The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Bean, Chair
Senator Sobel, Vice Chair

MEETING DATE: Tuesday, January 26, 2016
TIME: 9:00—11:00 a.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Bean, Chair; Senator Sobel, Vice Chair; Senators Braynon, Flores, Gaetz, Galvano, Garcia, Grimsley, and Joyner

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 1722** Stargel (Similar H 1411)	Termination of Pregnancies; Defining the term "gestation" and revising the term "third trimester"; revising the requirements for disposal of fetal remains; prohibiting state agencies, local governmental entities, and Medicaid managed care plans from expending or paying funds to or initiating or renewing contracts under certain circumstances with certain organizations that perform abortions, etc. HP 01/26/2016 Favorable AHS FP	Favorable Yeas 5 Nays 3

TAB	OFFICE and APPOINTMENT (HOME CITY)	FOR TERM ENDING	COMMITTEE ACTION

Senate Confirmation Hearing: A public hearing will be held for consideration of the below-named executive appointment to the office indicated.

State Surgeon General

2	Armstrong, John H. (Ocala)	Pleasure of Governor	Temporarily Postponed

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	**SB 818** Latvala (Similar H 469)	Instruction on Human Trafficking; Providing that certain licensing boards must require specified licensees to complete a continuing education course on human trafficking as a condition of relicensure or recertification; providing that failure to complete the course is grounds for disciplinary action, etc. HP 01/26/2016 Fav/CS AHS FP	Fav/CS Yeas 9 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 764** Hays (Identical H 633)	Public Food Service Establishments; Revising the definition of the term "public food service establishment" to exclude certain events; clarifying that a food service license is not required to be obtained if an event is excluded under the definition of the term "public food service establishment", etc. HP 01/26/2016 Favorable RI FP	Favorable Yeas 9 Nays 0
5	**SB 878** Sachs (Identical CS/H 173)	Medical Faculty Certification; Revising the list of schools at which certain faculty members are eligible to receive a medical faculty certificate, etc. HP 01/26/2016 Favorable HE RC	Favorable Yeas 9 Nays 0
6	**SB 1686** Bean (Similar H 1353, Compare H 7087)	Telehealth; Creating the Telehealth Task Force within the Agency for Health Care Administration; requiring the agency to use existing and available resources to administer and support the task force, etc. HP 01/26/2016 Fav/CS AHS AP	Fav/CS Yeas 9 Nays 0
7	**SB 1504** Bean (Compare H 941, CS/S 918)	Credit for Relevant Military Service; Providing for the issuance of a license to practice under certain conditions to a military health care practitioner in a profession for which licensure in a state or jurisdiction is not required to practice in the military; requiring the Construction Industry Licensing Board and the Electrical Contractors' Licensing Board to provide a method by which honorably discharged veterans may apply for licensure, etc. HP 01/26/2016 Temporarily Postponed AGG AP	Temporarily Postponed
8	**SB 1604** Grimsley (Similar H 1211, Compare H 261, S 176)	Drugs, Devices, and Cosmetics; Providing, revising, and deleting definitions for purposes of the Florida Drug and Cosmetic Act; revising prohibited acts related to the distribution of prescription drugs; removing cosmetics from registration requirements; revising the definition of "wholesale distribution" for purposes of medical gas requirements, etc. HP 01/26/2016 Fav/CS AGG AP	Fav/CS Yeas 8 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
	Consideration of proposed bill:		
9	**SPB 7056**	Long-term Care Managed Care Prioritization; Requiring the Department of Elderly Affairs to maintain a statewide wait list for enrollment for home and community-based services through the Medicaid long-term care managed care program; requiring the department to prioritize individuals for potential enrollment using a frailty-based screening tool that provides a priority score; providing for determinations regarding offers of enrollment, etc.	Submitted as Committee Bill Yeas 9 Nays 0
10	**SB 1116** Joyner (Identical H 947)	Long-acting Reversible Contraception Pilot Program; Requiring the Department of Health to establish a long-acting reversible contraception (LARC) pilot program in Hillsborough, Palm Beach, and Pinellas Counties; requiring the department to contract with family planning providers to implement the pilot program; requiring the department to apply for grants for additional funding; providing an appropriation subject to certain requirements, etc. HP 01/26/2016 Favorable AHS FP	Favorable Yeas 7 Nays 2
	Other Related Meeting Documents		

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1722
INTRODUCER:	Senator Stargel
SUBJECT:	Termination of Pregnancies
DATE:	January 20, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.			AHS	
3.			FP	

I. Summary:

SB 1722 amends various statutes related to the termination of pregnancies. The bill:

- Defines the terms "gestation," "first trimester," "second trimester," and "third trimester";
- Prohibits the sale and donation of fetal remains from an abortion and increases penalties for the improper disposal of fetal remains;
- Restricts state agencies, local governmental entities, and Medicaid managed care plans from contracting with, or expending funds for the benefit of, an organization that owns, operates, or is affiliated with one or more clinics that perform abortions with some exceptions;
- Requires the Agency for Health Care Administration (AHCA) to collect certain data from medical facilities in which abortions are performed and to submit data to the federal Centers for Disease Control and Prevention (CDC);
- Requires the AHCA to:
  - Perform annual licensure inspections of abortion clinics;
  - Inspect at least 50 percent of abortion clinic records during a license inspection; and
  - Promptly investigate all credible allegations of unlicensed abortions being performed;
- Requires, in clinics that only perform first trimester abortions, that either:
  - The clinic have a written patient transfer agreement with a hospital within reasonable proximity; or
  - All physicians who perform abortions in the clinic have admitting privileges at a hospital within reasonable proximity of the clinic;
- Requires, in clinics that perform second trimester abortions, that:
  - The clinic have a written patient transfer agreement with a hospital within reasonable proximity; and
  - All physicians who perform abortions in the clinic have admitting privileges at a hospital within reasonable proximity of the clinic;
- Requires the AHCA to submit an annual report to the Legislature summarizing regulatory actions taken by the AHCA pursuant to its authority under ch. 390, F.S.; and

- Requires abortion referral and counseling agencies to register with the AHCA and pay a registration fee with some exceptions.

II. Present Situation:

Abortion in Florida

Under Florida law, abortion is defined as the termination of a human pregnancy with an intention other than to produce a live birth or remove a dead fetus.[1] The termination of a pregnancy must be performed by a physician[2] 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.[3]

The termination of a pregnancy may not be performed in the third trimester or if a physician determines that the fetus has achieved viability unless there is a medical necessity. Florida law defines the third trimester to mean the weeks of pregnancy after the 24th week and defines viability to mean the state of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.[4] Specifically, an abortion may not be performed after viability or within the third trimester unless two physicians certify in writing that, in reasonable medical judgment, the termination of the pregnancy is necessary to save the pregnant woman's life or avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition. If a second physician is not available, one physician may certify in writing to the medical necessity for legitimate emergency medical procedures for the termination of the pregnancy.[5]

Sections 390.0111(4) and 390.01112(3), F.S., provide that if a termination of pregnancy is performed during the third trimester or during viability, the physician who performs or induces the termination of pregnancy must use that degree of professional skill, care, and diligence to preserve the life and health of the fetus, which the physician would be required to exercise in order to preserve the life and health of any fetus intended to be born and not aborted. However, the woman's life and health constitute an overriding and superior consideration to the concern for the life and health of the fetus when the concerns are in conflict. This termination of a pregnancy must be performed in a hospital.[6]

Case Law on Abortion

Federal Case Law

In 1973, the U.S. Supreme Court issued the landmark *Roe v. Wade* decision.[7] Using the strict scrutiny standard, the Court determined that a woman's right to terminate a pregnancy is protected by a fundamental right to privacy guaranteed under the Due Process Clause of the

[1] Section 390.011(1), F.S.
[2] Section 390.0111(2), F.S.
[3] Section 390.011(8), F.S.
[4] Sections 390.011(11) and (12), F.S.
[5] Sections 390.0111(1) and 390.01112(1), F.S.
[6] Sections 797.03(3), F.S.
[7] 410 U.S. 113 (1973).

Fourteenth Amendment of the U.S. Constitution.[8] Further, the Court reasoned that state regulations limiting the exercise of this right must be justified by a compelling state interest, and must be narrowly drawn.[9]

In 1992, the U.S. Supreme Court ruled on the constitutionality of a Pennsylvania statute involving a 24-hour waiting period between the provision of information to a woman and the performance of an abortion. In that decision, *Planned Parenthood of Southeastern Pennsylvania v. Casey*,[10] the Court upheld the statute and relaxed the standard of review in abortion cases involving adult women from "strict scrutiny" to "unduly burdensome." An undue burden exists and makes a statute invalid if the statute's purpose or effect is to place a substantial obstacle in the way of a woman seeking an abortion before the fetus is viable.[11] The Court held that the undue burden standard is an appropriate means of reconciling a state's interest in human life with the woman's constitutionally protected liberty to decide whether to terminate a pregnancy. The Court determined that, prior to fetal viability, a woman has the right to an abortion without being unduly burdened by government interference. Before viability, a state's interests are not strong enough to support prohibiting an abortion or the imposition of a substantial obstacle to the woman's right to elect the procedure.[12] However, once viability occurs, a state has the power to restrict abortions if the law contains exceptions for pregnancies that endanger a woman's life or health.

Florida Law on Abortion

Florida law embraces more privacy interests and expressly extends more privacy protection to its citizens than the U.S. Constitution does. Article I, s. 23 of the State Constitution provides an express right to privacy. The Florida Supreme Court has recognized that this constitutional right to privacy "is clearly implicated in a woman's decision whether or not to continue her pregnancy."[13] The Florida Supreme Court ruled in *In re T. W.*[14]

> Under Florida law, prior to the end of the first trimester, the abortion decision must be left to the woman and may not be significantly restricted by the state. Following this point, the state may impose significant restrictions only in the least intrusive manner designed to safeguard the health of the mother. Insignificant burdens during either period must substantially further important state interests… Under our Florida Constitution, the state's interest becomes compelling upon viability …. Viability under Florida law occurs at that point in time when the fetus becomes capable of meaningful life outside the womb through standard medical measures.[15]

[8] *Id.*
[9] *Id.*
[10] 505 U.S. 833 (1992).
[11] *Id*. at 878.
[12] *Id*. at 846.
[13] *In re T.W.*, 551 So. 2d 1186 (Fla. 1989).
[14] 551 So. 2d 1186, 1192 (Fla. 1989) (holding that a parental consent statute was unconstitutional because it intrudes on a minor's right to privacy).
[15] *Id*. at 1193-94.

The Court concluded that, "Following viability, the state may protect its interest in the potentiality of life by regulating abortion, provided that the mother's health is not jeopardized."[16]

Unlike the U.S. Supreme Court, however, the Florida Supreme Court reached a different standard of review for privacy laws involving abortion. The Florida Supreme Court held that, when determining the constitutionality of a statute that impinges upon a right of privacy under the Florida Constitution, the strict scrutiny standard of review applies.[17]

Abortion and Related Services Funding

Currently, neither the federal government nor the state of Florida funds abortion procedures except in limited situations.[18] Federal funding for abortions, including Medicaid funding, has been restricted since 1977 with the passage of the Hyde amendment.[19] The Hyde amendment restricts the federal government from spending funds or administrative expenses in connection with abortions unless the pregnancy was the result of rape or incest or if the life of the mother would be in danger if the fetus were carried to term. However, the Hyde amendment and state law do not restrict federal or state funds from being expended for other services offered by abortion providers, such as family planning services, and Medicaid under fee-for-service arrangements may not exclude qualified health care providers because they separately provide abortion services.[20] This provision is often referred to as the "any willing provider" provision. However, the Florida Medicaid managed care program is exempt from the any willing provider provision.[21]

Regulation of Clinics Providing Only First Trimester Abortions vs. Regulation of Clinics Providing Second Trimester Abortions

As detailed above, the constitutionality of regulations on abortion differs for abortions performed in the first trimester and the second trimester. The effect of this difference can be seen in Florida statute and rule. Section 390.012, F.S., details numerous requirements for clinics providing second trimester abortions, but only requires that AHCA rules "be comparable to rules that apply to all surgical procedures requiring approximately the same degree of skill and care" for first trimester abortions.[22] The AHCA currently has no rules specific to first trimester clinics, but has

[16] *Id*. at 1194.
[17] *North Florida Women's Health and Counseling Services, Inc., et al., v. State of Florida*, 866 So. 2d 612 (Fla. 2003).
[18] See ss. 627.64995, 627.66996, and 641.31099, F.S.
[19] For an example of Hyde amendment language passed in a Federal appropriations act, see Pub. Law 111-8, ss. 613 and 614, March 11, 2009.
[20] CMCS Informational Bulletin, Cindy Mann director of the Center for Medicaid, CHIP and Survey and Certification, June 1, 2011, available at https://www.medicaid.gov/Federal-Policy-Guidance/downloads/6-1-11-Info-Bulletin.pdf (last visited on January 22, 2016).
[21] See s. 409.975, F.S., and Centers for Medicare and Medicaid Services Special Terms and Conditions Number 11-w-00206/4 Florida Medicaid Medical Assistance Program, Number 37 Freedom of Choice, p. 22, October 15, 2015.
[22] The Department of Health's rules on office surgery (Rule 64B15-14.007, F.A.C.) regulate procedures that may be comparable to first trimester abortions. Specifically, a comparison can most closely be drawn between first trimester abortions and either level I or level II office surgery. Criteria for level I and level II office surgery are detailed in Rule 64B15-14.007(3) and (4), F.A.C., respectively. Rules for level I office surgery have no requirements for patient transfer agreements or admitting privileges. Rules for level II office surgery require either that the physician's office have a transfer agreement with a hospital within reasonable proximity or that the physician performing the surgery have privileges at hospital within reasonable proximity.

issued guidelines for clinics as to which requirements must be met by clinics providing first and second trimester abortions and those providing only first trimester abortions.[23] In general, clinics providing only first trimester abortions must be licensed, inspected annually,[24] and must adhere to the restrictions on abortions in general[25] but are not required to meet specific regulations regarding clinic staffing, physical plant, equipment, medical screening, the abortion procedure, and recovery room standards.

