DUTIES OF THE DEPARTMENT.—The department shall administer and provide services required pursuant to this section and shall:

(a) Furnish to all physicians, county health departments, perinatal centers, birth centers, and hospitals forms on which the results of tests for critical congenital heart disease shall

732876

be reported to the department.

(b) Have the authority to charge and collect fees sufficient to administer the newborn screening program required under this section.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete lines 264 - 265

and insert:

An act relating to health care; creating s. 383.146, F.S.; providing definitions; providing requirements for screening newborns for critical congenital heart disease; providing an exception; requiring that the physician, midwife, or other person attending the newborn maintain a record if the screening has not been performed and attach a written objection signed by the parent or guardian; requiring appropriate documentation of the screening completion in the medical record; requiring that each hospital and each licensed birth center designate a lead physician and a licensed health care provider, respectively, to provide programmatic oversight for the screening; requiring that the screening for critical congenital heart disease be conducted on all newborns in hospitals and birth centers in this state; authorizing the Department of Health to adopt rules to administer the screening program; providing powers and duties of the department; amending s. 499.003, F.S.; revising the

942294

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/23/2012	.	
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The Committee on Health Regulation (Norman) recommended the following:

Senate Amendment to Amendment (416374) (with directory and title amendments)

Between lines 56 and 57

insert:

(54) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other

942294

health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "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, by voting rights, by contract, or otherwise.

4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the State Surgeon General or his or her designee.

942294

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

~~d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.~~

d.~~c.~~ The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e.~~f.~~ The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d ~~sub-subparagraph c~~.

942294

f.g. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

Delete line 5
and insert:

Section 1. Subsections (17), (19), (20), and (43), and paragraph (a) of subsection (54) of

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:

Delete lines 267 - 268
and insert:

"distribution," "drug," "establishment," "prescription drug," and "wholesale distribution"; amending s. 499.01, F.S.;

549850

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/23/2012	.	
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The Committee on Health Regulation (Jones) recommended the following:

Senate Amendment to Amendment (416374) (with directory and title amendments)

Between lines 150 and 151
insert:

(t) *Health care clinic establishment permit.*—Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the

549850

term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time

549850

when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license. A professional corporation or limited liability company composed of dentists and operating as authorized in s. 466.0285 may pay for prescription drugs obtained by a practitioner licensed under chapter 466, and the licensed practitioner is deemed the purchaser and owner of the prescription drugs.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

Delete line 57

and insert:

Section 2. Paragraphs (c), (e), and (t) of subsection (2) of

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:

Delete line 274

and insert:

intracompany sale or transfer of prescription drugs; authorizing certain business entities to pay for prescription drugs obtained by practitioners licensed under ch. 466, F.S.;

585952

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/23/2012	.	
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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment to Amendment (416374) (with directory and title amendments)

Between lines 256 and 257
insert:
(4) A restricted prescription drug distributor permitholder that is under common ownership, directly or indirectly, with an entity licensed under chapter 395, may repackage prescription drugs, from a centralized location or otherwise, for transfer or distribution to or among entities that are also under common ownership, directly or indirectly, with an entity licensed under chapter 395.

585952

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:
Delete lines 58 - 59
and insert:
section 499.01, Florida Statutes, are amended, and subsections (3) and (4) are added to that section, to read:

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:
Delete line 337
and insert:
relating to controlled substances; authorizing a restricted prescription drug distributor permitholder to repackage prescription drugs for a specific purpose; providing an

790972

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/23/2012	.	
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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment to Amendment (416374) (with directory and title amendments)

Between lines 256 and 257
insert:

(4) 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 that repackages prescription drugs in this state for its own use or distributes prescription drugs to a hospital or other health care entity in the state for its own use pursuant to s. 499.003(54)(a)3. if the restricted prescription drug distributor:

(a) Notifies the department in writing of its intention to engage in repackaging under this exemption 30 days before actually engaging in the repackaging of prescription drugs at the permitted establishment;

(b) Is under common control with the hospital or other health care entity to which the restricted prescription drug distributor distributes prescription drugs. For purposes of this paragraph, the term "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, by voting rights, by contract, or otherwise;

(c) Repackages the prescription drugs in accordance with proper manufacturing practices and current state and federal laws and rules; and

(d) Labels the prescription drugs in accordance with state and federal laws and rules.

The restricted 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.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

Delete lines 58 - 59
and insert:

Section 499.01, Florida Statutes, are amended, and subsections (3) and (4) are added to that section, to read:

790972

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 337
and insert:
relating to controlled substances; providing that a prescription drug repackager permit is not required for certain restricted prescription drug distributor permitholders that distribute prescription drugs to certain hospitals or other health care entities; exempting certain restricted prescription drug distributors from product registration requirements; providing an

355720

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/23/2012	.	
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The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment to Amendment (416374) (with title amendment)

Between lines 256 and 257
insert:
Section 3. Paragraph (c) of subsection (15) 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

355720

and for the establishment and maintenance of prescription drug distribution records.

(15) DUE DILIGENCE OF PURCHASERS.—

(c) A wholesale distributor shall review documentation of the receiving entity's state and federal licenses and permits before distributing a controlled substance to that entity. A wholesale distributor may not distribute controlled substances to an entity without verification of the required state and federal licenses and permits ~~if any criminal history record check for any person associated with that entity shows that the person has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.~~

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 337

and insert:

relating to controlled substances; amending s. 499.0121, F.S.; requiring wholesale distributors to review a receiving entity's licenses and permits before distributing a controlled substance to the entity; prohibiting such distribution without verification of the licenses and permits; deleting provisions prohibiting such distribution if the receiving entity has been convicted of, or pled guilty of nolo contendere to, certain crimes; providing an

282212

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/23/2012	.	
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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment to Amendment (416374) (with directory and title amendments)

Between lines 256 and 257

insert:

(4) 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 that repackages prescription drugs in this state for its own use or distributes prescription drugs to a hospital or other health care entity in the state for its own use pursuant to s. 499.003(54)(a)3. if the restricted prescription drug

282212

distributor:

(a) Notifies the department in writing of its intention to engage in repackaging under this exemption 30 days before actually engaging in the repackaging of prescription drugs at the permitted establishment;

(b) Is under common control with the hospital or other health care entity to which the restricted prescription drug distributor distributes prescription drugs. For purposes of this paragraph, the term "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, by voting rights, by contract, or otherwise;

(c) Repackages the prescription drugs in accordance with federal and state current good manufacturing practices; and

(d) Labels the prescription drugs in accordance with state and federal laws and rules.

The restricted 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.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

Delete lines 58 - 59

and insert:

Section 499.01, Florida Statutes, are amended, and subsections (3) and (4) are added to that section, to read:

282212

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:

Delete line 337

and insert:

relating to controlled substances; providing that a prescription drug repackager permit is not required for certain restricted prescription drug distributor permitholders that distribute prescription drugs to certain hospitals or other health care entities; exempting certain restricted prescription drug distributors from product registration requirements; providing

576758

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/23/2012	.	
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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment (with directory and title amendments)

Between lines 64 and 65
insert:
(3) 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 that repackages prescription drugs in this state for its own use or distributes prescription drugs to a hospital or other health care entity in the state for its own use pursuant to s. 499.003(54)(a)3. if the restricted prescription drug distributor:

576758

(a) Notifies the department in writing of its intention to engage in repackaging under this exemption 30 days before actually engaging in the repackaging of prescription drugs at the permitted establishment;
(b) Is under common control with the hospital or other health care entity to which the restricted prescription drug distributor distributes prescription drugs. For purposes of this paragraph, the term "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, by voting rights, by contract, or otherwise;
(c) Repackages the prescription drugs in accordance with proper manufacturing practices and current state and federal laws and rules; and
(d) Labels the prescription drugs in accordance with state and federal laws and rules.

The restricted 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.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:
Delete line 15
and insert:
499.01, Florida Statutes, is amended, and subsection (3) is added to that section, to read:

576758

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 9
and insert:
that permit until its expiration; providing that a prescription drug repackager permit is not required for certain restricted prescription drug distributor permitholders that distribute prescription drugs to certain hospitals or other health care entities; exempting certain restricted prescription drug distributors from product registration requirements; providing an

By Senator Latvala

16-00907-12 20121006__

A bill to be entitled

An act relating to prescription drug wholesale regulations; amending s. 499.01, F.S.; requiring the Department of Health to issue a permit by endorsement to an out-of-state prescription drug wholesale distributor that meets certain requirements; authorizing out-of-state wholesale distributors holding a valid permit to continue to operate under that permit until its expiration; providing an effective date.

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

Section 1. Paragraph (e) of subsection (2) of section 499.01, Florida Statutes, is amended to read:

499.01 Permits.—

(2) The following permits are established:

(e) *Out-of-state prescription drug wholesale distributor permit.*—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to

16-00907-12 20121006__

the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

1. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. The department shall issue an out-of-state permit by endorsement to an applicant who, upon applying to the department and remitting a filing fee, set by the board, demonstrates to the board that the applicant satisfies the requirements of this chapter and holds a valid drug wholesale distributor license or permit from another state. An out-of state prescription drug wholesale distributor that holds a valid permit under this chapter on the effective date of this act may continue to operate under that permit until its expiration, after which the distributor may apply for a permit by endorsement as provided in this subparagraph.

2. An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in

its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.

Section 2. This act shall take effect July 1, 2012.

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Health Care Clinic establishment permit
Bill Number SB 1006 *(if applicable)*

Name Ron Watson
Amendment Barcode 549850 *(if applicable)*

Job Title Lobbyist

Address 118 E Jefferson St
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850 224-1089

E-mail rwatson@floridadental.org

Speaking: ☒ For ☐ Against ☐ Information

Representing FDA Florida Dental Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic
Bill Number SB 1006 *(if applicable)*

Name Steve Ecenia
Amendment Barcode 282212 *(if applicable)*

Job Title

Address 119 S. Monroe St Suite 202
Street

City *State* *Zip*

Phone 681-6788

E-mail steve@reuphlaw.com

Speaking: ☑ For ☐ Against ☐ Information

Representing HCA

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Support Norman Amendment to Amendment

Bill Number 1006 *(if applicable)*

Name Chris Hansen

Amendment Barcode 416374 *(if applicable)*

Job Title

Address Gray Robinson
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 577-9090

E-mail Chansen@gray-robinson.com

Speaking: ☐ For ☐ Against ☐ Information

Representing Walgreens

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

Waive in Support

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic

Bill Number SB 1006 *(if applicable)*

Name Ron Watson

Amendment Barcode *(if applicable)*

Job Title Lobbyist

Address 118 E Jefferson St
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-224-1089

E-mail rwatson@floridadental.org

Speaking: ☒ For ☐ Against ☐ Information

Representing FDA - Florida Dental Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

Topic SB 1006 - Pharmaceutical

Bill Number 1006 *(if applicable)*

Name Alan Suskey

Amendment Barcode *(if applicable)*

Job Title V.P.

Address 201 S. Monroe Suite 201 *Street*

Phone

Tallahassee FL *City State Zip*

E-mail ASUSKEY@Threebridgesadvisors.com

Speaking: ☑ For ☐ Against ☐ Information

Representing Dermazone Solutions

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

22 FEB 12 *Meeting Date*

Topic PRESCRIPTION DRUG WHOLESALE REGULATION

Bill Number SB 1006 *(if applicable)*

Name MIKE MCQUONE

Amendment Barcode *(if applicable)*

Job Title EXECUTIVE VICE PRESIDENT AND CEO

Address 2910 KERRY FOREST PARKWAY D-4 STE 376 *Street*

Phone (850) 906-9333 ext 103

TALLAHASSEE, FL 32309 *City State Zip*

E-mail mikemcquone@fshp.org

Speaking: ☒ For ☐ Against ☐ Information

Representing FLORIDA SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: CS/SB 1116

INTRODUCER: Health Regulation Committee and Senator Altman

SUBJECT: Human Papillomavirus

DATE: February 22, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Davlantes	Stovall	HR	**Fav/CS**
2.			ED	
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill requires that, beginning with the 2012-2013 school year, the parent or guardian of each rising sixth grade student must be provided information on the availability of vaccination against human papillomavirus (HPV) as recommended by the Centers for Disease Control and Prevention (CDC) and the types of diseases which may be caused by HPV. Such information must be approved by the Department of Health (DOH) for dissemination by the Department of Education (DOE).

The bill creates one undesignated section of law.

II. Present Situation:

CDC and FDA

The Food and Drug Administration (FDA) is a federal agency within the Department of Health and Human Services (HHS) responsible for protecting public health by assuring that foods are safe, sanitary, and properly labeled; human and veterinary drugs, vaccines, and biological products, and medical devices are safe and effective; assuring cosmetics and dietary supplements

are safe and properly labeled; regulating tobacco products; and helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health.[1] The Center for Biologics Evaluation Research (CBER) within the FDA employs highly trained medical personnel to determine the indications, effectiveness, and side effects of all vaccines as well as to monitor their manufacturing for quality control.[2] The CBER approves vaccines for use in certain populations but does not provide recommendations for their administration.