Confusion Over the Timing of the First and Second Trimester

In recent months there has been some widely publicized confusion over the definitions of first and second trimester. Currently, AHCA rule defines the "first trimester" as "the first 12 weeks of pregnancy (the first 14 completed weeks from the last normal menstrual period)" and "second trimester" as "the portion of a pregnancy following the 12th week and extending through the 24th week of gestation."[26] These definitions are important due to the much more stringent regulation of clinics providing second trimester abortions.

In August of 2015, the AHCA cited several clinics associated with Planned Parenthood of Southwest and Central Florida for performing unlicensed second trimester abortions. The clinics were licensed only to provide first trimester abortions but the citation reports that several patient reports from the clinics indicated that abortions had been performed after 13 weeks of gestation.[27] The AHCA cited the clinics for performing abortions beyond their license. Planned Parenthood challenged the citations alleging that the clinics had not violated the law and that the AHCA redefined first trimester to mean 12 weeks from the last normal menstrual cycle, rather than 12 weeks from point of gestation.[28] The lawsuit is currently ongoing, however, it is interesting to note that as a part of the requirement to file a corrective action plan with the AHCA, the citation given to Planned Parenthood of Collier County requires that the corrective action plan must "educate staff to ensure that…the field titled 'WEEKS OF GESTATION' is correctly completed using 'weeks of gestation'…and not erroneously using last normal menstrual period.[29]

Centers for Disease Control Abortion Surveillance

In 1969, the CDC began abortion surveillance in order to document the number and characteristics of women obtaining legal induced abortions. States voluntarily report abortion data to the CDC and the CDC's Division of Reproductive Health prepares surveillance reports as

[23] AHCA ASPEN: Regulation Set (RS), Aug. 11, 2015, available at http://ahca.myflorida.com/mchq/Current_Reg_Files/Abortion_Clinic_ST_A.pdf, (last visited Jan. 21, 2016).
[24] Rule 59A-9.021, F.A.C.
[25] General restrictions include, but are not limited to: the requirement that all abortions must be performed by a physician, the requirement to obtain informed consent before performing an abortion, requirements regarding the disposal of fetal remains, and the requirement that the physician performing the abortion notify the parent or guardian of a minor before performing such abortion. See ss. 390.0111 and 390.01114, F.S.
[26] Rule 59A-9.019, F.S.
[27] For an example see: AHCA statement of deficiencies for Planned Parenthood of Collier County, available at http://apps.ahca.myflorida.com/dm_web/DMWeb_Docs/6359763.pdf, (last visited Jan. 21, 2016).
[28] See http://www.capitalnewyork.com/article/florida/2015/08/8574447/planned-parenthood-sues-says-state-trying-redefine-1st-trimester (last visited on January 21, 2016).
[29] Id. n. 22

data becomes available.[30] Information reported to the CDC includes maternal age, gestational age of the fetus in weeks at the time of the abortion, race, ethnicity, method of abortion, marital statutes, maternal residence, the number of previous live births, and the number of previous abortions. Currently, Florida is one of six states and the District of Columbia that does not report data to the CDC.[31]

Disposal of Fetal Remains

Currently, Florida statute and rule require that fetal remains be disposed of in a sanitary and appropriate manner in accordance with standard health practices and the laws and rules covering the disposal of biomedical waste.[32] As such an abortion clinic must obtain a biomedical waste generator permit from the Department of Health (DOH), unless the clinic generates less than 25 pounds of biomedical waste per month. Also, s. 873.05, F.S., prohibits any knowing advertisement or offer to purchase or sell a human embryo for valuable consideration.[33] This violation is classified as a second degree felony.

If an abortion clinic fails to dispose of fetal remains properly, the clinic could be liable for penalties under both s. 381.0098, F.S., and ch. 390, F.S. Section 381.0098, F.S., states that any person or public body that violates that section or applicable rules is subject to DOH sanction as well as an administrative fine of up to $2,500 for each day of a continuing violation. Additionally, any failure by an abortion clinic to dispose of fetal remains in accordance with DOH rule and standard health practices is a second degree misdemeanor[34] and any failure by an owner, operator, or employee of an abortion clinic to dispose of fetal remains and tissue consistent with the disposal of other human tissue is a first degree misdemeanor and allows the AHCA to suspend, revoke, or deny the clinic's license.[35]

Abortion Referral and Counseling Agencies

Section 390.025, F.S., defines an abortion referral and counseling agency as "any person, group, or organization, whether funded publicly or privately, that provides advice or help to persons in obtaining abortions." The section requires that such an agency provide a full and detailed explanation of abortion, including the effects and alternatives to abortion, to a person seeking an abortion before making a referral or aiding the person in obtaining an abortion. If the person seeking a referral is a minor, the agency must make a good faith effort to furnish the required information to his or her parents or guardian. Additionally, the section prohibits an agency from accepting fees, kickbacks, or other compensation in return for referring a person for an abortion. Any violation of the provisions of the section is a misdemeanor of the first degree.

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[30] CDCs Abortion Surveillance System FAQ, available at http://www.cdc.gov/reproductivehealth/Data_Stats/Abortion.htm, (last visited on January 21, 2016).
[31] Abortion Surveillance Report for 2012, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6410a1.htm?s_cid=ss6410a1_e#tab2, (last visited on January 21, 2016).
[32] s. 390.0111(7), F.S., and rule 59A-9.030, F.A.C. (laws and rules governing the disposal of biomedical waste are contained in s. 381.0098, F.S., and rule ch, 64E-16, F.A.C.)
[33] "Valuable consideration" does not include the reasonable costs associate with the removal, storage, and transportation of human embryos.
[34] s. 390.0111(7), F.S.
[35] s. 390.012(7), F.S.

III. Effect of Proposed Changes:

SB 1722 amends various sections of law related to the termination of pregnancies. In addition to the substantive changes detailed below, the bill also makes various technical and conforming changes.

Section 1 amends s. 390.011, F.S., to define the terms:

- "Gestation" to mean the development of a human embryo or fetus between fertilization and birth;
- "First trimester" to mean the period of time from fertilization through the end of the 11th week of gestation;
- "Second trimester" to mean the period of time from the beginning of the 12th week of gestation through the end of the 23rd week of gestation; and
- "Third trimester" to mean the period of time from the beginning of the 24th week of gestation to birth.

Section 2 amends s. 390.0111, F.S., to;

- Clarify that the disposal of fetal remains must be in accordance with s. 381.0098, F.S., and DOH rules;
- To increase the penalty for improperly disposing of fetal remains from a second degree misdemeanor to a first degree misdemeanor; and
- To restrict state agencies, local governmental entities, and Medicaid managed care plans from expending funds for the benefit of, paying funds to, or initiating or renewing a contract with any organization that owns, operates, or is affiliated with one or more clinics that are licensed under ch. 390, F.S., and perform abortions. The bill exempts:
  - Clinics that only perform abortions on fetuses that are the result of rape or incest or abortions that are necessary to preserve the life of the pregnant woman or to avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman, other than a psychological condition;
  - Funds that must be expended to fulfill the terms of a contract entered into before July 1, 2016; and
  - Funds that must be expended as reimbursement for Medicaid services provided on a fee-for-service basis.

Section 3 amends s. 390.0112, F.S., to update the reporting requirements for abortion clinics to, beginning no later than January 1, 2017, include information consistent with the United States Standard Report of Induced Termination of Pregnancy adopted by the CDC. Additionally, the bill requires that the AHCA submit all such reported data to the CDC as requested by the CDC.

Section 4 of the bill amends s. 390.012, F.S., to:

- Require that the AHCA:
  - Perform annual license inspections of all abortion clinics;[36]
  - When performing a licensure inspection of an abortion clinic, review at least 50 percent of patient records generated since the clinic's last license inspection;

[36] Note: the AHCA currently performs annual inspections of abortion clinics; however, this requirement is not established in statute.

  - Promptly investigate all credible allegations of abortions being performed at a clinic that is not licensed to perform such abortions; and
  - Beginning February 1, 2017, annually report to the Legislature on all regulatory actions taken during the prior year by the AHCA under ch. 390, F.S.
- Require, in clinics that only perform first trimester abortions, that either:
  - The clinic have a written patient transfer agreement with a hospital within reasonable proximity that includes the transfer of the patient's medical records; or
  - All physicians who perform abortions in the clinic must have admitting privileges at a hospital within reasonable proximity of the clinic;
- Require, in clinics that perform second trimester abortions, that:
  - The clinic have a written patient transfer agreement with a hospital within reasonable proximity that includes the transfer of the patient's medical records; and
  - All physicians who perform abortions in the clinic must have admitting privileges at a hospital within reasonable proximity of the clinic;

Section 5 amends s. 390.014, F.S., to allow the AHCA to establish in rule a license fee that may not be more than required to pay for the costs incurred by the AHCA in administering ch. 390, F.S. Current law caps the license fee at $500.

Section 6 amends s. 390.025, F.S., to require that abortion referral and counseling agencies registered with the AHCA and pay a registration fee. The amount of the initial and renewal fees are to be established in rule in an amount not to exceed the costs incurred by the AHCA in administering this section of law. The AHCA is granted rulemaking authority to implement this section and registrants are required to include the registration number issued by the AHCA in any advertising materials disseminated by the registrant. The AHCA may also assess costs related to investigations that result in a successful prosecution under the provisions in the section. The following are exempt from the requirement to register:

- Facilities licensed under chs. 390, 395, 400, and 408, F.S.;
- Facilities that are exempt from the requirement to be licensed as a clinic and that refer five or fewer patients for abortions per month; and
- Health care practitioners who do not, in the course of their practice outside of a licensed facility, refer more than five patients for abortions each month.

Section 7 amends s. 873.05, F.S., to prohibit any advertisement for or offer to sell, purchase, donate, or transfer fetal remains obtained from an abortion other than the transportation or transfer of fetal remains for disposal pursuant to s. 381.0098, F.S., and applicable rules. A violation of this prohibition is a first degree felony.

Section 8 establishes, unless otherwise expressly provided, an effective date for the act of July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

It is unclear, given stricter constitutional prohibition against regulations of abortions in the first trimester, whether or not the changes in the bill relating to clinics providing only first trimester abortions may be successfully challenged under Florida's constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 1722 may have a negative fiscal impact on clinics providing abortions due to the additional requirements established in the bill. Additionally, the bill may have a negative fiscal impact on organizations affiliated with clinics providing abortions if such organizations currently receive funds which would be restricted by the bill.

The bill will likely have a negative fiscal impact on abortion referral and counseling agencies due to the requirement to register with the AHCA and pay a registration fee.

C. Government Sector Impact:

The AHCA will incur additional costs due to the increased time required for inspections at licensed abortion clinics and for the registration and oversight functions of abortion referral and counseling agencies. The AHCA is required to set fees at a level to cover these costs. The estimated fiscal impact is not available at this time..

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 390.011, 390.0111, 390.0112, 390.012, 390.014, 390.025, and 873.05.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Stargel

15-01209E-16 20161722__

A bill to be entitled

An act relating to termination of pregnancies; amending s. 390.011, F.S.; defining the term "gestation" and revising the term "third trimester"; amending s. 390.0111, F.S.; revising the requirements for disposal of fetal remains; revising the criminal punishment for failure to properly dispose of fetal remains; prohibiting state agencies, local governmental entities, and Medicaid managed care plans from expending or paying funds to or initiating or renewing contracts under certain circumstances with certain organizations that perform abortions; providing exceptions; amending s. 390.0112, F.S.; requiring directors of certain hospitals and physicians' offices and licensed abortion clinics to submit monthly reports to the Agency for Health Care Administration on a specified form; prohibiting the report from including personal identifying information; requiring the agency to submit certain data to the Centers for Disease Control and Prevention on a quarterly basis; amending s. 390.012, F.S.; requiring the agency to develop and enforce rules relating to license inspections and investigations of certain clinics; requiring the agency to adopt rules that require certain clinics to have written agreements with local hospitals for certain contingencies; specifying that the rules must require physicians who perform abortions at a clinic that performs abortions in the first trimester of pregnancy to have admitting privileges at a hospital within reasonable proximity to the clinic; revising requirements for rules that prescribe minimum recovery

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room standards; revising requirements for the disposal of fetal remains; requiring the agency to submit an annual report to the Legislature; amending s. 390.014, F.S.; providing a different limitation on the amount of a fee; amending s. 390.025, F.S.; requiring certain organizations that provide abortion referral services or abortion counseling services to register with the agency, pay a specified fee, and include certain information in advertisements; requiring biennial renewal of a registration; providing exemptions from the registration requirement; requiring the agency to adopt rules; providing for the assessment of costs in certain circumstances; amending s. 873.05, F.S.; prohibiting an offer to purchase, sell, donate, or transfer fetal remains obtained from an abortion and the purchase, sale, donation, or transfer of such remains, excluding costs associated with certain transportation of remains; providing effective dates.

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

Section 1. Present subsections (6) through (12) of section 390.011, Florida Statutes, are redesignated as subsections (7) through (13), respectively, a new subsection (6) is added to that section, and present subsection (11) of that section is amended, to read:

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

(6) "Gestation" means the development of a human embryo or fetus between fertilization and birth.

(12)~~(11)~~ "~~Third~~ Trimester" means one of the following three distinct periods of time in the duration of a pregnancy:

(a) "First trimester," which is the period of time from fertilization through the end of the 11th week of gestation.

(b) "Second trimester," which is the period of time from the beginning of the 12th week of gestation through the end of the 23rd week of gestation.

(c) "Third trimester," which is the period of time from the beginning of the 24th week of gestation through birth ~~the weeks of pregnancy after the 24th week of pregnancy~~.