The CDC is a part of HHS which focuses on public health, both nationally and internationally. The CDC works with partners throughout the nation and the world to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies, promote healthy behaviors, and foster safe and healthful environments.[3] The Advisory Committee on Immunization Practices (ACIP) within the CDC develops written recommendations for the administration of vaccines, including the appropriate timing, dosage, and contraindications. The ACIP is the only entity in the federal government which makes such recommendations.[4]

Human Papillomavirus and Vaccines

HPV is a virus which infects the skin and mucous membranes. More than 100 types of HPV have been discovered. The virus is transmitted by skin-to-skin contact during sexual activity and is so prevalent that almost everyone is infected by one or various strains. HPV infection is usually asymptomatic, although certain types cause diseases such as genital warts and cervical cancer.

Vaccines currently exist for HPV types 6, 11, 16, and 18. HPV types 6 and 11 cause benign warts to grow around the genitals, in the respiratory tract, in the eye, or on whatever body part is exposed to infection during sexual activity; however, these strains can also lead to lung or vulvar cancer. HPV types 16 and 18 cause more malignant diseases such as cancer of the lung, respiratory tract, sinuses, eye, mouth, esophagus, anus, vulva, cervix, and penis.[5] The most common cancer caused by HPV types 16 and 18 is cervical cancer, which affects more than 12,000 women per year. Oropharyngeal (mouth and throat) cancers are the most common cancers caused by HPV in men.[6]

The FDA has approved two vaccines against HPV. The first, Gardasil, protects against HPV types 6, 11, 16, and 18 and is recommended for all people aged 9 to 26.[7] The second, Cervarix,

[1] FDA, *What does FDA do?*, available at: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm (last visited on January 11, 2012).
[2] FDA, *How does FDA assess the safety of vaccines?*, available at: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194586.htm (last visited on January 11, 2012).
[3] CDC, *CDC Mission*, available at: http://www.cdc.gov/about/organization/mission.htm (last visited on January 11, 2012).
[4] CDC, *About ACIP*, available at: http://www.cdc.gov/vaccines/recs/acip/default.htm (last visited on January 11, 2012).
[5] Medscape Reference, *Human Papillomavirus*, available at: http://emedicine.medscape.com/article/219110-overview (last visited on January 11, 2012).
[6] CDC, *HPV Vaccine- Questions & Answers*, available at: http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm (last visited on January 11, 2012).
[7] FDA, *Gardasil*, available at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM094042 (last visited on January 11, 2012).

protects against types 16 and 18 and is recommended for women aged 9 to 25.[8] Both vaccines are given as three shots over six months and are most effective when administered before the onset of sexual activity.[9]

The CDC recommends that all children be vaccinated against HPV at age 11 or 12.[10]

Vaccines Currently Required by Rule or Statute

Certain vaccines are required before any person can be educated in the state, either in public, private, or virtual schools, unless that person is given a religious or medical exemption.[11] Immunization requirements vary by the grade of the student. There are currently no *recommended* vaccines mentioned in statute or rule.

Before entering pre-kindergarten, a child must be vaccinated against diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B, chicken pox, and *Haemophilus influenzae* type b. Before entering kindergarten, a child must have received at least four doses of the diphtheria, tetanus, and pertussis vaccine; at least three doses of the polio vaccine; two doses of the measles, mumps, and rubella vaccine; at least two doses of the hepatitis B vaccine; and one or two doses of the chicken pox vaccine, depending on the age of the child. Additionally, one dose of the tetanus-diptheria-pertussis vaccine is required before a student may begin seventh grade.[12]

III. Effect of Proposed Changes:

Section 1 states that, beginning with the 2012-2013 school year, the parent or guardian of each rising sixth grade student must be provided information on the availability of vaccination against HPV as recommended by the ACIP. Such information will be approved by the DOH for dissemination by the DOE and should include, at a minimum, the connection between HPV various diseases and notification that the HPV vaccine is recommended to be administered before grade 7 entry.

Section 2 provides that the bill will take effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

[8] FDA, *Cervarix*, available at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm186957.htm (last visited on January 11, 2012).
[9] CDC, *HPV Vaccines*, available at: http://www.cdc.gov/hpv/vaccine.html (last visited on January 11, 2012).
[10] *Supra* fn. 6.
[11] Section 1003.22, F.S., and Rule 64D-3.046, F.A.C.
[12] DOH, *Immunization Guidelines*, available at http://www.doh.state.fl.us/disease_ctrl/immune/schoolguide.pdf (last visited on January 11, 2012).

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Public school students and their parents and guardians will be better educated about HPV, its effects, and available vaccines.

C. Government Sector Impact:

The DOH will experience negligible fiscal impact.[13]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

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

CS by Health Regulation on February 22, 2012:
The CS eliminates the requirement that the DOH add HPV to the list of communicable diseases for which immunizations are recommended, since no such list exists in statute or rule. The CS requires the parents and guardians of all rising sixth graders, not simply public school students, to receive information about HPV and requires such information to include the connection between HPV and a variety of other diseases, not simply cervical cancer. The CS references the ACIP rather than the FDA as the source of immunization guidelines and requires the DOE to disseminate the HPV information that the DOH approves.

[13] Department of Health, *2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 1116*. A copy is on file with the Senate Health Regulation Committee.

B. Amendments:

None.

168688

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/23/2012	.	
	.	
	.	
	.	

The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Beginning with the 2012-2013 school year, the parent or guardian of each student entering grade 6 shall be provided information on the availability of vaccination against human papillomavirus as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP). Such information shall be approved by the Department of Health for dissemination by the Department of Education. The information will, at a minimum, include the

168688

connection between the human papillomavirus and cervical cancer as well as other cancers and diseases. The information must also notify the parent or guardian that a vaccine is available to help prevent human papillomavirus infection and that the vaccine is recommended to be given before grade 7 entry.

Section 2. This act shall take effect upon becoming a law.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to the human papillomavirus; requiring information regarding the human papillomavirus, its effects, and available vaccines to parents or guardians of all children entering grade 6; providing an effective date.

By Senator Altman

24-00520-12 20121116__

A bill to be entitled

An act relating to the human papillomavirus; requiring that the Department of Health adopt a rule adding the human papillomavirus to the list of communicable diseases for which immunizations are recommended; requiring that schools provide the parents or guardians of certain public school students information regarding the human papillomavirus and the availability of a vaccine; requiring that the Department of Health prescribe the required information; providing an effective date.

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

Section 1. (1) By July 1, 2012, the Department of Health shall adopt a rule adding the human papillomavirus to the list of communicable diseases for which immunizations are recommended.

(2) Beginning with the 2012-2013 school year, each school shall provide the parent or guardian of a public school student entering grade 6 for whom the human papillomavirus vaccine is approved by the United States Food and Drug Administration information, which the Department of Health shall prescribe, regarding the connection between the human papillomavirus and cervical cancer. The information must also notify the parent or guardian that a vaccine is available to help prevent human papillomavirus infection and that the vaccine is recommended to be given to females before they enter grade 8.

Section 2. This act shall take effect upon becoming a law.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Military Affairs, Space, and Domestic Security, *Chair*
Budget - Subcommittee on Finance and Tax, *Vice Chair*
Budget
Budget - Subcommittee on Higher Education Appropriations
Communications, Energy, and Public Utilities
Education Pre-K - 12
Higher Education
Reapportionment
Regulated Industries

SENATOR THAD ALTMAN
24th District

January 11, 2012

The Honorable Rene Garcia, Chair
Committee on Health Regulation
310 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Garcia:

Senate Bill 1116, relating Human Papillomavirus, has been referred to your committee for the first committee of reference.

I respectfully request SB 1116 be placed on the Health Regulation committee agenda at your earliest convenience. Thank you for your consideration and please do not hesitate to contact me should you have any questions or concerns.

Sincerely,

Thad Altman

Thad Altman

TA/kj

cc: Sandra Stovall, Staff Director
530 Knott Building

ENTERED
1-11-12

REPLY TO:
❒ 6767 North Wickham Road, Suite 211, Melbourne, Florida 32940 (321) 752-3138
❒ 314 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5053

Senate's Website: *www.flsenate.gov*

MIKE HARIDOPOLOS
President of the Senate

MICHAEL S. "MIKE" BENNETT
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

Topic HPV — Bill Number 1116 *(if applicable)*

Name Amy Young — Amendment Barcode _____ *(if applicable)*

Job Title Leg. Consultant

Address 403 S. Park Avenue — Phone 561-655-1166
Street

Tall, FL — E-mail _____
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing FL OB-GYN Society waive in support

Appearing at request of Chair: ☐ Yes ☑ ~~No~~ — Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Human Papillomavirus Virus

Bill Number 1116 *(if applicable)*

Name Merritt Martin

Amendment Barcode _____ *(if applicable)*

Job Title Legislative Director

Address 10902 Magnolia Dr.
Street

Phone 813-240-3454

Tampa FL 33612
City *State* *Zip*

E-mail merritt.martin@moffitt.org

Speaking: ☐ For ☐ Against ☐ Information

Representing Moffitt Cancer Center

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	SB 290
INTRODUCER:	Senator Flores and others
SUBJECT:	Abortions
DATE:	February 15, 2012
REVISED:	02/22/12

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Favorable**
2.			CJ	
3.			BC	
4.				
5.				
6.				

I. Summary:

This bill consolidates provisions relating to abortion that are currently located in several chapters of the Florida Statutes into chapter 390, F.S. Provisions that have been struck down by the courts are repealed. The bill substitutes the term "abortion," which is defined in s. 390.011(1), F.S., for the term "termination of pregnancy," throughout the chapter.

The bill prohibits abortions from being performed while a woman is in her third trimester of pregnancy or after a fetus has attained viability, unless:

- Two physicians certify that the abortion is necessary to prevent the death of the pregnant woman or the substantial and irreversible impairment of a major bodily function of the pregnant woman; or
- The physician certifies to the existence of a medical emergency, and another physician is not available for consultation.

The bill requires an abortion clinic to provide conspicuous written notice on its premises and on any advertisement that the clinic is prohibited from performing abortions in the third trimester or after viability and requires the Agency for Health Care Administration (AHCA) to adopt rules to regulate such advertisements. Violation of the advertising requirements is a first-degree misdemeanor.

The bill requires any physician who performs abortions in an abortion clinic to annually complete at least 3 hours of continuing education that relate to ethics, as part of the licensure and renewal process. The bill also provides for restrictions as to where an abortion may be performed.

The bill specifies that consent to an abortion is voluntary and informed only if the statutory requirements for informed consent are completed at least 24 hours before the abortion is performed.

This bill increases the penalty for failure to properly dispose of fetal remains from a second-degree to a first-degree misdemeanor. The Department of Health is required to revoke the license of any licensed health care practitioner who has been convicted or found guilty of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, certain felonies relating to the performance of an abortion in violation of s. 390.0111, F.S.

The bill provides certain rights, powers, and privileges to an infant born alive subsequent to an attempted abortion and requires health care practitioners present at the time to exercise diligence to preserve the life and health of the infant. The bill specifies that, in the third trimester or after viability when two physicians determine that an abortion is necessary to prevent the death of the pregnant woman or the substantial and irreversible impairment of a major bodily function of the pregnant woman, the abortion may only be performed if a physician other than the physician performing the abortion is in attendance to take control of any infant born alive to provide immediate medical care to the infant.

This bill also provides that it is a misdemeanor of the first degree if:

- A person establishes, conducts, manages, or operates an abortion clinic without a valid current license.
- An abortion clinic is not wholly owned and operated by a physician who has received certain training during residency, unless the clinic was licensed before July 1, 2012.

It is also a misdemeanor of the first-degree for a person to advertise or facilitate an advertisement of services or drugs for the purpose of performing an abortion in violation of ch. 390, F.S. A licensed health care practitioner who is guilty of a felony for providing unlawful abortion services is subject to licensure revocation. The maximum fine that the AHCA may impose on an abortion clinic for violation of licensure requirements is increased from $1,000 to $5,000.

This bill also requires a director of a hospital, validly licensed abortion clinic, or physician's office where abortions are performed to report to the AHCA specific information, which the AHCA must then submit to the Centers for Disease Control and Prevention (CDC) and make available on the AHCA website prior to each general legislative session. Additionally, the AHCA must provide an annual report to the Governor and Legislature, which contains such information. None of the reported or published information is to contain any personal indentifying information.

This bill substantially amends the following sections of the Florida Statutes: 390.011, 390.0111, 390.01114, 390.0112, 390.012, 390.014, 390.018, 456.013, and 765.113.

This bill repeals the following sections of the Florida Statutes: 782.30, 782.32, 782.34, 782.36, 797.02 and 797.03.

This bill also creates an undesignated section of the Florida Statutes.