Section 2. Subsection (7) of section 390.0111, Florida Statutes, is amended, and subsection (15) is added to that section, to read:

390.0111 Termination of pregnancies.—

(7) FETAL REMAINS.—Fetal remains shall be disposed of in a sanitary ~~and appropriate~~ manner pursuant to s. 381.0098 and rules adopted thereunder ~~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 this subsection ~~department rules~~ is a misdemeanor of the first ~~second~~ degree, punishable as provided in s. 775.082 or s. 775.083.

(15) USE OF PUBLIC FUNDS RESTRICTED.—A state agency, a local governmental entity, or a managed care plan providing services under part IV of chapter 409 may not expend funds for the benefit of, pay funds to, or initiate or renew a contract with an organization that owns, operates, or is affiliated with one or more clinics that are licensed under this chapter and perform abortions unless one or more of the following applies:

(a) All abortions performed by such clinics are:

1. On fetuses that are conceived through rape or incest; or

2. Are medically necessary to preserve the life of the pregnant woman or to avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman, other than a psychological condition.

(b) The funds must be expended to fulfill the terms of a contract entered into before July 1, 2016.

(c) The funds must be expended as reimbursement for Medicaid services provided on a fee-for-service basis.

Section 3. Subsection (1) of section 390.0112, Florida Statutes, is amended, present subsections (2), (3), and (4) of that section are redesignated as subsections (3), (4), and (5), respectively, and a new subsection (2) is added to that section, to read:

390.0112 Termination of pregnancies; reporting.—

(1) The director of any medical facility in which abortions are performed, including a physician's office, ~~any pregnancy is terminated~~ shall submit a ~~monthly~~ report each month to the agency. The report may be submitted electronically, may not include personal identifying information, and must include:

(a) Until the agency begins collecting data under paragraph (e), the number of abortions performed.

(b) The reasons such abortions were performed.

(c) For each abortion, the period of gestation at the time the abortion was performed.

(d) ~~which contains the number of procedures performed, the reason for same, the period of gestation at the time such procedures were performed, and~~ The number of infants born alive or alive ~~during or~~ immediately after an attempted abortion.

(e) Beginning no later than January 1, 2017, information consistent with the United States Standard Report of Induced Termination of Pregnancy adopted by the Centers for Disease Control and Prevention.

(2) The agency shall keep ~~be responsible for keeping~~ such reports in a central location for the purpose of compiling and analyzing ~~place from which~~ statistical data and shall submit data reported pursuant to paragraph (1)(e) to the Division of Reproductive Health within the Centers for Disease Control and Prevention, as requested by the Centers for Disease Control and Prevention ~~analysis can be made~~.

Section 4. Paragraph (c) of subsection (1), subsection (2), and paragraphs (c) and (f) of subsection (3) of section 390.012, Florida Statutes, are amended, present paragraphs (g) and (h) of subsection (3) are redesignated as paragraphs (h) and (i), respectively, a new paragraph (g) is added to that subsection, subsection (7) of that section is amended, and subsection (8) is added to that section, 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.

(c) The rules shall provide for:

1. The performance of 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. When performing a license inspection of a clinic, the agency shall inspect at least 50 percent of patient records generated since the clinic's last license inspection.

3. Annual inspections by the agency of all clinics licensed under this chapter to ensure that such clinics are in compliance with this chapter and agency rule.

4. The prompt investigation of credible allegations of abortions being performed at a clinic that is not licensed to perform such procedures.

(2) For clinics that perform abortions in the first trimester of pregnancy only, these rules must ~~shall~~ be comparable to rules that apply to all surgical procedures requiring approximately the same degree of skill and care as the performance of first trimester abortions and must require:

(a) Clinics to have a written patient transfer agreement with a hospital within reasonable proximity to the clinic which includes the transfer of the patient's medical records held by the clinic and the treating physician to the licensed hospital; or

(b) Physicians who perform abortions at the clinic to have admitting privileges at a hospital within reasonable proximity to the clinic.

(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:

(c) Rules relating to abortion clinic personnel. At a minimum, these rules shall require that:

1. The abortion clinic designate a medical director who is

licensed to practice medicine in this state, and all physicians who perform abortions in the clinic have ~~who has~~ admitting privileges at a ~~licensed~~ hospital ~~in this state~~ within reasonable proximity to the clinic ~~or has a transfer agreement with a licensed hospital within reasonable proximity of the clinic~~.

2. If a physician is not present after an abortion is performed, a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant ~~shall~~ be present and remain at the clinic to provide postoperative monitoring and care until the patient is discharged.

3. Surgical assistants receive training in counseling, patient advocacy, and the specific responsibilities associated with the services the surgical assistants provide.

4. Volunteers receive training in the specific responsibilities associated with the services the volunteers provide, including counseling and patient advocacy as provided in the rules adopted by the director for different types of volunteers based on their responsibilities.

(f) Rules that prescribe minimum recovery room standards. At a minimum, these rules must ~~shall~~ require that:

1. Postprocedure recovery rooms be ~~are~~ supervised and staffed to meet the patients' needs.

2. Immediate postprocedure care consist ~~consists~~ of observation in a supervised recovery room for as long as the patient's condition warrants.

3. ~~The clinic arranges hospitalization if any complication beyond the medical capability of the staff occurs or is~~

~~suspected.~~

~~4.~~ A registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant who is trained in the management of the recovery area and is capable of providing basic cardiopulmonary resuscitation and related emergency procedures remain ~~remains~~ on the premises of the abortion clinic until all patients are discharged.

4.~~5.~~ A physician ~~shall~~ sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary.

5.~~6.~~ A physician discuss ~~discusses~~ Rho(D) immune globulin with each patient for whom it is indicated and ensure ~~ensures~~ that it is offered to the patient in the immediate postoperative period or ~~that it~~ will be available to her within 72 hours after completion of the abortion procedure. If the patient refuses the Rho(D) immune globulin, she and a witness must sign a refusal form approved by the agency which must be ~~shall be signed by the patient and a witness and~~ included in the medical record.

6.~~7.~~ Written instructions with regard to postabortion coitus, signs of possible problems, and general aftercare which are specific to the patient be ~~are~~ given to each patient. The instructions must include information ~~Each patient shall have specific written instructions~~ regarding access to medical care for complications, including a telephone number for use in the event of a ~~to call for~~ medical emergency ~~emergencies~~.

7.~~8.~~ ~~There is~~ A ~~specified~~ minimum length of time be specified, by type of abortion procedure and duration of gestation, during which ~~that~~ a patient must remain ~~remains~~ in

the recovery room ~~by type of abortion procedure and duration of gestation~~.

8.~~9.~~ The physician ensure ~~ensures~~ that, with the patient's consent, a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the abortion clinic makes a good faith effort to contact the patient by telephone~~, with the patient's consent,~~ within 24 hours after surgery to assess the patient's recovery.

9.~~10.~~ Equipment and services be ~~are~~ readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or viable fetus to the hospital.

(g) Rules that require clinics to have a written patient transfer agreement with a hospital within reasonable proximity to the clinic which includes the transfer of the patient's medical records held by both the clinic and the treating physician.

(7) If an ~~any~~ owner, operator, or employee of an abortion clinic fails to dispose of fetal remains and tissue in a sanitary manner pursuant to s. 381.0098, rules adopted thereunder, and rules adopted by the agency pursuant to this section ~~consistent with the disposal of other human tissue in a competent professional manner~~, the license of such clinic may be suspended or revoked, and such person commits ~~is guilty of~~ a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(8) Beginning February 1, 2017, and annually thereafter, the agency shall submit a report to the President of the Senate and the Speaker of the House of Representatives which summarizes

all regulatory actions taken during the prior year by the agency under this chapter.

Section 5. Subsection (3) of section 390.014, Florida Statutes, is amended to read:

390.014 Licenses; fees.—

(3) In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted under this chapter and part II of chapter 408. The amount of the fee shall be established by rule and may not be more than required to pay for the costs incurred by the agency in administering this chapter ~~less than $70 or more than $500~~.

Section 6. Effective January 1, 2017, present subsection (3) of section 390.025, Florida Statutes, is amended, and new subsections (3), (4), and (5) are added to that section, to read:

390.025 Abortion referral or counseling agencies; penalties.—

(3) An abortion referral or counseling agency, as defined in subsection (1), shall register with the Agency for Health Care Administration. To register or renew a registration an applicant must pay an initial or renewal registration fee established by rule, which must not exceed the costs incurred by the agency in administering this section. Registrants must include in any advertising materials the registration number issued by the agency and must renew their registration biennially.

(4) The following are exempt from the requirement to register pursuant to subsection (3):

(a) Facilities licensed pursuant to chapter 390, chapter

395, chapter 400, or chapter 408;

(b) Facilities that are exempt from licensure as a clinic under s. 400.9905(4) and that refer five or fewer patients for abortions per month; and

(c) Health care practitioners, as defined in s. 456.001, who, in the course of their practice outside of a facility licensed pursuant to chapter 390, chapter 395, chapter 400, or chapter 408, refer five or fewer patients for abortions each month.

(5) The agency shall adopt rules to administer this section and part II of chapter 408.

(6)~~(3)~~ Any person who violates the provisions of subsection (2) ~~this section~~ is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. In addition to any other penalties imposed pursuant to this chapter, the Agency for Health Care Administration may assess costs related to an investigation of violations of this section which results in a successful prosecution. Such costs may not include attorney fees.

Section 7. Section 873.05, Florida Statutes, is amended to read:

873.05 Advertising, purchase, ~~or~~ sale, or transfer of human embryos or fetal remains prohibited.—

(1) A ~~No~~ person may not ~~shall~~ knowingly advertise or offer to purchase or sell, or purchase, sell, or otherwise transfer, a ~~any~~ human embryo for valuable consideration.

~~(2)~~ As used in this subsection ~~section~~, the term "valuable consideration" does not include the reasonable costs associated with the removal, storage, and transportation of a human embryo.

(2) A person may not advertise or offer to purchase, sell, donate, or transfer, or purchase, sell, donate, or transfer, fetal remains obtained from an abortion, as defined in s. 390.011. This subsection does not prohibit the transportation or transfer of fetal remains for disposal pursuant to s. 381.0098 or rules adopted thereunder.

(3) A person who violates ~~the provisions of~~ this section is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 8. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2016.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Higher Education, *Chair*
Appropriations Subcommittee on Education
Fiscal Policy
Judiciary
Military and Veterans Affairs, Space, and Domestic Security
Regulated Industries

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR KELLI STARGEL
15th District

January 15, 2016

The Honorable Aaron Bean
Senate Health Policy Committee, Chair
302 Senate Office Building
404 S. Monroe Street
Tallahassee, FL 32399

Dear Chair Bean:

I respectfully request that SB 1722, related to *Termination of Pregnancies*, be placed on the committee agenda at your earliest convenience.

Thank you for your consideration and please do not hesitate to contact me should you have any questions.

Sincerely,

Kelli Stargel

Kelli Stargel
State Senator, District 15

Cc: Sandra Stovall/ Staff Director
Celia Georgiades/ AA

REPLY TO:
❒ 2033 East Edgewood Drive, Suite 1, Lakeland, Florida 33803
❒ 324 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5015

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

ANDY GARDINER
President of the Senate

GARRETT RICHTER
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/11
Meeting Date

1722
Bill Number (if applicable)

Topic Termination of Pregnancies

Amendment Barcode (if applicable)

Name Molly McKinstry

Job Title Dep. Sec. HQA

Address 2727 Mahan Drive
Street

Phone 850-412-3612

Tallahassee FL 32308
City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☒ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Agency for Health Care Administration

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

SB 1722
Bill Number (if applicable)

Topic Termination of Pregnancies

Amendment Barcode (if applicable)

Name Josh Spagnola

Job Title Legislative Affairs Director

Address 2727 Mahan Drive
Street

Phone 850-412-3612

Tallahassee
City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☒ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Agency for Health Care Administration

Appearing at request of Chair: ☒ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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1/26/2016
Meeting Date

1722
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Termination of Pregnancies

Name Teresa Ward

Job Title Attorney

Address P.O. Box 1125
Street
Tallahassee FL 32302
City *State* *Zip*

Phone 850-544-5171

Email teresacooperward@gma

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

Waive Speaking: [X] In Support [ ] Against
(The Chair will read this information into the record.)

Representing FLORIDA RIGHT TO LIFE

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

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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1/26/16
Meeting Date

1722
Bill Number (if applicable)

Topic Termination of Pregnancies

Amendment Barcode (if applicable)

Name Ingrid Delgado

Job Title Associate for Social Concerns & Respect Life

Address 201 W Park Av
Street

Phone

Tallahassee FL 32301
City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Conference of Catholic Bishops

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

Meeting Date

SB 1722
Bill Number (if applicable)

Topic Relating To Termination of Pregnancies

Amendment Barcode (if applicable)

Name David Borrero

Job Title

Address 1750 NW 107th Avenue
Street

Phone (305) 305-6122

Sweetwater FL 33172
City State Zip

Email

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Family Policy Council

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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1/26/16
Meeting Date

SB 1722
Bill Number (if applicable)

Topic SB 1722

Amendment Barcode (if applicable)

Name Pamela Berman

Job Title Occupational Therapist & Massage Therapist

Address 6580 Grant Court
Street

Phone 954 240 7979

Hollywood FL 33024
City *State* *Zip*

Email OTRGAL.b@gmail.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

26 JANUARY 2016
Meeting Date

SB 1722
Bill Number (if applicable)

Topic LIFE

Amendment Barcode (if applicable)

Name BILL SNYDER

Job Title SELF EMPLOYED

Address 925 HIAWATHA FARMS ROAD
Street

Phone

MONTICELLO FL 32344
City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

SB1722
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic PRO-LIFE

Name BOB WILDER

Job Title

Address 1007 MEADOW LN
Street
BRANDON FL
City *State* *Zip*

Phone 8138928487

Email Bobwilder2@aol.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

Meeting Date

1722.
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Termination of Pregnancies

Name Pam Olsen.

Job Title Pastor.