II. Present Situation:

Background

Under Florida law the term "abortion" means the termination of human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.[1] "Viability" means that stage of fetal development when the life of the unborn child may, with a reasonable degree of medical probability, be continued indefinitely outside the womb.[2] Induced abortion can be elective (performed for nonmedical indications) or therapeutic (performed for medical indications). An abortion can be performed by surgical or medical means (medicines that induce a miscarriage).[3]

An abortion in Florida must be performed by a physician licensed to practice medicine or osteopathic medicine who is licensed under ch. 458, F.S., or ch. 459, F.S., or a physician practicing medicine or osteopathic medicine in the employment of the United States.[4] No person who is a member of, or associated with, the staff of a hospital, or any employee of a hospital or physician in which, or by whom, the termination of a pregnancy has been authorized or performed, who states an objection to the procedure on moral or religious grounds is required to participate in the procedure. The refusal to participate may not form the basis for any disciplinary or other recriminatory action.[5]

Currently, abortion clinics, hospitals, and physicians that perform abortions provide a monthly report to the AHCA that provides aggregate data regarding the number of abortions performed, the reason for the abortion, and the gestational age of the fetus. According to the AHCA, for the calendar year 2009, providers submitted a total of 1,210 monthly reports that reported a total of 81,916 abortions. During calendar year 2010, a total of 1,203 monthly reports were submitted that reported a total of 79,908 abortions.[6]

Abortion provisions are included in ch. 390, F.S., ss. 782.30 – 782.36, F.S., and ch. 797, F.S.

Partial-Birth Abortion

Florida has enacted two prohibitions upon partial-birth abortion.[7] Both have been invalidated by the courts.[8] Section 390.011(6), F.S., defines partial-birth abortion as a termination of pregnancy

[1] Section 390.011(1), F.S.
[2] Section 390.0111(4), F.S.
[3] Suzanne R. Trupin, M.D., *Elective Abortion*, Updated January 31, 2012. Found at: <http://www.emedicine.com/med/TOPIC3312.HTM> (Last visited on February 15, 2012).
[4] Section 390.0111(2) and s. 390.011(7), F.S.
[5] Section 390.0111(8), F.S.
[6] Agency for Health Care Administration, *2012 Bill Analysis & Economic Impact Statement for SB 290*, on file with the Senate Health Regulation Committee.
[7] *See* ss. 782.30-782.36, F.S. (the Partial-Birth Abortion Act) and ss. 390.011(6) and 390.0111(5) and (11), F.S.
[8] *A Choice for Women v. Butterworth*, 2000 WL 34403086 (S.D.Fla. July 11, 2000) invalidated the Partial-Birth Abortion Act (ss. 782.30-782.36, F.S.) and *A Choice for Women v. Butterworth*, 54 F.Supp.2d 1148 (S.D. Fla. December 2, 1998) invalidated the partial-birth abortion provisions of ss. 390.011(6) and 390.0111(5) and (11), F.S.

in which the physician performing the termination of pregnancy partially vaginally delivers a living fetus before killing the fetus and completing the delivery. Section 782.32(1), F.S., defines "partially born" to mean that the living fetus's intact body, with the entire head attached, is presented so that:

(a) There has been delivered past the mother's vaginal opening:
1. The fetus's entire head, in the case of a cephalic presentation, up until the point of complete separation from the mother whether or not the placenta has been delivered or the umbilical cord has been severed; or
2. Any portion of the fetus's torso above the navel, in the case of a breech presentation, up until the point of complete separation from the mother whether or not the placenta has been delivered or the umbilical cord has been severed.

(b) There has been delivered outside the mother's abdominal wall:
1. The fetus's entire head, in the case of a cephalic presentation, up until the point of complete separation from the mother whether or not the placenta has been delivered or the umbilical cord has been severed; or
2. Any portion of the child's torso above the navel, in the case of a breech presentation, up until the point of complete separation from the mother whether or not the placenta has been delivered or the umbilical cord has been severed.

Section 782.34, F.S., provides that, except to save the life of the mother, any person who intentionally kills a living fetus while that fetus is partially born commits the crime of partial-birth abortion, which is a felony of the second degree.

Congress enacted the Partial-Birth Abortion Ban Act of 2003.[9] The United States Supreme Court has upheld the federal ban.[10] Partial-birth abortion is defined to mean an abortion in which the person performing the abortion –

(A) deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and

(B) performs the overt act, other than completion of delivery, that kills the partially delivered living fetus.

Abortion Clinics

Abortion clinics are licensed and regulated by the AHCA under ch. 390, F.S., and part II of ch. 408, F.S. The AHCA has adopted rules in Chapter 59A-9, Florida Administrative Code, related to abortion clinics. Section 390.012, F.S., requires these rules to address the physical facility, supplies and equipment standards, personnel, medical screening and evaluation of patients, abortion procedures, recovery room standards, and follow-up care. The rules relating to the medical screening and evaluation of each abortion clinic patient, at a minimum, shall require:

- A medical history, including reported allergies to medications, antiseptic solutions, or latex; past surgeries; and an obstetric and gynecological history;

[9] 18 U.S.C. s. 1531.
[10] *Gonzales v. Carhart*, 550 U.S. 124, 127 S.Ct. 1610 (Decided April 18, 2007).

- A physical examination, including a bimanual examination estimating uterine size and palpation of the adnexa;
- The appropriate laboratory tests, including:
  - For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy performed before the abortion procedure,
  - A test for anemia,
  - Rh typing, unless reliable written documentation of blood type is available, and
  - Other tests as indicated from the physical examination;
- An ultrasound evaluation for patients who elect to have an abortion after the first trimester. If a person who is not a physician performs the ultrasound examination, that person must have documented evidence that he or she has completed a course in the operation of ultrasound equipment. If a patient requests, the physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant must review the ultrasound evaluation results and the estimate of the probable gestational age of the fetus with the patient before the abortion procedure is performed; and
- The physician to estimate the gestational age of the fetus based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age and write the estimate in the patient's medical history. The physician must keep original prints of each ultrasound examination in the patient's medical history file.

Section 390.0111(4), F.S., provides for the standard of medical care to be used during viability. If a termination of pregnancy is performed during viability, a person who performs or induces the termination of pregnancy may not fail to use that degree of professional skill, care, and diligence to preserve the life and health of the fetus which the person would be required to exercise in order to preserve the life and health of any fetus intended to be born and not aborted.

The biennial license fee for an abortion clinic is $514. The administrator responsible for the day to day operations of the abortion clinic and the chief financial officer are required to submit to a level 2 (statewide and nationwide) background screening.[11]

Relevant Case Law

In 1973, the landmark case of *Roe v. Wade* established that restrictions on a woman's access to secure an abortion are subject to a strict scrutiny standard of review.[12] In *Roe*, the U.S. Supreme Court determined that a woman's right to have an abortion is part of the fundamental right to privacy guaranteed under the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution, justifying the highest level of review.[13] Specifically, the Court concluded that: (1) during the first trimester, the state may not regulate the right to an abortion; (2) after the first trimester, the state may impose regulations to protect the health of the mother; and (3) after viability, the state may regulate and proscribe abortions, except when it is necessary to preserve

[11] Agency for Health Care Administration, *Abortion Clinic*. Found at: <http://www.fdhc.state.fl.us/mchq/health_facility_regulation/hospital_outpatient/abortion.shtml> (Last visited on February 15, 2012).
[12] 410 U.S. 113 (1973).
[13] 410 U.S. 113, 154 (1973).

the life or health of the mother.[14] Therefore, a state regulation limiting these rights may be justified only by a compelling state interest, and the legislative enactments must be narrowly drawn to express only legitimate state interests at stake.[15]

In 1992, in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the U.S. Supreme Court relaxed the standard of review in abortion cases involving adult women from strict scrutiny to unduly burdensome, while still recognizing that the right to an abortion emanates from the constitutional penumbra of privacy rights.[16] In *Planned Parenthood*, the Court determined that, prior to fetal viability, a woman has the right to an abortion without being unduly burdened by government interference.[17] The Court concluded that the state may regulate the abortion as long as the regulation does not impose an undue burden on a woman's decision to choose an abortion.[18] If the purpose of a provision of law is to place substantial obstacles in the path of a woman seeking an abortion before viability, it is invalid; however, after viability the state may restrict abortions if the law contains exceptions for pregnancies endangering a woman's life or health.[19]

The unduly burdensome standard as applied in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, which is generally considered to be a hybrid between strict scrutiny and intermediate level scrutiny, shifted the Court's focus to whether a restriction creates a substantial obstacle to access. This is the prevailing standard today applied in cases in which abortion access is statutorily restricted.

However, the undue burden standard was held not to apply in Florida. The 1999 Legislature passed a parental notification law, the Parental Notice of Abortion Act, requiring a physician to give at least 48 hours of actual notice to one parent or to the legal guardian of a pregnant minor before terminating the pregnancy of the minor. Although a judicial waiver procedure was included, the act was never enforced.[20] In 2003, the Florida Supreme Court[21] ruled this legislation unconstitutional on the grounds that it violated a minor's right to privacy, as expressly protected under Article I, s. 23 of the Florida Constitution.[22] Citing the principle holding of *In re T.W.*,[23] the Court reiterated that, as the privacy right is a fundamental right in Florida, any restrictions on privacy warrant a strict scrutiny review, rather than that of an undue burden. Here, the Court held that the state failed to show a compelling state interest and therefore, the Court permanently enjoined the enforcement of the Parental Notice of Abortion Act.[24]

[14] 410 U.S. 113, 162-65 (1973).
[15] 410 U.S. 113, 152-56 (1973).
[16] 505 U.S. 833, 876-79 (1992).
[17] *Id.*
[18] *Id*.
[19] *Id.*
[20] *See* s. 390.01115, F.S. (repealed by s. 1, ch. 2005-52, Laws of Florida). Ch. 2005-52, Laws of Florida created s. 390.01114, F.S., the revised Parental Notice of Abortion Act.
[21] *North Florida Women's Health and Counseling Services, Inc., et al., v. State of Florida*, 866 So. 2d 612, 619-20 (Fla. 2003).
[22] The constitutional right of privacy provision reads: "Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law." FLA. CONST. art. I, s. 23.
[23] 551 So. 2d 1186, 1192 (Fla. 1989).
[24] *North Florida Women's Health and Counseling Services, supra* note 21, at 622 and 639-40.

Centers for Disease Control and Prevention (CDC)

The CDC began collecting abortion data (abortion surveillance) in 1969 to document the number and characteristics of women obtaining "legal induced" abortions. The CDC's surveillance system counts legal induced abortions only. For the CDC's surveillance purposes, legal abortion is defined as a procedure performed by a licensed physician, or a licensed advanced practice clinician acting under the supervision of a licensed physician, to induce the termination of a pregnancy.[25]

States and other territories voluntarily report data to the CDC for inclusion in its annual Abortion Surveillance Report.[26] The CDC's Division of Reproductive Health prepares surveillance reports as data becomes available. There is no national requirement for data submission or reporting.[27]

Those states requiring the reporting of information on induced abortions use various methods to collect the data. Some states include induced abortion reporting as a part of their fetal death reporting system, while a majority of states use a separate form, usually called Report of Induced Termination of Pregnancy, for the reporting of induced abortions. Regardless of the reporting system used, all states with reporting systems require the reporting of all induced abortions regardless of length of gestation.[28]

The CDC has developed a Standard Report of Induced Termination of Pregnancy to serve as a model for use by states. The model report suggests that the state's report should include the:[29]

- Facility name where the induced termination of pregnancy occurred.
- City, town, or location where the pregnancy termination occurred.
- County where the pregnancy termination occurred.
- Hospital, clinic, or other patient identification number, which would enable the facility or physician to access the medical file of the patient.
- Age of the patient in years at her last birthday.
- Marital status of the patient.
- Date of the pregnancy termination.
- Place the patient actually and physically lives or resides, which is not necessarily a patient's home state, voting residence, mailing address, or legal residence.
- Name of the state, county, and city where the patient lives.
- Number of the ZIP code where the patient lives.
- Origin of the patient, if Hispanic.
- Ancestry of the patient.
- Race of the patient.
- Highest level of education completed by the patient.

[25] Centers for Disease Control and Prevention, *CDC's Abortion Surveillance System FAQs*. Found at: <http://www.cdc.gov/reproductivehealth/Data_Stats/Abortion.htm> (Last visited on February 15, 2012).
[26] Florida does not report abortion data to the CDC. *Supra* fn. 6.
[27] *Supra* fn. 25.
[28] Centers for Disease Control and Prevention, *Handbook on the Reporting of Induced Termination of Pregnancy*, April 1998. Found at: <http://www.cdc.gov/nchs/data/misc/hb_itop.pdf> (Last visited on March 23, 2011).
[29] *Id.*

- Date the patient's last normal menstrual period began.
- Length of gestation as estimated by the attending physician.
- Number of previous pregnancies, including live births and other terminations.
- Type of termination procedure used.
- Name of the attending physician.
- Name of the person completing the report.