Address PO Box 14017
Street
Tallahassee, FL 32317
City State Zip

Phone 850-906-9170

Email pam@ihopfl.org

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

1722

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

1/26/16
Meeting Date

~~1477~~
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Marcia Buterakos

Job Title Executive Director

Address 27 E. Pinehurst Blvd
Street
Eustis FL 32726
City *State* *Zip*

Phone 352-357-2202

Email litleschoiceslakeco gmail.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Life's Choices of Lake County

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1·26·16
Meeting Date

1722
Bill Number (if applicable)

Topic TERMINATION of PREGNANCIES

Amendment Barcode (if applicable)

Name BILL BUNKLEY

Job Title PRESIDENT

Address PO Box 341644 *Street*

Phone 813·264·2977

TAMPA *City* FL *State* 33694 *Zip*

Email

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FLORIDA Ethics AND Religious LIBERTY COMMISSION

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1.26.16
Meeting Date

1722
Bill Number (if applicable)

Topic TERMINATION of PREGNANCIES

Amendment Barcode (if applicable)

Name JOHN STEMBERGER

Job Title President and General Counsel

Address 4853 S. Orange Ave
Street

Phone 407-418-0250

Orlando FL 32806
City *State* *Zip*

Email

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1.26.16
Meeting Date

1722
Bill Number (if applicable)

Topic TERMINATION of PREGNANCIES

Amendment Barcode (if applicable)

Name AMBER KELLY

Job Title Legislative Assistant

Address PO Box 10626
Street

Phone (407) 418-0250

Tallahassee FL 32302
City *State* *Zip*

Email amberk@floridafamilyaction.org

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Family Action

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/2016
Meeting Date

1722
Bill Number (if applicable)

Topic Abortion bill

Amendment Barcode (if applicable)

Name Patty Burke

Job Title

Address 1317 Sandview Trail
Street

Phone 850-207-0494

Gulf Breeze FL 32561
City *State* *Zip*

Email pattyburke5@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/21/2016
Meeting Date

1722
Bill Number (if applicable)

Topic Abortion Bill

Amendment Barcode (if applicable)

Name Laurie Bartlett

Job Title

Address 15 Marlborough Rd
Street
Shalimar Florida 32579
City *State* *Zip*

Phone 512-584-4589

Email lauriejbartlett@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-16
Meeting Date

SB 1722
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Abortion

Name Amy Datz

Job Title Retiree

Address _____
Street
Tallahassee FL. 32303
City *State* *Zip*

Phone (850) 322 7599

Email Amaliedatz@mac.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing National Council of Jewish Women

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

1722
Bill Number (if applicable)

Topic SB 1722

Amendment Barcode (if applicable)

Name Chris Demesmin

Job Title Constituent

Address 3253 Grove rd
Street

Boynton Beach FL 33435
City *State* *Zip*

Phone 561-577-6495

Email ChrisDemesmin@Gmail.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing Constituent

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-16
Meeting Date

1722
Bill Number (if applicable)

Topic SB1722

Amendment Barcode (if applicable)

Name Sonuerro Alcide

Job Title Constituent

Address 60 S Atlantic Dr. E
Street

Phone

Boynton Beach FL 33435
City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing Constituent

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.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

SB 1722
Bill Number (if applicable)

Topic SB 1722

Amendment Barcode (if applicable)

Name Amanda Canete

Job Title Constituent

Address 2220 22nd In
Street

Phone

Greenacres FL 33463
City *State* *Zip*

Email

Speaking: ☐ For ☒ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing Constituent

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

1722
Bill Number (if applicable)

Topic Senate Bill 1722

Amendment Barcode (if applicable)

Name Briana Ceseretti

Job Title Consituent

Address 1645 Satin leaf Court
Street

Delray Beach FL 33445
City *State* *Zip*

Phone 561-665-0423

Email briannacess@gmail.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing Consituent

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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THE FLORIDA SENATE

APPEARANCE RECORD

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1/26/16
Meeting Date

1722
Bill Number (if applicable)

Topic Senate Bill 1722

Amendment Barcode (if applicable)

Name Natalia Reyes

Job Title Constituent

Address 501 E Gateway Blvd
Street

Phone (561) 291-3600

Boynton Beach FL 33435
City *State* *Zip*

Email nataliareyes64@gmail.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing Constituent

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.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

11/26/15
Meeting Date

1722
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Missy Wesolowski

Job Title Director of Governmental Affairs

Address 2300 N. Florida Mango Rd
Street

West Palm Beach FL 33409
City *State* *Zip*

Phone 561-472-9942

Email missy@ppsenfl.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☒ Against
(The Chair will read this information into the record.)

Representing Florida Alliance of Planned Parenthood Affiliates

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.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-15
Meeting Date

1722
Bill Number (if applicable)

Topic Senate Bill 1722

Amendment Barcode (if applicable)

Name Yaritza Morales

Job Title Constituent

Address 1200 NW 13th st #110
Street

Boca Raton FL 33486
City *State* *Zip*

Phone 954-274-3516

Email yaritzamorales199@gmail.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing Constituent

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

1722
Bill Number (if applicable)

Topic Termination of Pregnancies

Amendment Barcode (if applicable)

Name Pamela Burch Fort

Job Title

Address 104 S. Monroe Street
Street

Phone 850/425-1344

Tallahassee FL 32301
City *State* *Zip*

Email TcgLobby@aol.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing ACLU of Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-15
Meeting Date

1722
Bill Number (if applicable)

Topic Termination of Pregnancies

Amendment Barcode (if applicable)

Name Barbara DeVane

Job Title Ms.

Address 625 E. Brevard St
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 850-222-3969

Email barbaradevane1@yahoo.com

Speaking: ☐ For ☑ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FL NOW

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

SB 1722
Bill Number (if applicable)

Topic SB 1722

Amendment Barcode (if applicable)

Name Gianna Bonner

Job Title Ambassador VOX: Voices for Planned Parenthood @ FSU

Address 75 N Woodward Ave
Street

Phone

Tallahassee FL 32313
City *State* *Zip*

Email gmb14@my.fsu.edu

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing FSU VOX: Voices for Planned Parenthood

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1722

1/26/16
Meeting Date

~~SB 1718~~
Bill Number (if applicable)

Topic ~~SB 1718~~ 1722

Amendment Barcode (if applicable)

Name Gabriel Garcia-Vera

Job Title FL Field Coordinator

Address 8330 Biscayne Blvd
Street

Phone 786 6048310

Miami FL 33138
City *State* *Zip*

Email

Speaking: ☐ For ☑ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing Nat. Latina Institute for Repo. Health

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

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APPEARANCE RECORD

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1/26/16
Meeting Date

1722
Bill Number (if applicable)

Topic SB 1722

Amendment Barcode (if applicable)

Name Marian Rivera

Job Title Constituent

Address 1200 Scaba Dr. #304
Street

Phone 561-404-3859

Hypoluxo FL 33462
City *State* *Zip*

Email Mrivers196@yahoo.com

Speaking: ☐ For ☒ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Constituent

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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1/26/16
Meeting Date

SB 1722
Bill Number (if applicable)

Topic SB1722

Amendment Barcode (if applicable)

Name Madison Podes-Tolmin

Job Title Constituent

Address 1945 NW 4th Ave #34
Street

Boca Raton FL 33432
City *State* *Zip*

Phone 561 350 6106

Email

Speaking: ☐ For ☒ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Constituent

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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1/26/16
Meeting Date

1722
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic SB 1722

Name Cliff Myrtil

Job Title Constituent

Address 5709 Boynton Cove Way
Street

Boynton Beach FL 33437
City *State* *Zip*

Phone 561 860 1144

Email cliffmyrtil123@gmail.com

Speaking: ☐ For ☑ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Constituent

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

RICK SCOTT
GOVERNOR

May 4, 2015

Secretary Kenneth W. Detzner
Department of State
State of Florida
R. A. Gray Building, Room 316
500 South Bronough Street
Tallahassee, Florida 32399-0250

Dear Secretary Detzner:

Please be advised I have made the following reappointment under the provisions of Section 20.43, Florida Statutes:

Dr. John H. Armstrong

As State Surgeon General and Secretary of the Department of Health, subject to confirmation by the Senate. This appointment is effective May 4, 2015, for a term ending at the pleasure of the Governor.

Sincerely,

Rick Scott
Governor

RS/vh

THE CAPITOL
TALLAHASSEE, FLORIDA 32399 • (850) 488-2272

OATH OF OFFICE

(Art. II. § 5(b), Fla. Const.)

RECEIVED
DEPARTMENT OF STATE
2015 JUL -9 AM 10: 12
DIVISION OF ELECTIONS
TALLAHASSEE, FL

STATE OF FLORIDA

County of Leon

I do solemnly swear (or affirm) that I will support, protect, and defend the Constitution and Government of the United States and of the State of Florida; that I am duly qualified to hold office under the Constitution of the State, and that I will well and faithfully perform the duties of

STATE SURGEON GENERAL & SECRETARY OF HEALTH
(Title of Office)

on which I am now about to enter, so help me God.

[NOTE: If you affirm, you may omit the words "so help me God." *See* § 92.52, Fla. Stat.]

John H. Armstrong MD, FACS
Signature

Sworn to and subscribed before me this 30 *day of* June, 2015.

Margaret H Medina
Signature of Officer Administering Oath or of Notary Public

Margaret Harvard Medina
Print, Type, or Stamp Commissioned Name of Notary Public

MARGARET HARVARD MEDINA
Commission # FF 008844
Expires April 23, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

Personally Known ☑ ***OR*** *Produced Identification* ☐

Type of Identification Produced _____

ACCEPTANCE

I accept the office listed in the above Oath of Office.

Mailing Address: ☑ Home ☐ Office

_____
Street or Post Office Box

_____
City, State, Zip Code

JOHN H. ARMSTRONG, MD, FACS
Print name as you desire commission issued

John H Armstrong MD, FACS
Signature

DS-DE 56 (Rev. 02/10)

CERTIFICATION

STATE OF FLORIDA
COUNTY OF Leon

Before me, the undersigned Notary Public of Florida, personally appeared JOHN H. ARMSTRONG, MD, who, after being duty sworn, say: (1) that he/she has carefully and personally prepared or read the answers to the foregoing questions; (2) that the information contained in said answers is complete and true; and (3) that he/she will, as an appointee, fully support the Constitutions of the United States and of the State of Florida.

John H. Armstrong MD
Signature of Applicant-Affiant

Sworn to and subscribed before me this 29 day of July, 2015.

Margaret H Medina
Signature of Notary Public-State of Florida

MARGARET HARVARD MEDINA
Commission # FF 008844
Expires April 23, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

Margaret Harvard Medina
(Print, Type, or Stamp Commissioned Name of Notary Public)

My commission expires: April 23, 2017

Personally Known ☑ **OR** Produced Identification ☐

Type of Identification Produced _____

(seal)

The Florida Senate

Committee Notice Of Hearing

IN THE FLORIDA SENATE
TALLAHASSEE, FLORIDA

IN RE: Executive Appointment of

John H. Armstrong

State Surgeon General

NOTICE OF HEARING

TO: Dr. John H. Armstrong

YOU ARE HEREBY NOTIFIED that the Committee on Health Policy of the Florida Senate will conduct a hearing on your executive appointment on Tuesday, January 26, 2016, in the Pat Thomas Committee Room, 412 Knott Building, commencing at 9:00 a.m., pursuant to Rule 12.7(1) of the Rules of the Florida Senate.

Please be present at the time of the hearing.
DATED this the 22nd day of January, 2016

Committee on Health Policy

Aaron Bean

Senator Aaron Bean
As Chair and by authority of the committee

cc: Members, Committee on Health Policy
Office of the Sergeant at Arms

Drove to Tally just for this.

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

Bill Number (if applicable)

Topic Tab 2 - Dr. John Armstrong

Amendment Barcode (if applicable)

Name Michael Rajner

Job Title

Address PO Box 2133
Street

Phone 954 566-0144

Fort Lauderdale FL 33303
City *State* *Zip*

Email merajner@gmail.com

Speaking: ☐ For ☒ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing self

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.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

Bill Number (if applicable)

Topic Surgeon General Confirmation

Amendment Barcode (if applicable)

Name Chris Nuland

Job Title

Address 1000 Riverside Ave
Street
Jacksonville FL 32204
City *State* *Zip*

Phone 904-233-3051

Email nulandlaw@aol.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Public Health 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.

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S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 818
INTRODUCER:	Health Policy Committee and Senator Latvala
SUBJECT:	Instruction on Human Trafficking
DATE:	January 26, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Fav/CS**
2.			AHS	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 818 requires allopathic and osteopath physicians, physician assistants, anesthesiology assistants, nurses, dentists, dental hygienists, dental lab personnel, psychologists, social workers, mental health counselors, and marriage and family therapists to complete 2 hours of continuing medical education (CE) on domestic violence and human trafficking, approved by the respective board, every third biennial relicensure or recertification cycle. The bill sets requirements for the course content, reporting requirements, and penalties for failure to comply with the CE requirements. The bill grants the boards authority to adopt rules to implement this provision.

II. Present Situation:

Section 456.031, F.S., requires allopathic and osteopath physicians, physician assistants, anesthesiology assistants, nurses, dentists, dental hygienists, dental lab personnel, psychologists, social workers, mental health counselors, and marriage and family therapists licensed under chs. 458, 459, Part I of chs. 464, 466, 490 and 491, F.S., to obtain 2 hours of CE on domestic violence every third biennium, or every 6 years. The law allows each board to approve equivalent courses to satisfy this requirement. Reporting of CE hours is mandatory for these professions through the licensee's CE Broker account.

Florida law defines "domestic violence" as any assault, aggravated assault, battery, aggravated battery, sexual assault, sexual battery, stalking, aggravated stalking, kidnapping, false

imprisonment, or any criminal offense resulting in physical injury or death of one family or household member by another family or household member.[1]

Section 456.031, F.S., sets out the required CE course content for domestic violence, as follows:

- Data and information on the number of patients in that professional's practice who are likely to be victims of domestic violence;
- The number who are likely to be perpetrators of domestic violence;
- Screening procedures for determining whether a patient has any history of being either a victim or a perpetrator of domestic violence; and
- Instruction on how to provide patients with information on resources in the local community, such as domestic violence centers and other advocacy groups, that provide legal aid, shelter, victim counseling, batterer counseling, or child protection services.