The CDC reports that its surveillance data is used to:[30]

- Identify characteristics of women who are at high risk of unintended pregnancy.
- Evaluate the effectiveness of programs for reducing teen pregnancies and unintended pregnancy among women of all ages.
- Calculate pregnancy rates based on the number of pregnancies ending in abortion in conjunction with birth data and fetal loss estimates.
- Monitor changes in clinical practice patterns related to abortion, such as changes in the types of procedures used, and weeks of gestation at the time of abortion.

Additionally, demographers use information in the report to calculate pregnancy rates, which are combined estimates of births and fetal loss and managers of public health programs use this data to evaluate the programs' effectiveness to prevent unintended pregnancy. There have historically been other data uses; such as, the calculation of the mortality rate of specific abortion procedures.

The CDC reports that in 2008,[31] there were 825,564 legal induced abortions reported to the CDC from 49 reporting areas. This represents essentially no change from the number of abortions reported in 2007. The abortion rate for 2008 was 16.0 abortions per 1,000 women aged 15 through 44 years. This also is also is unchanged from 2007. The abortion ratio was 234 abortions per 1,000 live births in 2008. This is a 1 percent increase from 2007. During 1999 through 2008, the reported abortion numbers, rates, and ratios decreased 3 percent, 4 percent, and 10 percent, respectively. During 1999 through 2008, women aged 20 to 29 years accounted for the majority of abortions. The majority (62.8 percent) of abortions in 2008 were performed at 8 weeks' gestation or less and 91.4 percent were performed at 13 weeks' gestation or less; 14.6 percent of all abortions were medical abortions.[32]

Health Care Practitioner Licensure Authority of the Department of Health

The Department of Health is responsible for the licensure of most health care practitioners in the state. Chapter 456, F.S., provides general provisions for the regulation of health care professions in addition to the regulatory authority in specific practice acts for each profession or occupation. Section 456.001(4), F.S., defines "health care practitioner" as any person licensed under:

- Chapter 457 (acupuncture),
- Chapter 458 (medical practice),
- Chapter 459 (osteopathic medicine),

[30] *Supra* fn. 25.
[31] This is the most recent data available on the CDC website, which is available at: <http://www.cdc.gov/reproductivehealth/Data_Stats/Abortion.htm> (Last visited on February 15, 2012).
[32] *Supra* fn. 25.

- Chapter 460 (chiropractic medicine),
- Chapter 461 (podiatric medicine),
- Chapter 462 (naturopathy),
- Chapter 463 (optometry),
- Chapter 464 (nursing),
- Chapter 465 (pharmacy),
- Chapter 466 (dentistry),
- Chapter 467 (midwifery),
- Part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468 (speech-language pathology and audiology; nursing home administration; occupational therapy; respiratory therapy; dietetics and nutrition practice; athletic trainers; and orthotics, prosthetics, and pedorthics),
- Chapter 478 (electrolysis),
- Chapter 480 (massage practice),
- Part III or part IV of chapter 483 (clinical laboratory personnel and medical physicists),
- Chapter 484 (dispensing of optical devices and hearing aids),
- Chapter 486 (physical therapy practice),
- Chapter 490 (psychological services), and
- Chapter 491 (clinical, counseling, and psychotherapy services)

III. Effect of Proposed Changes:

Section 1 amends s. 390.011, F.S., to define the terms "born alive," "health care practitioner," "medical emergency," and "viability." These definitions apply to all of ch. 390, F.S. The definition of "health care practitioner" is identical to the definition of the same term in s. 456.001(4), F.S., relating to health professions and occupations. The definition of "medical emergency" is being moved from s. 390.01114(2)(d), F.S., to this section. The definition of "viability" is being moved from s. 390.0111(4), F.S., to this section.

The bill also significantly modifies the definition of "partial-birth abortion" to conform to the federal ban on partial-birth abortion[33] which the United States Supreme Court has upheld.[34]

Section 2 amends s. 390.0111, F.S., to prohibit abortions from being performed after the period at which, in the physician's best medical judgment, the fetus has attained viability or during the third trimester of pregnancy. However, an abortion may be performed after viability or during the third trimester of pregnancy if two physicians certify in writing to the fact that, to a reasonable degree of medical probability, the abortion is necessary to prevent the death of the pregnant woman or the substantial and irreversible impairment of a major bodily function of the pregnant woman, or if one physician certifies in writing to the existence of a medical emergency[35] and another physician is not available for consultation.

[33] *Supra*, fn. 9.
[34] *Supra* fn.10.
[35] Section 390.011(8), F.S., in the bill, defines a "medical emergency" as a condition that, on the basis of a physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate termination of her pregnancy to avert her death, or for which a delay in the termination of her pregnancy will create serious risk of substantial and irreversible impairment of a major bodily function.

This section also requires:

- An abortion clinic that advertises its services to provide conspicuous notice on its premises and on advertisements that it is prohibited from performing abortions in the third trimester or after viability.
- Physicians who offer to perform or perform abortions in abortion clinics to annually complete at least 3 hours of continuing education that relate to ethics.
- Abortions to be performed in a hospital, validly licensed abortion clinic, or physician's office, unless the law specifically requires the abortion to be performed in a hospital or an emergency care situation exists.

The bill specifies that consent to an abortion is voluntary and informed only if the statutory requirements for informed consent are completed at least 24 hours before the abortion is performed. The bill provides that, if noncompliance by a physician with the consent requirements is necessary to prevent the death or irreversible impairment of a major bodily function of the pregnant woman, it is a defense to a disciplinary action under the physician's licensing statute.

The Department of Health is required to permanently revoke the license of a licensed health care practitioner who has been convicted or found guilty of, or entered a plea of guilty or nolo contendre to, regardless of adjudication, a felony criminal act for willfully performing an unlawful abortion.

The bill creates a new subsection regarding the rights of infants born alive subsequent to an attempted abortion. Such infants are entitled to the same rights, powers, and privileges as are granted to any other child born alive in the course of birth that is not subsequent to an attempted abortion. If an infant is born alive subsequent to an attempted abortion, any health care practitioner present at the time must humanely exercise the same degree of professional skill, care, and diligence to preserve the life and health of the infant as a reasonably diligent and conscientious health care practitioner would render to an infant born alive in the course of birth that is not subsequent to an attempted abortion. This provision is similar to the standard of medical care to be used during viability in subsection (4) of this section.

The bill specifies that, in the third trimester or after viability when two physicians determine that an abortion is necessary to prevent the death of the pregnant woman or the substantial and irreversible impairment of a major bodily function of the pregnant woman, the abortion may only be performed if a physician other than the physician performing the abortion is in attendance to take control of any infant born alive to provide immediate medical care to the infant. The physician who performs the abortion must take all reasonable steps consistent with the abortion procedure to preserve the life and health of the unborn child.

This section increases the penalty for a person who fails to dispose of fetal remains in an appropriate manner. The penalty is increased from a misdemeanor of a second degree to a misdemeanor of the first degree, punishable as provided in s. 775.082, F.S., or s. 775.083, F.S. (maximum imprisonment of 1 year or maximum fine of $1,000). In addition, it is a misdemeanor of the first degree for a person to advertise or facilitate an advertisement of services or drugs for the purpose of performing an abortion in violation of ch. 390, F.S. This is the existing statutory

prohibition contained in s. 797.02, F.S., which is being repealed in s. 14 of the bill. It is also a first degree misdemeanor to fail to provide notice in advertisements that the abortion clinic is prohibited from performing abortions in the third trimester or after the fetus has attained viability.

The AHCA is required to report, prior to each regular legislative session, aggregate statistical data that relates to abortions and does not contain any personal identifying information, which has been reported to the Division of Reproductive Health within the CDC, on its website. In addition, the AHCA must submit such information in an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

Section 3 amends s. 390.01114, F.S., to make conforming changes and to delete the definition of "medical emergency," which has been moved to s. 390.011(8), F.S., in the bill.

Section 4 amends s. 390.0112, F.S., to require the director of any hospital, validly licensed abortion clinic, or physician's office in which an abortion is performed to submit a report to the AHCA each month. The report must be on a form developed by the AHCA which is consistent with the U.S. Standard Report of Induced Termination of Pregnancy from the CDC. The AHCA is required to submit this reported information to the Division of Reproductive Health within the CDC. The bill authorizes the AHCA to adopt rules to administer this section.

Section 5 amends s. 390.012, F.S., to require the AHCA to adopt rules to prescribe standards for advertisements used by an abortion clinic by requiring the clinic to provide conspicuous notice on its premises and on its advertisements that it is prohibited from performing abortions in the third trimester or after viability of the fetus.

Section 6 amends s. 390.014, F.S., to incorporate the existing requirement contained in s. 797.03(2), F.S., that each abortion clinic hold a valid and current license. The bill requires abortion clinics to be wholly owned and operated by one or more physicians with residency training in dilation-and-curettage[36] and dilation-and-evacuation[37] procedures or by a professional corporation or limited liability company composed solely of one or more such physicians. This requirement does not apply to clinics licensed before July 1, 2012, or to the renewal of licenses held by such clinics. The willful violation of these licensure requirements is a first-degree misdemeanor, punishable as provided in s. 775.082, F.S., or s. 775.083, F.S. (maximum imprisonment of 1 year or maximum fine of $1,000).

Section 7 amends s. 390.018, F.S., to increase the fine that the AHCA may impose on abortion clinics for certain violations from $1,000 to $5,000.

[36] Dilation-and-curettage is a medical procedure in which the uterine cervix is dilated and a curette is inserted into the uterus to scrape away the endometrium, also known as a D&C. Merriam-Webster, MedlinePlus Medical Dictionary, available at: <http://www.merriam-webster.com/medlineplus/dilation-and-curettage> (Last visited on February 15, 2012).
[37] Dilation-and-evacuation is a surgical abortion that is typically performed midway during the second trimester of pregnancy and in which the uterine cervix is dilated and fetal tissue is removed using surgical instruments and suction, also called a D&E. Merriam-Webster, MedlinePlus Medical Dictionary, available at: <http://www.merriam-webster.com/medlineplus/dilation-and-evacuation%20> (Last visited on February 15, 2012).

Section 8 amends s. 456.013, F.S., to require physicians who offer to perform or perform abortions in an abortion clinic to annually complete a 3-hour course related to ethics as part of the licensure and renewal process as required in section 2 of the bill. This section clarifies that the 3-hour course must count toward the total number of continuing education hours required for the profession and the applicable board, or department if there is no board, must approve of the course.

Section 9 amends s. 765.113, F.S., relating to health care surrogates or proxies, to conform a cross-reference to reflect the movement of the definition of "viability" in the bill.

Sections 10-13 repeal ss. 782.30-782.36, F.S., the Partial-Birth Abortion Act, which has been held unconstitutional by federal trial courts in Florida.

Section 14 repeals s. 797.02, F.S., the provisions of which are transferred to ch. 390, F.S., in section 2 of the bill.

Section 15 repeals s. 797.03, F.S., the provisions of which are transferred to ch. 390, F.S., in section 2 of the bill.

Section 16 is an undesignated section of law that provides for the severability of any provision in the bill that is held invalid.

Section 17 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

If the bill, should it become law, is challenged as an invasion of privacy, it will be subject to a strict scrutiny review, rather than that of an undue burden test pursuant to *North Florida Women's Health and Counseling Services, Inc., et al., v. State of Florida*,[38] as

[38] 866 So. 2d 612 (Fla. 2003).

discussed above under the subheading, "Relevant Case Law." Otherwise, any challenge that does not impinge on a constitutional fundamental right will be subject to the "undue burden" standard announced in *Planned Parenthood of Southeastern Pennsylvania v. Casey*.[39]

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Abortion clinics may incur indeterminate costs associated with complying with the advertisement requirements, ownership requirements, and report requirements provided for in the bill.

C. Government Sector Impact:

The Department of Health will experience a recurring increase in workload associated with auditing physicians specified in the bill to ensure compliance with completion of a 3 hour ethics course annually and with additional complaints and investigations due to non-compliance. The department indicates that current resources are adequate to absorb these costs.

The AHCA expects a total of 80,000 individual reports of abortions to be submitted annually as a result of this bill. The agency's Office of Information Technology will need to update the current reporting system or develop a new system that will collect the additional data elements (age in years of the woman, gestational age in weeks at the time of abortion, race, ethnicity, method used, marital status, number of previous live births, number of previous abortions, and location of residence) and develop reports that will provide the information which is requested by the CDC. The AHCA estimates the cost to comply with the requirements of the bill to be $50,000. A $50,000 appropriation from the Health Care Trust Fund would be required to implement the bill. No appropriation is provided in the bill.

The Office of State Courts Administrator indicates that the bill would have little direct impact on either judicial time or court workload, except as necessary to ensure judges are familiar with changes in the law.

VI. Technical Deficiencies:

On line 350, the word "cause" should be "caused."

On line 395, the word "department" should be replaced with "board, or the department if there is no board." Sections 456.072, 458.331, and 459.015, F.S., give the authority to the respective

[39] 505 U.S. 833 (1992).

boards to impose discipline, particularly revocation. The only time the department handles licensure or disciplinary issues is when there is no board.

VII. Related Issues:

On line 351, the bill retains existing statutory language relating to a partial-birth abortion that is necessary to save the life of the mother, which is not included in the federal partial-birth abortion ban. The specific statutory language that is retained is "no other medical procedure would suffice for that purpose."

VIII. Additional Information:

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

None.

B. Amendments:

None.

406072

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/24/2012	.	
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete lines 200 - 203
and insert:
~~termination of pregnancy~~ is necessary to save the life or preserve the health of the pregnant woman; or

Delete lines 317 - 322
and insert:
~~complying~~ with the requirements of informed consent would threaten the life or health of the patient is a defense to any action brought under this paragraph.

406072

Delete lines 334 - 337
and insert:
this subsection, the woman's life and health shall constitute an overriding and superior

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete lines 19 - 32
and insert:
informed; conforming terminology; deleting the definition of the term "viability"; prohibiting a physician

604606

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/24/2012	.	
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete line 457
and insert:
(c) A person may not knowingly advertise, print, publish, distribute, or circulate, or knowingly cause to be advertised, printed, published, distributed, or circulated, any pamphlet, printed paper, book, newspaper notice, advertisement, or reference containing words or language giving or conveying any notice, hint, or reference to any person, or the name of any person, real or fictitious, from whom, or to any place, house, shop, or office where any advice, direction, information, or

604606

knowledge may be obtained for the purpose of not undergoing an abortion.
(d) Any person who violates this subsection commits a

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 66
and insert:
after viability; providing that is a first-degree misdemeanor to advertise how not to undergo an abortion; providing a penalty; requiring the

713996

LEGISLATIVE ACTION

Senate	.	House
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete lines 789 - 799
and insert:
issued by the agency. A person who willfully violates this subsection commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete lines 99 - 104.

773162

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/24/2012	.	
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with directory and title amendments)

Delete lines 797 - 799
and insert:
(7) A pregnancy resource center must be wholly owned and operated by one or more physicians who received residency training in performing dilation-and-curettage and dilation-and-evacuation procedures or by a professional corporation or limited liability company composed solely of one or more such physicians.
(8) A person who willfully violates subsection (5), subsection (6), or subsection (7) commits a misdemeanor of the

773162

first degree, punishable as provided in s. 775.082 or s. 775.083.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:
Delete lines 776 - 778
and insert:
Section 6. Subsection (1) of section 390.014, Florida Statutes, is amended, and subsections (5), (6), (7), and (8) are added to that section to read:

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:
Delete line 104
and insert:
one or more such physicians; providing an exception; requiring a pregnancy resource center to be owned and operated by a physician who has received training during residency in performing a dilation-and-curettage procedure or a dilation-and-evacuation procedure or by a corporation or limited liability company composed of one or more such physicians;

574642

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/24/2012	.	
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete line 861
and insert:
Section 17. A pregnancy resource center must provide medically accurate information to its clients. A person who knowingly violates this requirement commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, Florida Statutes.
Section 18. This act shall take effect July 1, 2012.

================ T I T L E A M E N D M E N T ================

574642

And the title is amended as follows:

Delete line 123

and insert:

penalties; providing for severability; requiring pregnancy resource centers to provide medically accurate information; providing a penalty; providing an

681218

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/24/2012	.	
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete line 861

and insert:

Section 17. A legislator who offers to vote or who votes on legislation relating to human reproduction must annually complete a minimum of 3 hours of continuing education related to ethics.

Section 18. This act shall take effect July 1, 2012.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

681218

Delete line 123
and insert:
penalties; providing for severability; requiring a legislator who offers to vote or votes on legislation relating to abortions to complete continuing education related to ethics; providing an

622450

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/24/2012	.	
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment

Delete line 861
and insert:
Section 17. This act shall take effect July 1, 2020.

518540

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/24/2012	.	
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	.	
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete line 861
and insert:
Section 17. A vasectomy or treatment for erectile dysfunction may not be performed except with the voluntary and informed consent of the patient, or in the case of a mental incompetent, the voluntary and informed written consent of his court-appointed guardian. Except in the case of a medical emergency, consent to a vasectomy or treatment for erectile dysfunction is voluntary and informed only if the physician orally, in person, informs the patient of the nature and risks

518540

of undergoing or not undergoing the proposed procedure or treatment which a reasonable patient would consider material to making a knowing and willful decision at least 24 hours before the vasectomy is performed or the treatment is provided.
Section 18. This act shall take effect July 1, 2012.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 2
and insert:
An act relating to reproductive health; amending s. 390.011,

Delete line 123
and insert:
penalties; providing for severability; requiring that certain requirements be completed 24 hours before a vasectomy or treatment for erectile dysfunction is performed in order for the consent to be considered voluntary and informed; providing an

By Senator Flores

38-00165D-12 2012290__

A bill to be entitled

An act relating to abortions; amending s. 390.011, F.S.; providing definitions; amending s. 390.0111, F.S.; conforming terminology to changes made by the act; restricting the circumstances in which an abortion may be performed in the third trimester or after viability; providing certain physician and location requirements with regard to performing abortions; requiring a physician who offers to perform or who performs abortions to complete continuing education related to ethics; prohibiting an abortion from being performed in the third trimester in a location other than a hospital; prohibiting any abortion from being performed in a location other than a hospital, abortion clinic, or physician's office; requiring that certain requirements be completed 24 hours before an abortion is performed in order for consent to an abortion to be considered voluntary and informed; conforming terminology; providing that substantial compliance or reasonable belief that noncompliance with the requirements regarding consent is necessary to prevent the death of the pregnant woman or a substantial and irreversible impairment of a major bodily function of the pregnant woman is a defense to a disciplinary action under s. 458.331 or s. 459.015, F.S.; deleting the definition of the term "viability"; providing that the prevention of the death or a substantial and irreversible impairment of a major bodily function of the pregnant woman

38-00165D-12 2012290__

constitutes an overriding and superior consideration to the concern for the life and health of the fetus under certain circumstances; prohibiting a physician from knowingly performing a partial-birth abortion and thereby killing a human fetus; providing exceptions for when a partial-birth abortion is necessary; increasing the penalty imposed for failing to properly dispose of fetal remains; requiring the Department of Health to permanently revoke the license of any health care practitioner who is convicted or found guilty of, or enters a plea of guilty or nolo contendere to, regardless of adjudication, certain felony criminal acts; providing that an infant born alive subsequent to an attempted abortion is entitled to the same rights, powers, and privileges as are granted by the laws of this state; requiring a health care practitioner to exercise the same degree of professional skill, care, and diligence to preserve the life and health of an infant as a reasonably diligent and conscientious health care practitioner would render to any infant born alive if the infant is born alive subsequent to an attempted abortion; requiring that another physician be present in order to take control of any infant born alive; requiring the physician who performs the abortion to take all reasonable steps consistent with the abortion procedure to preserve the life and health of the unborn child; requiring a health care practitioner who has knowledge of any violations to report the

violations to the department; providing that it is a first-degree misdemeanor to unlawfully advertise how to obtain an abortion; requiring an abortion clinic to place a conspicuous notice on its premises and on any form or medium of advertisement of the abortion clinic which states that the abortion clinic is prohibited from performing abortions in the third trimester or after viability; providing a penalty; requiring the Agency for Health Care Administration to submit to the Governor and Legislature an annual report of aggregate statistical data relating to abortions and provide such data on its website; amending s. 390.01114, F.S.; conforming terminology to changes made by the act; deleting the definition of the term "medical emergency"; amending s. 390.0112, F.S.; requiring the director of a hospital, abortion clinic, or physician's office to submit a monthly report to the agency on a form developed by the agency which is consistent with the U.S. Standard Report of Induced Termination of Pregnancy from the Centers for Disease Control and Prevention; requiring that the submitted report not contain any personal identifying information; requiring the agency to submit reported data to the Division of Reproductive Health within the Centers for Disease Control and Prevention; requiring the physician performing the abortion procedure to report such data if the abortion was performed in a hospital, abortion clinic, or physician's office; requiring the agency to adopt rules; amending s.

390.012, F.S.; conforming a cross-reference; requiring the agency to adopt rules that prescribe standards for placing conspicuous notice to be provided on the premises and on any advertisement of an abortion clinic which states that the abortion clinic is prohibited from performing abortions in the third trimester or after viability; conforming terminology to changes made by the act; amending s. 390.014, F.S.; prohibiting a person from establishing, conducting, managing, or operating a clinic in this state without a valid and current license issued by the agency; requiring an abortion clinic to be owned and operated by a physician who has received training during residency in performing a dilation-and-curettage procedure or a dilation-and-evacuation procedure or by a corporation or limited liability company composed of one or more such physicians; providing an exception; providing a penalty; amending s. 390.018, F.S.; revising the amount of the fine that the agency may impose for a violation of ch. 390, F.S., relating to abortion, or part II of ch. 408, F.S., relating to licensure; amending s. 456.013, F.S.; requiring that each applicable board require a physician who offers to perform or performs abortions to annually complete a course relating to ethics as part of the licensure and renewal process; providing that the course counts toward the total number of continuing education hours required for the profession; requiring the applicable board to approve the course; amending s. 765.113,

F.S.; conforming a cross-reference; repealing ss. 782.30, 782.32, 782.34, and 782.36, F.S., relating to the Partial-Birth Abortion Act; repealing s. 797.02, F.S., relating to the advertising of drugs for abortions; repealing s. 797.03, F.S., relating to prohibited acts related to abortions and their penalties; providing for severability; providing an effective date.

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

Section 1. Section 390.011, Florida Statutes, is amended to read:

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

(1) "Abortion" means the termination of human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.

(2) "Abortion clinic" or "clinic" means any facility in which abortions are performed. The term does not include:

(a) A hospital; or

(b) A physician's office, provided that the office is not used primarily for the performance of abortions.

(3) "Agency" means the Agency for Health Care Administration.

(4) "Born alive" means the complete expulsion or extraction from the mother of a human infant, at any stage of development, who, after such expulsion or extraction, breathes or has a beating heart, pulsation of the umbilical cord, or definite and voluntary movement of muscles, regardless of whether the

umbilical cord has been cut and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, induced abortion, or other method.

(5)~~(4)~~ "Department" means the Department of Health.

(6) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

(7)~~(5)~~ "Hospital" means a facility as defined in s. 395.002(12) and licensed under chapter 395 and part II of chapter 408.

(8) "Medical emergency" means a condition that, on the basis of a physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate termination of her pregnancy to avert her death, or for which a delay in the termination of her pregnancy will create serious risk of substantial and irreversible impairment of a major bodily function.

(9)~~(6)~~ "Partial-birth abortion" means an abortion ~~a termination of pregnancy~~ in which the physician performing the abortion: ~~termination of pregnancy partially vaginally delivers a living fetus before killing the fetus and completing the delivery.~~

(a) Deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in

the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and

(b) Performs the overt act, other than completion of delivery, which kills the partially delivered living fetus.

(10)~~(7)~~ "Physician" means a physician licensed under chapter 458 or chapter 459 or a physician practicing medicine or osteopathic medicine in the employment of the United States.

(11)~~(8)~~ "Third trimester" means the weeks of pregnancy after the 24th week of pregnancy.

(12) "Viability" means that stage of fetal development when the life of the unborn child may, with a reasonable degree of medical probability, be continued indefinitely outside the womb.

Section 2. Section 390.0111, Florida Statutes, is amended to read:

390.0111 Abortions ~~Termination of pregnancies~~.—

(1) ABORTION ~~TERMINATION~~ IN THIRD TRIMESTER OR AFTER VIABILITY~~; WHEN ALLOWED~~.—An abortion may not ~~No termination of pregnancy shall~~ be performed ~~on any human being~~ in the third trimester or after the period at which, in the best medical judgment of the physician, the fetus has attained viability ~~of pregnancy~~ unless:

(a) Two physicians certify in writing to the fact that, to a reasonable degree of medical probability, the abortion ~~termination of pregnancy~~ is necessary to prevent the death of the pregnant woman or the substantial and irreversible impairment of a major bodily function ~~save the life or preserve the health~~ of the pregnant woman; or

(b) The physician certifies in writing to the existence of a medical emergency ~~medical necessity for legitimate emergency medical procedures for termination of pregnancy in the third trimester~~, and another physician is not available for consultation.

(2) PHYSICIAN AND LOCATION REQUIREMENTS ~~PERFORMANCE BY PHYSICIAN REQUIRED~~.—

(a) An abortion may not ~~No termination of pregnancy shall~~ be performed at any time except by a physician ~~as defined in s. 390.011~~.

(b) A physician who offers to perform or who performs abortions in an abortion clinic must annually complete a minimum of 3 hours of continuing education related to ethics.