Florida Statutes define "human trafficking" to mean transporting, soliciting, recruiting, harboring, providing, enticing, maintaining, or obtaining another person for the purpose of exploitation of that person.[2]

Currently there is no requirement for an allopathic and osteopath physicians, physician assistants, anesthesiology assistants, nurses, dentists, dental hygienists, dental lab personnel, psychologists, social workers, mental health counselors, and marriage and family therapists, to complete any CEs on human trafficking either at initial licensure or renewal.

According to the Division of Medical Quality Assurance (MQA) Annual Report and Long Range Plan for Fiscal Year 2014-2015, there are 48,941 in state active allopathic physicians,[3] 6,216 osteopathic physicians,[4] 6,744 physician assistants, 197 anesthesiologist assistants, 304,666 nurses,[5] 10,981 dentists, 11,589 dental hygienists, 1,023 dental lab personnel, 5,086 psychologists, 7,971 social workers, 9,054 mental health counselors and 1,667 marriage and family therapists holding active licenses in Florida.[6]

III. Effect of Proposed Changes:

CS/SB 818 amends s. 456.031, F.S., to require allopathic and osteopath physicians, physician assistants, anesthesiology assistants, nurses, dentists, dental hygienists, dental lab personnel, psychologists, social workers, mental health counselors, and marriage and family therapists to complete two hours of CE on domestic violence and human trafficking as part of every third

---

[1] *See* s. 741.28, F.S.
[2] *See* s. 787.06(2)(d), F.S.
[3] Florida Dep't of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan Fiscal Year 2014-2015*, p. 11-13, *available at* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1415.pdf, (last visited Jan. 26, 2016). The 48,941 active allopathic physicians includes: 226 house physicians; 146 limited license physicians; 335 critical need physicians, 8 medical expert physicians, 1 Mayo Clinic limited license physician; 40 medical facility physicians; 2 public health physicians; and 1 public psychiatry physician.
[4] *Id*. The 7216 osteopathic physicians includes 5,264 osteopathic physicians, 5 osteopathic limited license physicians, and 2 osteopathic expert physicians.
[5] *Id.* The 304,566 nurses includes 18,250 ARNPs, 26 ARNP/CNS, 131 CNS, 217,315 RNs, and 68,844 LPNs,
[6] *See* supra note 3.

biennial license renewal, which is every six years. The course content for domestic violence remains unchanged.

CS/SB 818 sets out the required course content for the human trafficking portion of the course as follows:

- Data and information on the types and extent of labor and sex trafficking;
- Factors that place a person at greater risk of being a trafficking victim;
- Patient safety and security;
- Management of medical records of patients who are trafficking victims;
- Public and private social services available for rescue, food, clothing, and shelter referrals;
- Hotlines for reporting human trafficking maintained by the National Human Trafficking Resource Center and the U.S. Department of Homeland Security;
- Validated assessment tools for the identification of trafficking victims;
- General indicators that a person may be a victim of human trafficking;
- Procedures for sharing information related to human trafficking with a patient; and
- Referral options for legal and social services as appropriate.

Confirmation of completing the CE hours is due when submitting fees for every third biennial relicensure or recertification. The form of the confirmation is left to the discretion of the board.[7] The board may approve equivalent courses to satisfy this statute's requirements. The two CE hours on domestic violence and human trafficking may be included in the total CE hours required by the profession, unless the CE requirement for the profession is less than 30 hours biennially. A person holding two or more licenses under this section may satisfy the CE requirements for each license upon proof of completion of one, 2-hour, course during the time frame.

CS/SB 818 provides for disciplinary action under s. 456.072(1)(k), F.S., for failure to comply with the CE requirements; and requires the board to include completion of a board approved course under this subsection as part of any discipline imposed. The bill allows each board to adopt rules to carry out this statute.

The bill has an effective date of July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

[7] See The Department of Health, *Continuing Education – CE*, http://www.floridahealth.gov/licensing-and-regulation/ce.html, (last visited Jan. 22, 2016). Currently, the DOH requires all licensees to report all CEs at the time of renewal through the department's electronic tracking system. It happens automatically when a licensee attempts to renew his or her license. If the licensee's CE records are complete, they will be able to renew without interruption. If the licensee's CE records are not complete, they will be prompted to enter their remaining CE hours before proceeding with their license renewal.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Licensees listed in s. 456.031, F.S., are now required to complete a 2-hour course on domestic violence and human trafficking every 6 years and they may incur additional costs to satisfy this requirement, if the cost of the course is increased because of the additional subject matter to be covered.

C. Government Sector Impact:

The boards will incur costs for rulemaking and the Department of Health (DOH) and boards will incur costs for handling complaints and discipline. The DOH has indicated that these costs can be absorbed within existing resources.[8]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill refers to reporting completion of the CEs on a form provided by the board. Currently the DOH uses CE Broker, an electronic tracking system, for licensees to report their CEs. An amendment may be appropriate to require reporting in a manner designated by the DOH.

VIII. Statutes Affected:

This bill substantially amends section 456.031 of the Florida Statutes.

IX. 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 Policy on January 26, 2016:
The committee substitute deletes the creation of new s. 456.0315, F.S., on CEs for human trafficking. It amends existing s. 456.031, F.S., on domestic violence CEs, and adds human trafficking to the required domestic violence CE, making the required course a 2-hour course on both domestic violence and human trafficking due every third biennium.

[8] *See* Florida Dep't of Health, *Senate Bill 818 Analysis*, p. 46, (Nov. 16, 2015) (on file with the Senate Committee on Health Policy).

It also increase the number of professions required to take the CEs to all those listed in s. 456.031, F.S.

B. Amendments:

None.

418944

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2016	.	
	.	
	.	
	.	

The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 456.031, Florida Statutes, is amended to read:

456.031 Requirement for instruction on domestic violence and human trafficking.—

(1)(a) The appropriate board shall require each person licensed or certified under chapter 458, chapter 459, part I of

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chapter 464, chapter 466, chapter 467, chapter 490, or chapter 491 to complete a 2-hour continuing education course, approved by the board, on domestic violence, as defined in s. 741.28, and on human trafficking, as defined in s. 787.06(2), as part of every third biennial relicensure or recertification.

1. The domestic violence section of the course must ~~shall~~ consist of data and information on the number of patients in that professional's practice who are likely to be victims of domestic violence and the number who are likely to be perpetrators of domestic violence, screening procedures for determining whether a patient has any history of being either a victim or a perpetrator of domestic violence, and instruction on how to provide such patients with information on, or how to refer such patients to, resources in the local community, such as domestic violence centers and other advocacy groups, that provide legal aid, shelter, victim counseling, batterer counseling, or child protection services.

2. The human trafficking section of the course must consist of data and information on the types of human trafficking, such as labor and sex, and the extent of human trafficking; factors that place a person at greater risk for being a victim of human trafficking; management of medical records of patients who are human trafficking victims; patient safety and security; public and private social services available for rescue, food, clothing, and shelter referrals; hotlines for reporting human trafficking maintained by the National Human Trafficking Resource Center and the United States Department of Homeland Security; validated assessment tools for identifying human trafficking victims and general indicators that a person may be

418944

a victim of human trafficking; procedures for sharing information related to human trafficking with a patient; and referral options for legal and social services.

(b) Each ~~such~~ licensee or certificateholder shall submit confirmation of having completed the continuing education ~~such~~ course, on a form provided by the board, when submitting fees for every third biennial relicensure or recertification ~~renewal~~.

(c) The board may approve additional equivalent courses that may be used to satisfy the requirements of paragraph (a). Each licensing board that requires a licensee to complete a continuing ~~an~~ educational course pursuant to this subsection may include the hour required for completion of the course in the total hours of continuing education required by law for the ~~such~~ profession, unless the continuing education requirements for the ~~such~~ profession consist of fewer than 30 hours of continuing education biennially.

(d) Any person holding two or more licenses subject to ~~the provisions of~~ this subsection shall be permitted to show proof of completion of ~~having taken~~ one board-approved course on domestic violence and human trafficking, for purposes of relicensure or recertification for additional licenses.

(e) Failure to comply with the requirements of this subsection shall constitute grounds for disciplinary action under each respective practice act and under s. 456.072(1)(k). In addition to discipline by the board, the licensee shall be required to complete the board-approved ~~such~~ course under this subsection.

(2) Each board may adopt rules to carry out the provisions of this section.

418944

Section 2. This act shall take effect July 1, 2016.

========== 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 instruction on human trafficking; amending s. 456.031, F.S.; providing that certain licensing boards must require specified licensees to complete a specified continuing education course that includes a section on human trafficking as a condition of relicensure or recertification; providing requirements and procedures related to the course; providing an effective date.

By Senator Latvala

20-00680-16 2016818__

A bill to be entitled

An act relating to instruction on human trafficking; creating s. 456.0315, F.S.; providing that certain licensing boards must require specified licensees to complete a continuing education course on human trafficking as a condition of relicensure or recertification; providing requirements and procedures related to the course; providing that failure to complete the course is grounds for disciplinary action; providing rulemaking authority; providing an effective date.

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

Section 1. Section 456.0315, Florida Statutes, is created to read:

456.0315 Requirement for continuing education on human trafficking.—

(1)(a) The appropriate board shall require each person licensed or certified under chapter 458 or chapter 459 to complete a 1-hour continuing education course, approved by the board, on human trafficking, as defined in s. 787.06(2), as part of every third biennial relicensure or recertification. The course shall consist of data and information on the extent of labor and sex trafficking; risk factors and indicators to recognize human trafficking victims; management of medical records of patients who are human trafficking victims; patient safety and security; public and private social services available for rescue, food, clothing, and shelter referrals;

20-00680-16 2016818__

hotlines for reporting human trafficking maintained by the National Human Trafficking Resource Center and the United States Department of Homeland Security; validated assessment tools for identifying human trafficking victims; procedures for sharing information related to human trafficking with a patient; and referral options for legal and social services as appropriate.

(b) Each licensee or certificateholder shall submit confirmation of having completed the continuing education course, on a form provided by the board, when submitting fees for every third biennial relicensure or recertification.

(c) The board may approve additional equivalent courses that may be used to satisfy the requirements of paragraph (a). Each licensing board that requires a licensee to complete a continuing education course pursuant to this subsection may include the hour required for completion of the course in the total hours of continuing education required by law for the profession, unless the continuing education requirements for the profession consist of fewer than 30 hours of continuing education biennially.

(d) Any person holding two or more licenses subject to the provisions of this subsection shall be permitted to show proof of completion of one board-approved course on human trafficking for purposes of relicensure or recertification for additional licenses.

(e) Failure to comply with the requirements of this subsection shall constitute grounds for disciplinary action under chapter 458 or chapter 459 and s. 456.072(1)(k). In addition to discipline by the board, the licensee shall be required to complete the board-approved course under this

subsection.

(2) Each board may adopt rules to carry out the provisions of this section.

Section 2. This act shall take effect July 1, 2016.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on Transportation, Tourism, and Economic Development, *Chair*
Appropriations
Commerce and Tourism
Governmental Oversight and Accountability
Regulated Industries
Rules

SENATOR JACK LATVALA
20th District

January 13, 2016

The Honorable Aaron Bean, Chair
Senate Committee on Health Policy
225 Knott Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chairman Bean:

I respectfully request consideration of Senate Bill 818/Instruction on Human Trafficking by the Senate Committee on Health Policy at your earliest convenience.

This bill requires that certain licensing boards must require specified licensees to complete a continuing education course on human trafficking as a condition of relicensure or recertification.

If you have any questions regarding this legislation, please contact me. Thank you in advance for your consideration.

Sincerely,

Jack Latvala
State Senator
District 20

Cc: Sandra Stovall, Staff Director; Celia Georgiades, Administrative Assistant

REPLY TO:
☐ 26133 U.S. Highway 19 North, Suite 201, Clearwater, Florida 33763 (727) 793-2797 FAX: (727) 793-2799
☐ 408 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5020

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on Transportation, Tourism, and Economic Development, *Chair*
Appropriations
Commerce and Tourism
Governmental Oversight and Accountability
Regulated Industries
Rules

SENATOR JACK LATVALA
20th District

January 25, 2016

The Honorable Aaron Bean, Chair
Senate Health Policy Committee
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Bean:

My bill on Instruction on Human Trafficking, Senate Bill 818, is scheduled to be heard in the Health Policy Committee on Tuesday, January 26th at 9 a.m. at the same time as my Governmental Oversight and Accountability Committee. I respectfully request that my legislative aide, Lizbeth Mabry, be permitted to present the bill before the Health Policy Committee.

Thank you for your consideration.

Sincerely,

Jack Latvala
Senator, District 20

Cc: Sandra Stovall, Staff Director; Celia Georgiades, Administrative Assistant

REPLY TO:
☐ 26133 U.S. Highway 19 North, Suite 201, Clearwater, Florida 33763 (727) 793-2797 FAX: (727) 793-2799
☐ 408 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5020

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

ANDY GARDINER
President of the Senate

GARRETT RICHTER
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-16
Meeting Date

SB 8
Bill Number (if applicable)

Topic Human Trafficking

Amendment Barcode (if applicable)

Name Barbara DeVane

Job Title Ms

Address 625 E. Brevard ST
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 850-222-3969

Email barbaradevane1@yahoo.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FL NOW

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-16
Meeting Date

~~SB~~ SB 818
Bill Number (if applicable)

Topic Human Trafficking

Amendment Barcode (if applicable)

Name Amy Datz

Job Title Retiree

Address _____
Street

_____
City *State* *Zip*

Phone (850) 322 7599

Email amalie datz @ mac.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing National Council of Jewish Women

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 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 764
INTRODUCER:	Senator Hays
SUBJECT:	Public Food Service Establishments
DATE:	January 22, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.			RI	
3.			FP	

I. Summary:

SB 764 amends s. 509.013, F.S., to exclude from the definition of "public food service establishment":

- Any temporary eating place used for food contests or cook offs and maintained by a school, college, university, church, religious organization, nonprofit fraternal organization, or nonprofit civic organization; and
- Any eating place maintained and operated by an individual or entity at a food contest, cook-off, or temporary event lasting up to three days hosted by a church, religious organization, nonprofit fraternal organization, or nonprofit civic organization.