(c) Except in the case of a medical emergency, an abortion may not be performed:

1. In the third trimester, or after the fetus has attained viability, in a location other than in a hospital.

2. In cases in which subparagraph 1. does not apply, in a location other than a hospital, a validly licensed abortion clinic, or a physician's office.

(3) CONSENTS REQUIRED.—An abortion ~~A termination of pregnancy~~ may not be performed or induced except with the voluntary and informed written consent of the pregnant woman or, in the case of a mental incompetent, the voluntary and informed written consent of her court-appointed guardian.

(a) Except in the case of a medical emergency, consent to an abortion ~~a termination of pregnancy~~ is voluntary and informed only if the following requirements are completed at least 24 hours before the abortion is performed:

1. The physician who is to perform the procedure, or the referring physician, has, at a minimum, orally, in person, informed the woman of:

a. The nature and risks of undergoing or not undergoing the proposed procedure which ~~that~~ a reasonable patient would consider material to making a knowing and willful decision of whether to obtain an abortion ~~terminate a pregnancy~~.

b. The probable gestational age of the fetus, verified by an ultrasound, at the time the abortion ~~termination of pregnancy~~ is to be performed.

(I) The ultrasound must be performed by the physician who is to perform the abortion or by a person having documented evidence that he or she has completed a course in the operation of ultrasound equipment as prescribed by rule and who is working in conjunction with the physician.

(II) The person performing the ultrasound must offer the woman the opportunity to view the live ultrasound images and hear an explanation of them. If the woman accepts the opportunity to view the images and hear the explanation, a physician or a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant working in conjunction with the physician must contemporaneously review and explain the images to the woman before the woman gives informed consent to having an abortion procedure performed.

(III) The woman has a right to decline to view and hear the explanation of the live ultrasound images after she is informed of her right and offered an opportunity to view the images and hear the explanation. If the woman declines, the woman shall

complete a form acknowledging that she was offered an opportunity to view and hear the explanation of the images but that she declined that opportunity. The form must also indicate that the woman's decision was not based on any undue influence from any person to discourage her from viewing the images or hearing the explanation and that she declined of her own free will.

(IV) Unless requested by the woman, the person performing the ultrasound may not offer the opportunity to view the images and hear the explanation and the explanation may not be given if, at the time the woman schedules or arrives for her appointment to obtain an abortion, a copy of a restraining order, police report, medical record, or other court order or documentation is presented which provides evidence that the woman is obtaining the abortion because the woman is a victim of rape, incest, domestic violence, or human trafficking or that the woman has been diagnosed as having a condition that, on the basis of a physician's good faith clinical judgment, would create a serious risk of substantial and irreversible impairment of a major bodily function if the woman delayed terminating her pregnancy.

c. The medical risks to the woman and fetus of carrying the pregnancy to term.

2. Printed materials prepared and provided by the department have been provided to the pregnant woman, if she chooses to view these materials, including:

a. A description of the fetus, including a description of the various stages of development.

b. A list of entities that offer alternatives to abortion

~~terminating the pregnancy~~.

c. Detailed information on the availability of medical assistance benefits for prenatal care, childbirth, and neonatal care.

3. The woman acknowledges in writing~~, before the termination of pregnancy,~~ that the information required to be provided under this subsection has been provided.

~~Nothing in~~ This paragraph does not ~~is intended to~~ prohibit a physician from providing any additional information that ~~which~~ the physician deems material to the woman's informed decision to obtain an abortion ~~terminate her pregnancy~~.

(b) If a medical emergency exists and a physician cannot comply with the requirements for informed consent, a physician may perform an abortion ~~terminate a pregnancy~~ if he or she has obtained at least one corroborative medical opinion attesting to the medical necessity for emergency medical procedures and to the fact that to a reasonable degree of medical certainty the continuation of the pregnancy would threaten the life of the pregnant woman. If a second physician is not available for a corroborating opinion, the physician may proceed but shall document reasons for the medical necessity in the patient's medical records.

(c) Violation of this subsection by a physician constitutes grounds for disciplinary action under s. 458.331 or s. 459.015. Substantial compliance or reasonable belief that noncompliance ~~complying~~ with the requirements of this subsection is necessary to prevent the death of the pregnant woman or a substantial and irreversible impairment of a major bodily function of the

pregnant woman ~~informed consent would threaten the life or health of the patient~~ is a defense to any action brought under this paragraph.

(4) STANDARD OF MEDICAL CARE TO BE USED DURING VIABILITY.—If an abortion ~~a termination of pregnancy~~ is performed during viability, a ~~no~~ person who performs or induces the abortion ~~termination of pregnancy~~ shall ~~fail to~~ use that degree of professional skill, care, and diligence to preserve the life and health of the fetus which such person would be required to exercise in order to preserve the life and health of any fetus intended to be born and not aborted. ~~"Viability" means that stage of fetal development when the life of the unborn child may with a reasonable degree of medical probability be continued indefinitely outside the womb.~~ Notwithstanding the provisions of this subsection, the prevention of the death of the pregnant woman or a substantial and irreversible impairment of a major bodily function of the pregnant woman constitutes ~~the woman's life and health shall constitute~~ an overriding and superior consideration to the concern for the life and health of the fetus when such concerns are in conflict.

(5) PARTIAL-BIRTH ABORTION PROHIBITED; EXCEPTION.—

(a) A ~~No~~ physician may not ~~shall~~ knowingly perform a partial-birth abortion and thereby kill a human fetus.

(b) A woman upon whom a partial-birth abortion is performed may not be prosecuted under this section for a conspiracy to violate the provisions of this section.

(c) This subsection does ~~shall~~ not apply to a partial-birth abortion that is necessary to save the life of a mother whose life is endangered by a physical disorder, physical illness, or

physical injury, including a life-endangering physical condition cause by or arising from the pregnancy itself, if ~~provided that~~ no other medical procedure would suffice for that purpose.

(6) EXPERIMENTATION ON FETUS PROHIBITED; EXCEPTION.—A ~~No~~ person may not ~~shall~~ use any live fetus or live, premature infant for any type of scientific, research, laboratory, or other kind of experimentation before ~~either prior to~~ or subsequent to any abortion ~~termination of pregnancy~~ procedure except as necessary to protect or preserve the life and health of such fetus or premature infant.

(7) FETAL REMAINS.—Fetal remains shall be disposed of in a sanitary and appropriate manner and in accordance with standard health practices, as provided by rule of the department ~~of Health~~. Failure to dispose of fetal remains in accordance with department rules is a misdemeanor of the first ~~second~~ degree, punishable as provided in s. 775.082 or s. 775.083.

(8) REFUSAL TO PARTICIPATE IN ABORTION ~~TERMINATION~~ PROCEDURE.~~ Nothing in~~ This section does not ~~shall~~ require any hospital or any person to participate in an abortion ~~the termination of a pregnancy~~, and a ~~nor shall any~~ hospital or ~~any~~ person is not ~~be~~ liable for such refusal. A ~~No~~ person who is a member of, or associated with, the staff of a hospital, or ~~nor~~ any employee of a hospital or physician in which or by whom the abortion ~~termination of a pregnancy~~ has been authorized or performed, who states ~~shall state~~ an objection to such procedure on moral or religious grounds is not ~~shall be~~ required to participate in the procedure that ~~which~~ will result in the abortion ~~termination of pregnancy~~. The refusal of any such person or employee to participate does ~~shall~~ not form the basis

for any disciplinary or other recriminatory action against such person.

(9) EXCEPTION.—The provisions of this section do ~~shall~~ not apply to the performance of a procedure that ~~which~~ terminates a pregnancy in order to deliver a live child.

(10) PENALTIES FOR VIOLATION.— Except as provided in subsections (3) and (7):

(a) Any person who willfully performs, or actively participates in, an abortion ~~a termination of pregnancy~~ procedure in violation of the requirements of this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) Any person who performs, or actively participates in, an abortion ~~a termination of pregnancy~~ procedure in violation of ~~the provisions of~~ this section which results in the death of the woman commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) The department shall permanently revoke the license of any licensed health care practitioner who has been convicted or found guilty of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony as provided in this subsection.

(11) CIVIL ACTION PURSUANT TO PARTIAL-BIRTH ABORTION; RELIEF.—

(a) The father, if married to the mother at the time she receives a partial-birth abortion, and, if the mother has not attained the age of 18 years at the time she receives a partial-birth abortion, the maternal grandparents of the fetus may, in a civil action, obtain appropriate relief, unless the pregnancy

resulted from the plaintiff's criminal conduct or the plaintiff consented to the abortion.

(b) In a civil action under this section, appropriate relief includes:

1. Monetary damages for all injuries, psychological and physical, occasioned by the violation of subsection (5).

2. Damages equal to three times the cost of the partial-birth abortion.

(12) INFANTS BORN ALIVE.—

(a) An infant born alive subsequent to an attempted abortion is entitled to the same rights, powers, and privileges as are granted by the laws of this state to any other child born alive in the course of birth that is not subsequent to an attempted abortion.

(b) If an infant is born alive subsequent to an attempted abortion, any health care practitioner present at the time shall humanely exercise the same degree of professional skill, care, and diligence to preserve the life and health of the infant as a reasonably diligent and conscientious health care practitioner would render to an infant born alive in the course of birth that is not subsequent to an attempted abortion.

(c) An abortion may not be attempted pursuant to paragraph (1)(a) unless a physician other than the physician performing the abortion is in attendance to take control of any infant born alive, to provide immediate medical care to the infant, and to discharge the obligations imposed by paragraph (b). The physician who performs the abortion shall take all reasonable steps consistent with the abortion procedure to preserve the life and health of the unborn child.

(d) A health care practitioner who has knowledge of a violation of this subsection shall report the violation to the department.

(13) PUBLIC NOTICES AND ADVERTISEMENTS.—

(a) A person may not knowingly advertise, print, publish, distribute, or circulate, or knowingly cause to be advertised, printed, published, distributed, or circulated, any pamphlet, printed paper, book, newspaper notice, advertisement, or reference containing words or language giving or conveying any notice, hint, or reference to any person, or the name of any person, real or fictitious, from whom, or to any place, house, shop, or office where any poison, drug, mixture, preparation, medicine, or noxious thing, or any instrument or means whatever, or any advice, direction, information, or knowledge that may be obtained for the purpose of performing an abortion in violation of this chapter.

(b) An abortion clinic must provide conspicuous written notice on its premises and on any advertisement that the abortion clinic is prohibited, except in a medical emergency, from performing abortions in the third trimester or after the fetus has attained viability.

(c) Any person who violates this subsection commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(14) RESPONSIBILITIES OF THE AGENCY.—Before each regular legislative session, the agency shall report aggregate statistical data relating to abortions, which has been reported to the Division of Reproductive Health within the Centers for Disease Control and Prevention, on its website and provide an

annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding such data. Any information required to be reported under this subsection must not include any personal identifying information.

(15)~~(12)~~ FAILURE TO COMPLY.—Failure to comply with the requirements of this section constitutes grounds for disciplinary action under each respective practice act and under s. 456.072.

(16)~~(13)~~ RULES.—The applicable boards, or the department if there is no board, shall adopt rules necessary to implement the provisions of this section.

Section 3. Section 390.01114, Florida Statutes, is amended to read:

390.01114 Parental Notice of Abortion Act.—

(1) SHORT TITLE.—This section may be cited as the "Parental Notice of Abortion Act."

(2) DEFINITIONS.—As used in this section, the term:

(a) "Actual notice" means notice that is given directly, in person or by telephone, to a parent or legal guardian of a minor, by a physician, at least 48 hours before the inducement or performance of an abortion ~~a termination of pregnancy~~, and documented in the minor's files.

(b) "Child abuse" means abandonment, abuse, harm, mental injury, neglect, physical injury, or sexual abuse of a child as those terms are defined in ss. 39.01, 827.04, and 984.03.

(c) "Constructive notice" means notice that is given in writing, signed by the physician, and mailed at least 72 hours before the inducement or performance of the abortion ~~termination of pregnancy~~, to the last known address of the parent or legal

guardian of the minor, by first-class mail and by certified mail, return receipt requested, and delivery restricted to the parent or legal guardian. After the 72 hours have passed, delivery is deemed to have occurred.

~~(d) "Medical emergency" means a condition that, on the basis of a physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate termination of her pregnancy to avert her death, or for which a delay in the termination of her pregnancy will create serious risk of substantial and irreversible impairment of a major bodily function.~~

(d)~~(e)~~ "Sexual abuse" has the meaning ascribed in s. 39.01.

(e)~~(f)~~ "Minor" means a person under the age of 18 years.

(3) NOTIFICATION REQUIRED.—

(a) Actual notice shall be provided by the physician performing or inducing an abortion with respect to ~~the termination of pregnancy before the performance or inducement of the termination of~~ the pregnancy of a minor. The notice may be given by a referring physician. The physician who performs or induces the abortion ~~termination of pregnancy~~ must receive the written statement of the referring physician certifying that the referring physician has given notice. If actual notice is not possible after a reasonable effort has been made, the physician performing or inducing the abortion ~~termination of pregnancy~~ or the referring physician must give constructive notice. Notice given under this subsection by the physician performing or inducing the abortion ~~termination of pregnancy~~ must include the name and address of the facility providing the abortion ~~termination of pregnancy~~ and the name of the physician providing

notice. Notice given under this subsection by a referring physician must include the name and address of the facility where he or she is referring the minor and the name of the physician providing notice. If actual notice is provided by telephone, the physician must actually speak with the parent or guardian, and must record in the minor's medical file the name of the parent or guardian provided notice, the phone number dialed, and the date and time of the call. If constructive notice is given, the physician must document that notice by placing copies of any document related to the constructive notice, including, but not limited to, a copy of the letter and the return receipt, in the minor's medical file. Actual notice given by telephone shall be confirmed in writing, signed by the physician, and mailed to the last known address of the parent or legal guardian of the minor, by first-class mail and by certified mail, return receipt requested, with delivery restricted to the parent or legal guardian.

(b) Notice is not required if:

1. In the physician's good faith clinical judgment, a medical emergency exists and there is insufficient time for the attending physician to comply with the notification requirements. If a medical emergency exists, the physician shall make reasonable attempts, whenever possible, without endangering the minor, to contact the parent or legal guardian, and may proceed, but must document reasons for the medical necessity in the patient's medical records. The physician shall provide notice directly, in person or by telephone, to the parent or legal guardian, including details of the medical emergency and any additional risks to the minor. If the parent or legal

guardian has not been notified within 24 hours after the abortion ~~termination of the pregnancy~~, the physician shall provide notice in writing, including details of the medical emergency and any additional risks to the minor, signed by the physician, to the last known address of the parent or legal guardian of the minor, by first-class mail and by certified mail, return receipt requested, with delivery restricted to the parent or legal guardian;

2. Notice is waived in writing by the person who is entitled to notice and such waiver is notarized, dated not more than 30 days before the abortion ~~termination of pregnancy~~, and contains a specific waiver of the right of the parent or legal guardian to notice of the minor's abortion ~~termination of pregnancy~~;

3. Notice is waived by the minor who is or has been married or has had the disability of nonage removed under s. 743.015 or a similar statute of another state;

4. Notice is waived by the patient because the patient has a minor child dependent on her; or

5. Notice is waived under subsection (4).

(c) Violation of this subsection by a physician constitutes grounds for disciplinary action under s. 458.331 or s. 459.015.

(4) PROCEDURE FOR JUDICIAL WAIVER OF NOTICE.—

(a) A minor may petition any circuit court in which the minor resides for a waiver of the notice requirements of subsection (3) and may participate in proceedings on her own behalf. The petition may be filed under a pseudonym or through the use of initials, as provided by court rule. The petition must include a statement that the petitioner is pregnant and

notice has not been waived. The court shall advise the minor that she has a right to court-appointed counsel and shall provide her with counsel upon her request at no cost to the minor.

(b)1. Court proceedings under this subsection must be given precedence over other pending matters to the extent necessary to ensure that the court reaches a decision promptly. The court shall rule, and issue written findings of fact and conclusions of law, within 3 business days after the petition is filed, except that the 3-business-day limitation may be extended at the request of the minor. If the court fails to rule within the 3-business-day period and an extension has not been requested, the minor may immediately petition for a hearing upon the expiration of the 3-business-day period to the chief judge of the circuit, who must ensure a hearing is held within 48 hours after receipt of the minor's petition and an order is entered within 24 hours after the hearing.

2. If the circuit court does not grant judicial waiver of notice, the minor has the right to appeal. An appellate court must rule within 7 days after receipt of appeal, but a ruling may be remanded with further instruction for a ruling within 3 business days after the remand. The reason for overturning a ruling on appeal must be based on abuse of discretion by the court and may not be based on the weight of the evidence presented to the circuit court since the proceeding is a nonadversarial proceeding.

(c) If the court finds, by clear and convincing evidence, that the minor is sufficiently mature to decide whether to obtain an abortion ~~terminate her pregnancy~~, the court shall

issue an order authorizing the minor to consent to the performance or inducement of an abortion ~~a termination of pregnancy~~ without the notification of a parent or guardian. If the court does not make the finding specified in this paragraph or paragraph (d), it must dismiss the petition. Factors the court shall consider include:

1. The minor's:

a. Age.

b. Overall intelligence.

c. Emotional development and stability.

d. Credibility and demeanor as a witness.

e. Ability to accept responsibility.

f. Ability to assess both the immediate and long-range consequences of the minor's choices.

g. Ability to understand and explain the medical risks of an abortion ~~terminating her pregnancy~~ and to apply that understanding to her decision.

2. Whether there may be any undue influence by another on the minor's decision to have an abortion.

(d) If the court finds, by a preponderance of the evidence, that the petitioner is the victim of child abuse or sexual abuse inflicted by one or both of her parents or her guardian, or by clear and convincing evidence that the notification of a parent or guardian is not in the best interest of the petitioner, the court shall issue an order authorizing the minor to consent to the performance or inducement of an abortion ~~a termination of pregnancy~~ without the notification of a parent or guardian. The best-interest standard does not include financial best interest or financial considerations or the potential financial impact on

the minor or the minor's family if the minor does not obtain the abortion ~~terminate the pregnancy~~. If the court finds evidence of child abuse or sexual abuse of the minor petitioner by any person, the court shall report the evidence of child abuse or sexual abuse of the petitioner, as provided in s. 39.201. If the court does not make the finding specified in this paragraph or paragraph (c), it must dismiss the petition.

(e) A court that conducts proceedings under this section shall:

1. Provide for a written transcript of all testimony and proceedings;

2. Issue a final written order containing factual findings and legal conclusions supporting its decision, including factual findings and legal conclusions relating to the maturity of the minor as provided under paragraph (c); and

3. Order that a confidential record be maintained, as required under s. 390.01116.

(f) All hearings under this section, including appeals, shall remain confidential and closed to the public, as provided by court rule.

(g) An expedited appeal shall be made available, as the Supreme Court provides by rule, to any minor to whom the circuit court denies a waiver of notice. An order authorizing an abortion ~~a termination of pregnancy~~ without notice is not subject to appeal.

(h) Filing fees or court costs may not be required of any pregnant minor who petitions a court for a waiver of parental notification under this subsection at either the trial or the appellate level.

(i) A county is not obligated to pay the salaries, costs, or expenses of any counsel appointed by the court under this subsection.

(5) PROCEEDINGS.—The Supreme Court is requested to adopt rules and forms for petitions to ensure that proceedings under subsection (4) are handled expeditiously and in a manner consistent with this act. The Supreme Court is also requested to adopt rules to ensure that the hearings protect the minor's confidentiality and the confidentiality of the proceedings.

(6) REPORT.—The Supreme Court, through the Office of the State Courts Administrator, shall report by February 1 of each year to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the number of petitions filed under subsection (4) for the preceding year, and the timing and manner of disposal of such petitions by each circuit court. For each petition resulting in a waiver of notice, the reason for the waiver shall be included in the report.

Section 4. Section 390.0112, Florida Statutes, is amended to read:

390.0112 Abortions ~~Termination of pregnancies~~; reporting.—

(1) The director of any hospital, validly licensed abortion clinic, or physician's office ~~medical facility~~ in which an abortion is performed ~~any pregnancy is terminated~~ shall submit a ~~monthly~~ report each month to the agency on a form developed by the agency which is consistent with the U.S. Standard Report of Induced Termination of Pregnancy from the Centers for Disease Control and Prevention. The report must not contain any personal identifying information ~~which contains the number of procedures~~

~~performed, the reason for same, and the period of gestation at the time such procedures were performed to the agency~~. The agency shall be responsible for keeping such reports in a central place from which statistical data and analysis can be made. The agency shall submit reported data to the Division of Reproductive Health within the Centers for Disease Control and Prevention.

(2) If the abortion ~~termination of pregnancy~~ is not performed in a hospital, validly licensed abortion clinic, or physician's office ~~medical facility~~, the physician performing the procedure shall report ~~be responsible for reporting~~ such information as required in subsection (1).

(3) Reports submitted pursuant to this section shall be confidential and exempt from the provisions of s. 119.07(1) and shall not be revealed except upon the order of a court of competent jurisdiction in a civil or criminal proceeding or as required in subsection (1).

(4) Any person required under this section to file a report or keep any records who willfully fails to file such report or keep such records may be subject to a $200 fine for each violation. The agency shall ~~be required to~~ impose such fines when reports or records required under this section have not been timely received. For purposes of this section, timely received is defined as 30 days following the preceding month.

(5) The agency may adopt rules necessary to administer this section.

Section 5. Paragraphs (b) and (c) of subsection (1), paragraph (a) of subsection (3), and subsection (6) of section 390.012, Florida Statutes, are amended to read:

390.012 Powers of agency; rules; disposal of fetal remains.—

(1) The agency may develop and enforce rules pursuant to ss. 390.011-390.018 and part II of chapter 408 for the health, care, and treatment of persons in abortion clinics and for the safe operation of such clinics.

(b) The rules shall be in accordance with s. 390.0111(2) ~~s. 797.03~~ and may not impose an unconstitutional burden on a woman's freedom to decide whether to obtain an abortion ~~terminate her pregnancy~~.

(c) The rules shall provide for:

1. The performance of abortion ~~pregnancy termination~~ procedures only by a licensed physician.

2. The making, protection, and preservation of patient records, which shall be treated as medical records under chapter 458.

(3) For clinics that perform or claim to perform abortions after the first trimester of pregnancy, the agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter, including the following:

(a) Rules for an abortion clinic's physical facilities. At a minimum, these rules shall prescribe standards for:

1. Adequate private space that is specifically designated for interviewing, counseling, and medical evaluations.

2. Dressing rooms for staff and patients.

3. Appropriate lavatory areas.

4. Areas for preprocedure hand washing.

5. Private procedure rooms.

6. Adequate lighting and ventilation for abortion

procedures.

7. Surgical or gynecological examination tables and other fixed equipment.

8. Postprocedure recovery rooms that are equipped to meet the patients' needs.

9. Emergency exits to accommodate a stretcher or gurney.

10. Areas for cleaning and sterilizing instruments.

11. Adequate areas for the secure storage of medical records and necessary equipment and supplies.

12. The display in the abortion clinic, in a place that is conspicuous to all patients, of the clinic's current license issued by the agency.

13. Conspicuous written notice to be provided on the premises and on any advertisement of the abortion clinic, which must state that the abortion clinic is prohibited, except in a medical emergency, from performing abortions in the third trimester or after the fetus has attained viability.

(6) The agency may adopt and enforce rules, in the interest of protecting the public health, to ensure the prompt and proper disposal of fetal remains and tissue resulting from an abortion ~~pregnancy termination~~.

Section 6. Subsection (1) of section 390.014, Florida Statutes, is amended, and subsections (5), (6), and (7) are added to that section to read:

390.014 Licenses; fees.—

(1) The requirements of part II of chapter 408 ~~shall~~ apply to the provision of services that require licensure pursuant to ss. 390.011-390.018 and part II of chapter 408 and to entities licensed by or applying for such licensure from the agency ~~for~~

~~Health Care Administration~~ pursuant to ss. 390.011-390.018. ~~A license issued by the agency is required in order to operate a clinic in this state.~~

(5) A person may not establish, conduct, manage, or operate a clinic in this state without a valid and current license issued by the agency.

(6) A clinic must be wholly owned and operated by one or more physicians who received residency training in performing dilation-and-curettage and dilation-and-evacuation procedures or by a professional corporation or limited liability company composed solely of one or more such physicians. This subsection does not apply to clinics licensed before July 1, 2012, or to the renewal of licenses held by such clinics.

(7) A person who willfully violates subsection (5) or subsection (6) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 7. Section 390.018, Florida Statutes, is amended to read:

390.018 Administrative fine.—In addition to the requirements of part II of chapter 408, the agency may impose a fine upon the clinic in an amount not to exceed $5,000 ~~$1,000~~ for each violation of any provision of this chapter, part II of chapter 408, or applicable rules.

Section 8. Subsection (7) of section 456.013, Florida Statutes, is amended to read:

456.013 Department; general licensing provisions.—

(7)(a) The boards, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the licensure and

renewal process. The 2-hour course shall count towards the total number of continuing education hours required for the profession. The course shall be approved by the board or department, as appropriate, and shall include a study of root-cause analysis, error reduction and prevention, and patient safety. In addition, the course approved by the Board of Medicine and the Board of Osteopathic Medicine shall include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed pursuant to chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

(b) In accordance with s. 390.0111, the board, or the department if there is no board, shall require a physician who offers to perform or performs abortions in an abortion clinic to annually complete a 3-hour course related to ethics as part of the licensure and renewal process. The 3-hour course shall count toward the total number of continuing education hours required for the profession. The applicable board, or the department if there is no board, shall approve the course, as appropriate.