The bill requires that, upon request by the Division of Hotels and Restaurants of the Department of Business and Professional Regulation (division), the organization claiming the exclusion must provide proof of its status as a church, religious organization, nonprofit fraternal organization, or nonprofit civic organization.

II. Present Situation:

Public Food Service Establishments

The Division of Hotels and Restaurants within the Department of Business and Professional Regulation (department) is the state agency charged with enforcing the provisions of part I of ch. 509, F.S., and all other applicable laws relating to the inspection and regulation of public food service establishments for the purpose of protecting the public health, safety, and welfare.

A "public food service establishment" is any building, vehicle, place, or structure, or any room or division therein where food is prepared, served, or sold for immediate consumption on or near

the premises; called for or taken out by customers; or prepared prior to being delivered to another location for consumption.[1]

At the end of the 2014-2015 fiscal year, there were 49,966 licensed public food service establishments, including seating, permanent non-seating, hotdog carts, and mobile food dispensing vehicles.[2]

Exclusions from the Definition of Public Food Service Establishments

There are several exclusions from the definition of public food service establishment, including:[3]

- Any place maintained and operated by a public or private school, college, or university for the use of students and faculty or temporarily to serve events such as fairs, carnivals, and athletic contests.
- Any eating place maintained and operated by a church or a religious, nonprofit fraternal, or nonprofit civic organization for the use of members and associates or temporarily to serve events such as fairs, carnivals, or athletic contests.
- Any eating place located on an airplane, train, bus, or watercraft which is a common carrier.
- Any eating place maintained by a facility certified or licensed and regulated by the Agency for Health Care Administration or the Department of Children and Families.[4]
- Any place of business issued a permit or inspected by the Department of Agriculture and Consumer Services (DACS) under s. 500.12, F.S.
- Any place of business serving only ice beverages, popcorn, and prepackaged items.
- Any vending machine that dispenses any food or beverage other than potentially hazardous foods.[5]
- Any research and development test kitchen limited to the use of employees and not open to the general public.

Temporary Food Service Events

In Florida, a "temporary food service event" is any event of 30 days or less where food is prepared, served, or sold to the general public.[6] During Fiscal Year 2014-2015, the division issued 7,849 temporary food service event licenses.[7] The division issues licenses for 1 - 3-day events, 4 - 30-day events, and an annual licenses. The division does not license temporary food service events located on the premises of a church, school, or nonprofit fraternal or civic

[1] Section 509.013(5)(a), F.S.
[2] Florida Dep't of Business and Professional Regulation, Division of Hotels and Restaurants, *Annual Report Fiscal Year 2014-2015, available at* http://www.myfloridalicense.com/dbpr/hr/reports/annualreports/documents/ar2014_15.pdf (last visited Jan. 22, 2016).
[3] Section 509.013(5)(b), F.S.
[4] Including other similar food service establishments that are regulated under s. 381.0072, F.S.
[5] Vending machines located in a facility regulated under s. 381.0072, F.S., that dispense potentially hazardous foods are also excluded from the definition.
[6] Section 509.13(8), F.S.
[7] *Supra* note 2.

organization or events located elsewhere and operated by such organizations because these types of organizations are excluded from the division's regulation.[8]

Current license fees are $91 for a 1 - 3-day license, $105 for a 4 - 30-day license, and $456 for an annual license.[9] The division collected an estimated $199,654 from 1 - 3-day license fees in Fiscal Year 2014-2015.[10]

III. Effect of Proposed Changes:

SB 764 amends s. 509.013, F.S., to exclude from the definition of "public food service establishment":

- Any temporary eating place used for food contests or cook offs and maintained by a school, college, university, church, religious organization, nonprofit fraternal organization, or nonprofit civic organization; and
- Any eating place maintained and operated by an individual or entity at a food contest, cook-off, or temporary event lasting up to three days hosted by a church, religious organization, nonprofit fraternal organization, or nonprofit civic organization.

The bill requires that, upon request by the division, the organization claiming the exclusion must provide proof of its status as a church, religious organization, nonprofit fraternal organization, or nonprofit civic organization.

The bill also makes technical and conforming changes.

The bill establishes an effective date of July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

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[8] Florida Dep't of Business and Professional Regulation, *Do churches, schools, or nonprofit organizations need a temporary food service event license?* (updated 06/01/2012) *available at* http://myfloridalicense.custhelp.com/app/answers/detail/a_id/104 (last visited Jan. 22, 2016).
[9] Rule 61C-1.008, F.A.C.
[10] Florida Dep't of Business and Professional Regulation, *Senate Bill 764 Analysis* (Nov. 23, 2016) (on file with the Senate Committee on Health Policy).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 764 may have a positive fiscal impact on any person or entity that would have been required to obtain a license for a temporary food service event, is no longer required to obtain such license.

C. Government Sector Impact:

The department estimates that SB 764 will likely have a negative fiscal impact on the department of up to $199,654 annually due to the reduction in license fees being generated. Additionally, the revenue reduction will also cause a $15,972 annual reduction in the 8 percent service charge transferred to general revenue.[11]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 509.013 and 509.032.

IX. Additional Information:

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

None.

B. Amendments:

None.

[11] Supra note 10

By Senator Hays

11-00079-16 2016764__

A bill to be entitled

An act relating to public food service establishments; amending s. 509.013, F.S.; revising the definition of the term "public food service establishment" to exclude certain events; amending s. 509.032, F.S.; clarifying that a food service license is not required to be obtained if an event is excluded under the definition of the term "public food service establishment"; providing an effective date.

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

Section 1. Subsection (5) of section 509.013, Florida Statutes, is amended to read:

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

(5)(a) "Public food service establishment" means any building, vehicle, place, or structure, or any room or division in a building, vehicle, place, or structure where food is prepared, served, or sold for immediate consumption on or in the vicinity of the premises; called for or taken out by customers; or prepared prior to being delivered to another location for consumption.

(b) The following are excluded from the definition in paragraph (a):

1. Any place maintained and operated by a public or private school, college, or university:

a. For the use of students and faculty; or

b. Temporarily to serve such events as fairs, carnivals, food contests, cook-offs, and athletic contests.

11-00079-16 2016764__

2. Any eating place maintained and operated by a church or a religious, nonprofit fraternal, or nonprofit civic organization:

a. For the use of members and associates; or

b. Temporarily to serve such events as fairs, carnivals, food contests, cook-offs, or athletic contests.

Upon request by the division, a church or a religious, nonprofit fraternal, or nonprofit civic organization claiming an exclusion under this subparagraph must provide the division documentation of its status as a church or a religious, nonprofit fraternal, or nonprofit civic organization.

3. Any eating place maintained and operated by an individual or entity at a food contest, cook-off, or a temporary event lasting from 1 to 3 days which is hosted by a church or a religious, nonprofit fraternal, or nonprofit civic organization. Upon request by the division, the event host must provide the division documentation of its status as a church or a religious, nonprofit fraternal, or nonprofit civic organization.

4.~~3.~~ Any eating place located on an airplane, train, bus, or watercraft which is a common carrier.

5.~~4.~~ Any eating place maintained by a facility certified or licensed and regulated by the Agency for Health Care Administration or the Department of Children and Families or other similar place that is regulated under s. 381.0072.

6.~~5.~~ Any place of business issued a permit or inspected by the Department of Agriculture and Consumer Services under s. 500.12.

7.~~6.~~ Any place of business where the food available for

consumption is limited to ice, beverages with or without garnishment, popcorn, or prepackaged items sold without additions or preparation.

8.~~7.~~ Any theater, if the primary use is as a theater and if patron service is limited to food items customarily served to the admittees of theaters.

9.~~8.~~ Any vending machine that dispenses any food or beverages other than potentially hazardous foods, as defined by division rule.

10.~~9.~~ Any vending machine that dispenses potentially hazardous food and which is located in a facility regulated under s. 381.0072.

11.~~10.~~ Any research and development test kitchen limited to the use of employees and which is not open to the general public.

Section 2. Paragraph (c) of subsection (3) of section 509.032, Florida Statutes, is amended to read:

509.032 Duties.—

(3) SANITARY STANDARDS; EMERGENCIES; TEMPORARY FOOD SERVICE EVENTS.—The division shall:

(c) Administer a public notification process for temporary food service events and distribute educational materials that address safe food storage, preparation, and service procedures.

1. Sponsors of temporary food service events shall notify the division not less than 3 days before the scheduled event of the type of food service proposed, the time and location of the event, a complete list of food service vendors participating in the event, the number of individual food service facilities each vendor will operate at the event, and the identification number

of each food service vendor's current license as a public food service establishment or temporary food service event licensee. Notification may be completed orally, by telephone, in person, or in writing. A public food service establishment or food service vendor may not use this notification process to circumvent the license requirements of this chapter.

2. The division shall keep a record of all notifications received for proposed temporary food service events and shall provide appropriate educational materials to the event sponsors and notify the event sponsors of the availability of the food-recovery brochure developed under s. 595.420.

3.a. Unless excluded under s. 509.013(5)(b), a public food service establishment or other food service vendor must obtain one of the following classes of license from the division: an individual license, for a fee of no more than $105, for each temporary food service event in which it participates; or an annual license, for a fee of no more than $1,000, that entitles the licensee to participate in an unlimited number of food service events during the license period. The division shall establish license fees, by rule, and may limit the number of food service facilities a licensee may operate at a particular temporary food service event under a single license.

b. Public food service establishments holding current licenses from the division may operate under the regulations of such a license at temporary food service events.

Section 3. This act shall take effect July 1, 2016.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR ALAN HAYS
11th District

COMMITTEES:
Appropriations Subcommittee on General Government, *Chair*
Governmental Oversight and Accountability, *Vice Chair*
Appropriations
Environmental Preservation and Conservation
Ethics and Elections
Fiscal Policy

JOINT COMMITTEE:
Joint Select Committee on Collective Bargaining, *Alternating Chair*

MEMORANDUM

To: Senator Aaron Bean
Committee on Health Policy
CC: Sandra Stovall, Staff Director
Celia Georgiades, Committee Administrative Assistant

From: Senator D. Alan Hays

Subject: Request to agenda SB 764- Public Food Service Establishments

Date: December 12, 2015

I respectfully request that you agenda the above referenced bill at your earliest convenience. If you have any questions regarding this legislation, I welcome the opportunity to meet with you one-on-one to discuss it in further detail. Thank you so much for your consideration of this request.

Sincerely,

D. Alan Hays, DMD

D. Alan Hays, DMD
State Senator, District 11

REPLY TO:
- 871 South Central Avenue, Umatilla, Florida 32784-9290 (352) 742-6441
- 320 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5011
- 1104 Main Street, The Villages, Florida 32159 (352) 360-6739 FAX: (352) 360-6748
- 685 West Montrose Street, Suite 210, Clermont, Florida 34711 (352) 241-9344 FAX: (888) 263-3677

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

ANDY GARDINER
President of the Senate

GARRETT RICHTER
President Pro Tempore

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR D. ALAN HAYS
20th District

COMMITTEES:
Budget - Subcommittee on General Government Appropriations, *Chair*
Agriculture
Banking and Insurance
Budget
Budget - Subcommittee on Higher Education Appropriations
Children, Families, and Elder Affairs
Reapportionment

JOINT COMMITTEE:
Administrative Procedures

January 22, 2016

Senator Aaron Bean, Chair
Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

RE: SB 764- Public Food Service Establishments

Dear Chairman Bean,

I am unable to attend the Committee on Health Policy scheduled for January 26th at 9:00am because I will be in the Government Oversight and Accountability committee. Please allow my aide, Amy Nicotra, to present the above referenced bills before your committee.

Thank you for favorable consideration of this request.

Sincerely,

D. Alan Hays, DMD

D. Alan Hays, DMD
State Senator District 11

CC: Sandra Stovall, Staff Director
Celia Georgiades, Committee Administrative Assistant

REPLY TO:
☐ 871 South Central Avenue, Umatilla, Florida 32784-9290 (352) 742-6441
☐ 324 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5014

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 Committee on Health Policy

BILL:	SB 878
INTRODUCER:	Senator Sachs
SUBJECT:	Medical Faculty Certification
DATE:	January 20, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Favorable**
2.			HE	
3.			RC	

I. Summary:

SB 878 allows medical faculty certificates to be issued to qualified full time faculty appointed to teach at The Florida Atlantic University by adding it to the list of accredited Florida medical schools; and revises the name of the Mayo Medical School at the Mayo Clinic, to the Mayo Clinic College of Medicine, in Jacksonville, Florida.

II. Present Situation:

Section 458.3145, F.S., allows the Department of Health (DOH) to issue medical facility certificates to qualified physicians licensed in another jurisdiction, who have accepted a full time faculty position at an accredited Florida medical school, to practice medicine in that school's affiliated clinical facilities or teaching hospitals, without sitting for, and passing, a licensure examination.

Applicants seeking a medical faculty certificate must meet all of the following requirements:

- Have graduated from an accredited medical school listed with the World Health Organization;
- Hold a current, valid license to practice medicine in another jurisdiction;
- Have completed an approved residency or fellowship of at least 1 year or received training which has been determined by the Board to be equivalent to the 1 year requirement;
- Have been offered and accepted a full-time faculty appointment to teach in a program of medicine at:
  - University of Florida;
  - University of Miami;
  - University of South Florida;
  - Florida State University;
  - Florida International University;

- University of Central Florida; and
- Mayo Medical School at the Mayo Clinic in Jacksonville, Florida.

Florida Atlantic University is not included in that list. Legislation authorizing Florida Atlantic University's medical education program was signed into law by the Governor May 15, 2010.[1]

The medical faculty certificate is valid until the earlier of termination of the physician's relationship with the medical school or after a period of 24 months. The certificate is renewable and may be extended for 2 years if the physician provides a certification from the dean of the medical school that the physician is a distinguished medical scholar and an outstanding practicing physician. The maximum number of extended Medical faculty certificate holders is limited to 30 persons per each medical school, with the exception of the Mayo Clinic, which is limited to 10 certificate holders.[2]

As of the date of this analysis, there are 42 clear and active physicians who hold Medical faculty certificates.[3] Medical faculty at the listed medical schools may also hold unrestricted medical licenses issued through licensure by examination or licensure by endorsement according to the requirements in ss. 458.311 and 458.313, F.S., respectively. Holding an unrestricted medical license through either one of those avenues would not require a physician on the faculty to obtain a medical faculty certificate.

III. Effect of Proposed Changes:

SB 878 expands the current medical faculty certificate eligibility criteria by allowing a medical faculty certificate to be issued to an individual who has been offered and has accepted a full-time faculty appointment to teach in a program of medicine at the Florida Atlantic University. The bill also limits the number of extended medical faculty certificate holders allowed at the Florida Atlantic University to 30 persons, which is consistent with limitations for all but one of the other institutions eligible for such certificates.

The bill also changes the name of the Mayo Medical School at the Mayo Clinic in Jacksonville, Florida, in s. 458.3145, F.S., to the Mayo Clinic College of Medicine in Jacksonville, Florida. The Mayo Medical School is only one of five schools within the Mayo Clinic College of Medicine which includes the Mayo Medical School, Mayo Graduate School, Mayo School of Graduate Medical Education, Mayo School of Health Sciences, and Mayo School of Continuous Professional Development.[4] Therefore, the bill allows a physician hired to teach in any one of the five schools under the Mayo Clinic College of Medicine to be eligible for a medical faculty certificate.

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[1] *See* ch. 2010-88, s.1, Laws of Fla. (effective July 1, 2010), and FAU – *Mission and History – The Charles Schmidt College of Medicine*, (September 4, 2015) *available at* http://med.fau.edu/home/mission_history.php (last visited Jan. 21, 2016).
[2] Section 458.3145, F.S.
[3] Florida Dep't of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan Fiscal Year 2014-2015*, p. 11, *available at* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1415.pdf , (last visited Jan. 20, 2016).
[4] Mayo Clinic College of Medicine, *About*, available at http://www.mayo.edu/education/about (last visited on Jan. 21, 2016).

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

IV. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

V. Technical Deficiencies:

None.

VI. Related Issues:

None.

VII. Statutes Affected:

This bill substantially amends section 458.145 of the Florida Statutes.

VIII. Additional Information:

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

None.

B. Amendments:

None.

By Senator Sachs

34-00586A-16 2016878__

A bill to be entitled

An act relating to medical faculty certification; amending s. 458.3145, F.S.; revising the list of schools at which certain faculty members are eligible to receive a medical faculty certificate; providing an effective date.

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

Section 1. Paragraph (i) of subsection (1) and subsection (4) of section 458.3145, Florida Statutes, are amended to read:

458.3145 Medical faculty certificate.—

(1) A medical faculty certificate may be issued without examination to an individual who:

(a) Is a graduate of an accredited medical school or its equivalent, or is a graduate of a foreign medical school listed with the World Health Organization;

(b) Holds a valid, current license to practice medicine in another jurisdiction;

(c) Has completed the application form and remitted a nonrefundable application fee not to exceed $500;

(d) Has completed an approved residency or fellowship of at least 1 year or has received training which has been determined by the board to be equivalent to the 1-year residency requirement;

(e) Is at least 21 years of age;

(f) Is of good moral character;

(g) Has not committed any act in this or any other jurisdiction which would constitute the basis for disciplining a

34-00586A-16 2016878__

physician under s. 458.331;

(h) For any applicant who has graduated from medical school after October 1, 1992, has completed, before entering medical school, the equivalent of 2 academic years of preprofessional, postsecondary education, as determined by rule of the board, which must include, at a minimum, courses in such fields as anatomy, biology, and chemistry; and

(i) Has been offered and has accepted a full-time faculty appointment to teach in a program of medicine at:

1. The University of Florida;~~,~~

2. The University of Miami;~~,~~

3. The University of South Florida;~~,~~

4. The Florida State University;~~,~~

5. The Florida International University;~~,~~

6. The University of Central Florida;~~, or~~

7. The ~~Mayo Medical School at the~~ Mayo Clinic College of Medicine in Jacksonville, Florida; or

8. The Florida Atlantic University.

(4) In any year, the maximum number of extended medical faculty certificateholders as provided in subsection (2) may not exceed 30 persons at each institution named in subparagraphs (1)(i)1.-6. and 8. and at the facility named in s. 1004.43 and may not exceed 10 persons at the institution named in subparagraph (1)(i)7.

Section 2. This act shall take effect July 1, 2016.

The Florida Senate

Committee Agenda Request

To: Senator Aaron Bean, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: December 17, 2015

I respectfully request that **Senate Bill #878**, relating to Medical Faculty Certification, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Maria Lorts Sachs
Florida Senate, District 34

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

SB 878
Bill Number (if applicable)

Topic Medical Faculty Certificates

Amendment Barcode (if applicable)

Name Ryan Britton

Job Title Ex. Dir. of Government Relations

Address 777 Glades Rd. ADM 247
Street

Phone 561.297.2583

Boca Raton FL 33431
City *State* *Zip*

Email ryan.britton@fau.edu

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

Waive Speaking: [ ] In Support [ ] Against
(The Chair will read this information into the record.)

Representing Florida Atlantic University

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.

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-16
Meeting Date

SB 878
Bill Number (if applicable)

Topic Medical Faculty Certificates

Amendment Barcode (if applicable)

Name Layne Smith

Job Title Director, State Govt. Relations

Address 4500 San Pablo Rd.
Street

Phone 904-953-7334

Jacksonville FL 32224
City *State* *Zip*

Email smith.layne@mayo.edu

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

Waive Speaking: [X] In Support [ ] Against
(The Chair will read this information into the record.)

Representing Mayo Clinic College of Medicine

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.

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1686
INTRODUCER:	Health Policy Committee and Senators Bean and Joyner
SUBJECT:	Telehealth
DATE:	January 26, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1686 creates a Telehealth Task Force within the Agency for Health Care Administration (AHCA), authorizes healthcare practitioners in Florida to provide telehealth services, and defines telehealth.

The task force is chaired by the Secretary of the AHCA or his or her designee, the State Surgeon General and 17 other members, including other health care practitioners, providers, telehealth services providers and sellers, and facilities.

The bill requires the task force to compile data and submit a report by June 30, 2017, to the Governor, the President of the Senate, and the Speaker of the House of Representatives that analyzes:

- Frequency and extent of the use of telehealth nationally and in this state;
- Costs and cost savings associated with using telehealth;
- Types of telehealth services available;
- Extent of available health insurance coverage available for telehealth services; and
- Barriers to implementing the use of, using, or accessing telehealth services.

The bill requires the task force to hold its first meeting by September 1, 2016, and to meet as frequently as necessary to complete its work. The AHCA must support the task force within existing resources and its members serve without compensation or per diem reimbursement. The section of law creating the task force is repealed December 1, 2017.

The act has no fiscal impact and an effective date of July 1, 2016.

II. Present Situation:

The term telehealth is sometimes used interchangeably with telemedicine. Telehealth, however, generally refers to a wider range of health care services that may or may not include clinical services.[1] Telehealth often collectively defines the telecommunications equipment and technology that is used to collect and transmit the data for a telemedicine consultation or evaluation.

The federal Centers for Medicare & Medicaid Services (CMS) defines telehealth as:

> The use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance. Telehealth includes such technologies such as telephones, facsimile machines, electronic mail systems, and remote patient monitoring devises which are used to collect and transmit data for monitoring and interpretation.[2]

Telemedicine is not a separate medical specialty and does not change what constitutes proper medical treatment and services. According to the American Telemedicine Association, services provided through telemedicine include:[3]

- Primary care and specialist referral services that involve a primary care or allied health professional providing consultation with a patient or specialist assisting the primary care physician with a diagnosis;
- Remote patient monitoring;
- Consumer medical and health information that offers consumers specialized health information and online discussion groups for peer-to-peer support; and
- Medical education that provides continuing medical education credits.

Board of Medicine Rulemaking

Florida's Board of Medicine (board) convened a Telemedicine Workgroup in 2013 to review its rules on telemedicine, which had not been amended since 2003. The 2003 rules focused on standards for the prescribing of medicine via the Internet. On March 12, 2014, the board's new Telemedicine Rule, 64B8-9.0141, became effective for Florida-licensed physicians. The new rule defined telemedicine, established standards of care, prohibited the prescription of controlled

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[1] Anita Majerowicz and Susan Tracy, *"Telemedicine: Bridging Gaps in Healthcare Delivery,"* Journal of AHIMA 81, no. 5, (May 2010); 52-53, 56. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_047324.hcsp?dDocName=bok1_047324 (last visited Jan. 14, 2016).

[2] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Telemedicine*, http://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/telemedicine.html (last visited Jan. 14, 2016).

[3] American Telemedicine Association, *What is Telemedicine?* http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.Vpf-P03ot9A (last visited Jan. 14, 2016).

substances, permitted the establishment of a doctor-patient relationship via telemedicine, and exempted emergency medical services.[4]

An emergency rule followed shortly after the initial rule's implementation to address concerns that the prohibition on physicians ordering controlled substances may also preclude physicians from prescribing controlled substances via telemedicine for hospitalized patients. The board indicated such a prohibition was not intended.[5] The emergency rule went into effect on April 30, 2014, and was later incorporated during the regular rulemaking process.

Additional changes followed to clarify medical record requirements and the relationship between consulting or cross-coverage physicians. On December 4, 2015, the board proposed another rule change to allow controlled substances to be prescribed through telemedicine for the limited treatment of psychiatric disorders.[6] The proposed rule amendment, Rule 64B8-9.0141-Standards for Telemedicine Practice, has been noticed by the Board of Medicine and if requested within 21 days of its first publication date in the Florida Administrative Registrar (FAR), a public hearing on the rule amendment, would be held on the rule and announced at a later date in the FAR. The first publication date was December 18, 2015; no public hearing notice has been published, yet.

Telemedicine in Other States

As of May 2015, 24 states and the District of Columbia have mandated that private insurance plans cover telemedicine services at reimbursement rates equal to an in-person consultation.[7] Such laws require insurance companies and health plans to reimburse providers the same amount for the same visit regardless of whether the visit was conducted face-to-face or via electronic communications.

Forty-eight state Medicaid programs also reimburse for some form of telemedicine via live video.[8] A smaller number of states offer reimbursement for other types of telemedicine services, such as store-and-forward activities;[9] facility fees for hosting either the telemedicine provider, patient, or both; and remote patient monitoring. Florida, Idaho, and Montana only provide reimbursement for physician services.[10]

Hospitals in rural counties have utilized telemedicine to provide specialty care in their emergency rooms and to avoid costly and time-consuming transfers of patients from smaller hospitals to the larger tertiary centers for care.

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[4] Rule 64B15-14.0081, F.A.C., also went into effect March 12, 2014 for osteopathic physicians.
[5] Florida Board of Medicine, *Latest News - Emergency Rule Related to Telemedicine*, http://flboardofmedicine.gov/latest-news/emergency-rule-related-to-telemedicine/ (last visited Jan. 14, 2016).
[6] Vol. 42/02, Fla. Admin. Weekly, 22 (Jan. 5, 2016).
[7] American Telemedicine Association, *50 State Telemedicine Gaps Analysis: Coverage & Reimbursement*, p. 2, http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis---coverage-and-reimbursement.pdf (last visited Jan. 14, 2016).
[8] Id.
[9] Store and forward technology refers to the electronic transmission of medical information and data such as digital images, documents and pre-recorded images for review by a physician or specialist at a later date, not simultaneously with the patient.
[10] *Supra* note 7.

In a California project, rural hospital emergency rooms received video conference equipment to facilitate the telemedicine consultations. The rural hospital physicians and nurses were linked with pediatric critical care medicine specialists at the University of California, Davis.[11] As a *Futurity* article notes, "while 21 percent of children in the United States live in rural areas, only 3 percent of pediatric critical-care medicine specialists practice in such areas."[12]

Federal Provisions for Telemedicine

Federal laws and regulations address telemedicine from several angles, including prescriptions for controlled substances, hospital emergency room guidelines, and reimbursement rates for the Medicare program.

Prescribing Via the Internet

Federal law specifically prohibits the prescribing of controlled substances via the Internet without an in-person evaluation. Federal regulation 21 CFR §829 specifically states:

> No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed or dispensed by means of the Internet without a valid prescription.

A valid prescription is further defined under the same regulation as one issued by a practitioner who has conducted an in-person evaluation. The in-person evaluation requires that the patient be in the physical presence of the provider without regard to the presence or conduct of other professionals.[13] However, the Ryan Haight Online Pharmacy Consumer Protection Act,[14] signed into law in October 2008, created an exception for the in-person medical evaluation for telemedicine practitioners. The practitioner is still subject to the requirement that all controlled substances be issued for a legitimate purpose by a practitioner acting in the usual course of professional practice.

The Drug Enforcement Administration (DEA) of the federal Department of Justice issued its own definition of telemedicine in April 2009 as required under the Haight Act.[15] The federal regulatory definition of telemedicine under the DEA includes, but is not limited to, the following elements:

- The patient and practitioner are located in separate locations;
- Patient and practitioner communicate via a telecommunications system;
- The practitioner must meet other registration requirements for the dispensing of controlled substances via the Internet; and
- Certain practitioners (Department of Veterans Affairs' employees, for example) or practitioners in certain situations (public health emergencies) may be exempted from registration requirements.[16]

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[11] Futurity, *In Rural ERs, Kids Get Better Care with Telemedicine,* http://www.futurity.org/in-rural-ers-kids-get-better-care-with-telemedicine/ (last visited Jan. 14, 2016).
[12] Id.
[13] 21 CFR §829(e)(2).
[14] Ryan Haight Online Consumer Protection Act of 2008, Public Law 110-425 (H.R. 6353).
[15] Id., at sec. 3(j).
[16] 21 CFR §802(54).