Section 9. Section 765.113, Florida Statutes, is amended to read:

765.113 Restrictions on providing consent.—Unless the principal expressly delegates such authority to the surrogate in writing, or a surrogate or proxy has sought and received court approval pursuant to rule 5.900 of the Florida Probate Rules, a surrogate or proxy may not provide consent for:

(1) Abortion, sterilization, electroshock therapy,

psychosurgery, experimental treatments that have not been approved by a federally approved institutional review board in accordance with 45 C.F.R. part 46 or 21 C.F.R. part 56, or voluntary admission to a mental health facility.

(2) Withholding or withdrawing life-prolonging procedures from a pregnant patient prior to viability as defined in s. 390.011 ~~s. 390.0111(4)~~.

Section 10. Section 782.30, Florida Statutes, is repealed.

Section 11. Section 782.32, Florida Statutes, is repealed.

Section 12. Section 782.34, Florida Statutes, is repealed.

Section 13. Section 782.36, Florida Statutes, is repealed.

Section 14. Section 797.02, Florida Statutes, is repealed.

Section 15. Section 797.03, Florida Statutes, is repealed.

Section 16. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 17. This act shall take effect July 1, 2012.

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Abortion
Bill Number 290 *(if applicable)*

Name Sheila Hopkins
Amendment Barcode _____ *(if applicable)*

Job Title Associate Director

Address 201 W. Park Ave.
Street
Tallahassee, FL 32301
City *State* *Zip*

Phone 850-222-3803

E-mail _____

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Catholic Conference

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

_____
Meeting Date

Topic Abortion
Bill Number 290 *(if applicable)*

Name Maureen Ahern
Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 3201-70th Way N.
Street
St. Petersburg, Fl 33710
City *State* *Zip*

Phone 727-381-2166

E-mail maherna@tampabay.rr.com

Speaking: ☒ For ☐ Against ☐ Information

Representing Myself

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/2012
Meeting Date

Topic _____ Bill Number 290 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH Phone 727-897-9291
Street

SAINT PETERSBURG FLORIDA 33705 E-mail JUSTICE2JESUS@YAHOO.COM
City *State* *Zip*

Speaking: ☑ For ☐ Against ☑ Information

Representing JUSTICE-2-JESUS

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

~~290~~ 2/22/12
Meeting Date

Topic ABORTIONS Bill Number 290 *(if applicable)*

Name BILL BUNKLEY Amendment Barcode _____ *(if applicable)*

Job Title PRESIDENT

Address PO BOX 340288 Phone 813-264-2977
Street

TAMPA FL 33694 E-mail _____
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing FLORIDA ETHICS & RELIGIOUS LIBERTY COMMISSION, INC.

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-22-12
Meeting Date

Topic _____ Bill Number 290 *(if applicable)*

Name Bill Warren Amendment Barcode _____ *(if applicable)*

Job Title Policy Director

Address 4853 S. Orange Ave Phone 850 567-8143
Street

Orlando FL 32806 E-mail billw@flfamily.org
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information waive in support

Representing Florida Family Action

Appearing at request of Chair: ☐ Yes ☐ No Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Abortion Bill Number 290 *(if applicable)*

Name Jessica Lowe-Mindy Amendment Barcode _____ *(if applicable)*

Job Title Executive Director

Address 540 Beverly Court Phone 224-2545
Street

Tallahassee FL 32301 E-mail _____
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information Wave time in opposition

Representing League of Women Voters of FL.

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

Spoke

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/2012
Meeting Date

Topic _____ Bill Number 290 *(if applicable)*

Name Pamela Burch Fort Amendment Barcode _____ *(if applicable)*

Job Title Legislative Consultant

Address 104 S. Monroe St Phone 850-425-1344
Street

Tallahassee FL 32301 E-mail TcgLobby@aol.com
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing ACLU of Florida

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic _____ Bill Number SB 290 *(if applicable)*

Name Jane Jones Amendment Barcode _____ *(if applicable)*

Job Title Retired

Address 354 White Oak Dr. Phone 926-1177
Street

Crawfordville FL 32327 E-mail janefjones@hotmail.com
City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

Representing Self + Planned Parenthood

Appearing at request of Chair: ☐ Yes ☐ No Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-22-12
Meeting Date

Topic Abortion — Bill Number SB 290 *(if applicable)*

Name Barbara A. DeVane — Amendment Barcode _____ *(if applicable)*

Job Title independent contractor

Address 625 E. Brevard St — Phone 850-222-3969
Street

Tallahassee FL 32308 — E-mail barbaradevane1@yahoo.com
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing FL NOW (National Organization for Women)

Appearing at request of Chair: ☐ Yes ☑ No — Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-22-2010
Meeting Date

Topic _____ — Bill Number SB 290 *(if applicable)*

Name Joan E. Hendrix — Amendment Barcode _____ *(if applicable)*

Job Title Retired

Address 438 Beechwood Dr — Phone 926-7473
Street

Crawfordville FL 32327 — E-mail granpetunia@comcast.net
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing Planned Parenthood Self

Appearing at request of Chair: ☐ Yes ☐ No — Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

Topic _____ Bill Number SB 290 *(if applicable)*

Name Thomas Baxter Amendment Barcode _____ *(if applicable)*

Job Title _____

Address _____ Phone _____
Street

_____ E-mail _____
City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

Representing American Legion member

Appearing at request of Chair: ☐ Yes ☐ No Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

Topic Abortion SB290 Bill Number SB290 *(if applicable)*

Name Brittany Ballinger Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 637 E Call Street Phone _____
Street

Tallahassee FL 32301 E-mail _____
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Abortion Bill Number SB 290 *(if applicable)*

Name Jess Ekdahl Amendment Barcode *(if applicable)*

Job Title

Address *Street* Phone

City *State* *Zip* E-mail

Speaking: ☐ For ☒ Against ☐ Information

Representing

Appearing at request of Chair: ☐ Yes ☐ No Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic SB 290 Bill Number SB 290 *(if applicable)*

Name Whitney Green Amendment Barcode *(if applicable)*

Job Title

Address *Street* Phone

City *State* *Zip* E-mail

Speaking: ☐ For ☒ Against ☐ Information

Representing Catholics for Choice

Appearing at request of Chair: ☐ Yes ☐ No Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic Abortion — Bill Number SB 290 *(if applicable)*

Name Haley Gentile — Amendment Barcode _____ *(if applicable)*

Job Title _____

Address _____ *Street* — Phone _____

_____ *City* *State* *Zip* — E-mail _____

Speaking: ☐ For ☒ Against ☐ Information

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No — Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/20/11)

THE FLORIDA SENATE

Spoke

APPEARANCE RECORD

2/22/12
Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Topic _____ — Bill Number SB 290 *(if applicable)*

Name Staci Fox — Amendment Barcode _____ *(if applicable)*

Job Title CEO Planned Parenthood of North Florida

Address 3850 Beach Blvd — Phone _____

Street

Jacksonville Fl 32205 — E-mail _____

City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing _____

Appearing at request of Chair: ☐ Yes ☑ No — Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/22/12
Meeting Date

Topic SB 290 / Abortion

Bill Number SB 290 *(if applicable)*

Name Diane Wilson

Amendment Barcode _____ *(if applicable)*

Job Title _____

Address _____ *Street*

Phone _____

_____ *City* *State* *Zip*

E-mail _____

Speaking: ☐ For ☒ Against ☐ Information

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/20/11)

CourtSmart Tag Report

Room: KN 412 **Case:** **Type:**
Caption: 406072Senate Health Regulation Committee **Judge:**

Started: 2/22/2012 3:37:19 PM
Ends: 2/22/2012 6:01:17 PM Length: 02:23:59

3:37:22 PM Roll Call
3:37:32 PM SM 1836 by Senator Negron
3:38:20 PM Senator Sobel w/question
3:41:04 PM Senator Garcia w/comments
3:43:59 PM Amendment 441898 by Senator Gaetz
3:45:01 PM Michael Garner, Florida Association of Health Plans
3:45:20 PM Brian Pitts, Justice-2-Jesus
3:47:21 PM Roll call on SM 1836
3:47:46 PM SB 626 by Senator Richter
3:48:24 PM Brian Pitts, Justice-2-Jesus
3:48:34 PM Roll Call on SB 626
3:48:56 PM SB 624 by Senator Richter
3:49:15 PM Roll Call on SB 624
3:49:34 PM SB 1116 by Senator Altman
3:51:37 PM Senator Gaetz w/questions
3:52:11 PM Amendment 168688 by Senator Sobel
3:52:35 PM Merritt Martin, Moffitt Cancer Center
3:52:38 PM Amy Young, FL OB-GYN Society
3:52:55 PM Roll Call on SB 1116
3:53:24 PM SB 668 by Senator Hays
3:54:02 PM Amendment 766998 by Senator Gaetz
3:54:18 PM Senator Gaetz explains amendment
3:56:09 PM Amendment 671414
3:57:08 PM Amendment 279032
3:58:56 PM 409686 to 766998
4:00:50 PM Tammy Perdue, Associated Industries of Florida
4:01:58 PM Senator Fasano w/question
4:02:37 PM Lori Lovgren, NCCI
4:04:17 PM Senator Fasano w/question
4:05:11 PM Tom Panza, Automated Health Care Solutions
4:14:11 PM Dr. Gary Kelman
4:17:18 PM
4:18:46 PM Gerald Wester, American Insurance Association
4:24:55 PM Senator Sobel w/question
4:28:03 PM Senator Fasano w/question
4:33:50 PM Sally West, Florida Retail Federation
4:35:51 PM Jim Snyder, American Fire Sprinkler Association & Florida Fire Equipment Dealers, Assoc
4:36:20 PM Senator Garcia w/comments
4:40:40 PM 912394 to 409686
4:41:00 PM Senator Gaetz w/comments
4:42:11 PM Gary Guzzo, Florida Insurance Council
4:44:51 PM Senator Diaz de la Portilla w/comments
4:49:50 PM 695294 to 409686
4:50:27 PM Senator Norman w/question
4:51:39 PM Senator Fasano amendment
4:52:25 PM Senator Norman amendment
4:52:27 PM on the bill
4:52:50 PM Monte Stevens, Office of Insurance Regulation
4:52:53 PM Tom Panza
4:52:58 PM Dr Gary Kelman
4:53:01 PM Steven Johnson, Business People of Hardee County
4:53:08 PM Steven Southwell
4:53:15 PM Mike Hill, National Federation of Independent Business
4:53:20 PM Pablo Diaz, National Federation of Independent Businesses
4:57:05 PM Roll Call
4:59:13 PM SM 1840 by Senator Garcia
5:00:10 PM Brian Pitts, Justice-2-Jesus
5:02:25 PM Senator Sobel w/comments
5:04:18 PM Roll Call
5:04:58 PM SM 1854 by Senator Garcia
5:05:26 PM Brian Pitts, Justice-2-Jesus
5:09:11 PM Senator Sobel w/comments
5:11:03 PM Senator Garcia w/comments
5:12:46 PM Roll Call
5:13:07 PM SB 1006 by Senator Latvala
5:15:11 PM amendment
5:15:36 PM 942294
5:16:08 PM 549850
5:16:26 PM Ron Watson, FDA Florida Dental Association
5:16:35 PM 282212
5:17:03 PM Steve Ecenia, HCA
5:17:10 PM 355720 wd
5:17:23 PM amendment as amended
5:17:31 PM bill as amended
5:17:48 PM Senator Gaetz w/questions
5:18:20 PM Ron Watson, FDA Florida Dental Association
5:18:23 PM Chris Hansen, Walgreens
5:18:26 PM Alan Suskey, Dermazone Solutions
5:18:34 PM Mike McQuone, Florida Society of Health-System Pharmacists
5:18:48 PM Roll Call
5:19:32 PM SB 290 by Senator Flores
5:24:30 PM Senator Jones w/questions
5:29:37 PM Senator Sobel w/questions
5:34:05 PM 406072
5:35:15 PM 604606
5:39:12 PM 574642
5:41:53 PM 681218
5:44:54 PM 622450
5:46:06 PM 518540
5:49:54 PM 773162
5:51:37 PM Senator Sobel
5:51:37 PM Motion to vote time-certain
5:52:05 PM Jessica Lowe-mindy
5:52:17 PM Pamela Burch Fort, ACLU of Florida
5:54:47 PM Jane Jones, Planned Parenthood
5:54:53 PM Barbara DeVane, Fl NOW
5:54:58 PM Joan Hendrix
5:55:04 PM Thomas Baxter
5:55:12 PM Brittney Ballinger
5:55:15 PM Jess Ekdahl
5:55:28 PM Whitney Green
5:55:31 PM Haley Gentile
5:55:51 PM Staci Fox, CEO Planned Parenthood of North Florida
5:59:10 PM Roll Call
5:59:38 PM Meeting Adjourned