Medicare Coverage

Specific telehealth services delivered at designated sites are covered under Medicare. Regulations of federal CMS require both a distant site (location of physician delivering the service via telecommunications) and an originating site (location of the patient).

To qualify for Medicare reimbursement, the Medicare beneficiary must be located at an originating site that meets one of three qualifications. These three qualifications are:

- A rural health professional shortage area (HPSA) that is either outside of a metropolitan statistical area (MSA) or in a rural census tract;
- A county outside of a MSA; or
- Participation in a federal telemedicine demonstration project approved by the Secretary of Health and Human Services as of December 31, 2000.[17]

Additionally, federal requirements provide that an originating site must be one of the following location types as further defined in federal law and regulation:

- The offices of physicians or practitioners;
- Hospitals;
- Critical access hospitals (CAH);
- Rural health clinics;
- Federally qualified health centers;
- Hospital-based or CAH-based renal dialysis centers (including satellite offices);
- Skilled nursing facilities; and
- Community mental health centers.[18]

Distant site practitioners are limited, subject also to state law, under Medicare to:

- Physicians;
- Nurse practitioners;
- Physician assistants;
- Nurse-midwives;
- Clinical nurse specialists;
- Certified registered nurse anesthetists;
- Clinical psychologists and clinical social workers; and
- Registered dietitians and nutrition professionals.

For 2016, CMS added Certified Registered Nurse Anesthetists to the list of authorized distant site practitioners who can furnish telehealth services.[19]

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[17] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Telehealth Services- Rural Health Fact Sheet* (Dec. 2014), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf (last visited Jan. 20, 2016).

[18] *See* 42 U.S.C. sec. 1395(m)(m)(4)(C)(ii).

[19] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *MLN Matters - News Flash #MM9476* (Dec. 18, 2015), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9476.pdf (last visited Jan. 14, 2016).

For 2015, Medicare added new services under telehealth:

- Annual wellness visits;
- Psychoanalysis;
- Psychotherapy; and
- Prolonged evaluation and management services.[20]

For 2016, Medicare supplemented those services with two specific prolonged inpatient codes and end-stage renal disease service codes.[21]

Reimbursement for the distant site is established as "an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system."[22] Federal law also provides for a facility fee for the originating site of $20 through December 31, 2002, and then, by law, the facility fee is subsequently increased each year by the percentage increase in the Medicare Economic Index (MEI). For calendar year 2016, the originating fee for telehealth is 80 percent of the lesser of the actual charge or $25.10.[23]

Telemedicine Services in Florida

University of Miami

The University of Miami (UM) initiated telehealth services in 1973 and claims the first telehealth service in Florida, the first use of nurse practitioners in telemedicine in the nation, and the first telemedicine program in correctional facilities.[24] Today, UM has several initiatives in the area of telehealth, including:

- Tele-dermatology;
- Tele-trauma;
- Humanitarian and disaster response relief;
- School telehealth services; and
- Acute tele-neurology or tele-stroke.

While some of UM's activities reach its local community, others reach outside of Florida, including providing Haiti earthquake relief and tele-dermatology to cruise line employees. Telehealth communications are also used for monitoring hospital patients and conducting training exercises.

Florida Medicaid Program

Florida's Medicaid program reimburses only physicians for telemedicine services when there is two-way, real-time interactive communication between the patient and the physician at a distant

[20] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *MLN Matters - News Flash #MM9034* (Dec. 24, 2014), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9034.pdf (last visited Jan. 20, 2016).
[21] *Supra*, Note 19.
[22] *See* 42 U.S.C. s. 1395(m)(m)(2)(A).
[23] *Supra* note *19*.
[24] University of Miami, Miller School of Medicine, *UM Telehealth - Our History*, http://telehealth.med.miami.edu/about-us/our-history (last visited Jan. 14, 2016).

site.[25] Equipment is also required to meet specific technical safeguards under 45 CFR 164.312, where applicable, which require implementation of procedures for protection of health information, including unique user identifications, automatic log-offs, encryption, authentication of users, and transmission security. Telemedicine services must also comply with all other state and federal laws regarding patient privacy.

For Medicaid, the distant or hub site is where the consulting physician delivering the telemedicine service is located. The spoke site is the location of the Medicaid recipient at the time the service occurs. The spoke site does not receive any reimbursement unless the provider located at the spoke site performs a separate service for the Medicaid recipient on the same day as the telemedicine consultation. The telemedicine referral consultation requires the presence of the referring practitioner and the Medicaid recipient.[26]

Under Medicaid fee-for-service, Medicaid reimbursement for telemedicine services is limited to certain services and settings. The following services are currently covered:[27]

- Behavioral Health
  - Telepsychiatry services for psychiatric medication management by practitioners licensed under ch. 458 or 459, F.S.; and
  - Telebehavioral health services for provision of individual and family behavioral health therapy services by qualified practitioners licensed under ch. 490 or 491, F.S.
- Dental Services
  - Services provided using video conferencing between a registered dental hygienist employed by and under contract with a Medicaid-enrolled group provider and supervising dentist, including oral prophylaxis, topical fluoride application, and oral hygiene instructions.
- Physician Services
  - Services provided using audio and video equipment that allow for two-way, real-time, interactive communication between the physician and patient;
  - Consultation services provided via telemedicine;
  - Interpretation of diagnostic testing results through telecommunications and information technology; and
  - Synchronous emergency services provided under parts III and IV of ch. 409, F.S., using an all-inclusive rate.

Medicaid does not reimburse for the following telemedicine services:

- Telephone conversations;
- Video cell phone conversations;
- E-mail messages;
- Facsimile transmission;
- Telecommunication with recipient at a location other than the spoke; and

[25] Agency for Health Care Administration, *Practitioner Services Handbook - Telemedicine Services* (April 2014) p. 136, *available at* http://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/Practitioner%20Services%20Handbook_Adoption.pdf (last visited Jan. 14, 2016).
[26] Id at 137.
[27] Agency for Health Care Administration, *Senate Bill 478 Analysis* (Feb. 4, 2015) p. 3, (on file with the Senate Committee on Health Policy).

- "Store and forward" consultations that are transmitted after the recipient or physician is no longer available.[28]

Medicaid also does not reimburse providers for the costs of any equipment related to telemedicine services.

Coverage of telemedicine services under Medicaid includes specific documentation requirements. The clinical record must include the following information:

- A brief explanation of why the services were not provided face-to-face;
- Documentation of telemedicine services provided, including the results of the assessment; and
- A signed statement from the recipient (parent or guardian, if a child), indicating his or her choice to receive services through telemedicine.[29]

Under the Managed Medical Assistance (MMA) component of Statewide Medicaid Managed Care, managed care plans may use telemedicine for behavioral health, dental services, and physician services.[30] The AHCA may also approve of other telemedicine services provided by the managed care plans if approval is sought by those plans under the MMA component.

Child Protection Teams

The Child Protection Team (CPT) program under the Children's Medical Services Network utilizes a telemedicine network to perform child assessments. The CPT is a medically-directed, multi-disciplinary program that works with local sheriff's offices and the Department of Children and Families in cases of child abuse and neglect to supplement investigative activities.[31] The CPT patient is seen at a remote site and a registered nurse assists with the medical exam. A physician or Advanced Registered Nurse Practitioner (ARNP) is located at the hub site and has responsibility for directing the exam.[32]

Hub sites are comprehensive medical facilities that offer a wide range of medical and interdisciplinary staff, whereas the remote sites tend to be smaller facilities that may lack medical diversity.[33] Twenty-four hub sites throughout the state facilitate these child abuse assessments and the evaluation of suspected cases of child abuse. The University of Florida Child Abuse Protection Team, for example, serves a 12-county area and, for the first 6 months of 2012, provided over 250 telemedicine examinations with medical community partners.[34]

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[28] Id.
[29] Id.
[30] Agency for Health Care Administration, *2012-2015 Medicaid Health Plan Model Agreement Attachment II - Exhibit II-A,* p. 63-64 http://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/Attachment_II_Exhibit_II-A_MMA_Model_2014-01-31.pdf , (last visited Jan. 14, 2016).
[31] Florida Dep't of Health, *Child Protection Teams*, http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/child_protection_safety/child_protection_teams.html (last visited Jan. 14, 2016).
[32] Florida Dep't of Health, *Children Protection Team - Telemedicine Network* http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/child_protection_safety/documents/cpt_telemedicine_fact_sheet.pdf (last visited Jan. 14, 2016).
[33] Id.
[34] Sunshine Arnold and Debra Esernio-Jenssen, *Telemedicine: Reducing Trauma in Evaluating Abuse,* pp. 105-107, http://cdn.intechopen.com/pdfs-wm/41847.pdf (last visited Jan. 14, 2016).

Compliance with Health Insurance Portability and Accountability Act (HIPAA)

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information (PHI). Privacy rules were initially issued in 2000 by the federal Department of Health and Human Services and later modified in 2002. These rules address the use and disclosure of an individual's health information and create standards for privacy rights. Additional privacy and security measures were adopted in 2009 with the Health Information Technology for Economic Clinical Health (HITECH) Act.

Only certain entities are subject to HIPAA's provisions. These "covered entities" include:
- Health plans;
- Health care providers;
- Health care clearinghouses; and
- Business associates.

While not a covered entity as an individual, the patient still maintains his or her privacy and confidentiality rights regardless of the method in which the medical service is delivered. The HITECH Act specifically identified telemedicine as an area for review and consideration, and funding was provided to, in part, strengthen infrastructure and tools to promote telemedicine.[35]

Under the provisions of HIPAA and the HITECH Act, a health care provider or other covered entity participating in telemedicine is required to meet the same technical and physical HIPAA and HITECH requirements as would be required for a physical office visit. These requirements include ensuring that that the equipment and technology are HIPAA compliant.

Discount Medical Plans

Discount medical plans and discount medical plan organizations (DMPOs) are regulated by the Office of Insurance Regulation under part II of ch. 636, F.S. DMPOs offer a variety of health care services to consumers through discount medical plans at a discounted rate. These plans are not health insurance and therefore do not pay for services on behalf of members; instead, the plans offer members access to specific health care products and services at a discounted fee. These health products and services may include, but are not limited to, dental services, emergency services, mental health services, vision care, chiropractic services, and hearing care. Generally, a DMPO has a contract with a provider network under which the individual providers render the medical services at a discount.

III. Effect of Proposed Changes:

Section 1 establishes the Telehealth Task Force as a new section of law in s. 408.61, F.S. The task force is created within the AHCA and the AHCA shall use existing resources to administer and support its activities.

[35] Public Law 111-5, s. 3002(b)(2)(C)(iii) and s. 3011(a)(4).

Task force members will not receive any compensation or reimbursement for per diem for travel expenses. Meetings may be held in person, by conference call, or other electronic means. The Secretary of the AHCA or his or her designee serves as the task force chair and the state Surgeon General or his or her designee also serve along with 17 other members. The Secretary of the AHCA appoints 10 members:

- 3 representatives of hospitals or facilities licensed under chapter 395;
- 3 representatives of health insurers that offer coverage of telehealth services;
- 2 representatives of organizations that represent health care facilities; and
- 2 representatives of entities that create or sell telehealth products.

The State Surgeon General appoints 7 members:

- 5 health care practitioners, each of whom practices in a different area of medicine and
- 2 representatives of organizations that represent health care practitioners.

The bill requires the task force to compile data and submit a report by June 30, 2017, to the Governor, the President of the Senate, and the Speaker of the House of Representatives that analyzes:

- Frequency and extent of the use of telehealth nationally and in this state;
- Costs and cost savings associated with using telehealth technology and equipment;
- Types of telehealth services available;
- Extent of available health insurance coverage available for telehealth services, including:
  - A comparative analysis of such coverage to available coverage for in-person services;
  - A description of payment rates for such telehealth services and whether they are below, equal to, or above payment rates for in-person services;
  - Copayment, coinsurance, and deductible amounts; policy year, calendar year, lifetime, or other durational benefit limitations; and maximum benefits for telehealth and in-person services; and
  - Any unique conditions imposed as a prerequisite to obtaining coverage for telehealth services;
- Barriers to implementing the use of, using, or accessing telehealth services; and
- Consideration of opportunities for interstate cooperation in telehealth.

This section of law is repealed effective December 1, 2017.

Section 2 creates s. 456.51, F.S., relating to telehealth, which is applicable to healthcare practitioners generally. Telehealth permits a health care practitioner[36] certified under part III of chapter 401,[37] or a person certified under part IV or V of chapter 468[38] who is practicing within the scope of his or her license or certification to provide telehealth services.

[36] The definition of a "health care practitioner" includes 26 different disciplines: Acupuncture, medical practice, osteopathic medicine, chiropractic medicine, podiatry, naturopathy, optometry, nursing, pharmacy, dentistry, midwifery, speech-language-pathology-audiology, nursing home administration, occupational therapy, respiratory therapy, dietetics and nutrition practice, athletic trainers, orthotics, prosthetics, and pedorthotics, electrolysis, massage, clinical laboratory personnel, medical physicists, dispensing of optical devices and hearing aids, physical therapy, psychological services, and clinical, counseling, and psychotherapy.

[37] Persons certified under chapter 301 are those employed in the emergency medical services field, including emergency medical technicians, paramedics, and registered nurses.

[38] Part IV of Chapter 468 are those individuals certified as radiological personnel, and Part V regulates respiratory therapists.

A practitioner or person who provides telehealth services within the scope of his or her license, but is not a physician, will not be considered to be practicing medicine without a license.

Under this section, "telehealth" is specifically defined to mean:

> The use of synchronous or asynchronous telecommunications technology by a health care practitioner, a person certified under part III of chapter 401, or a person certified under part IV of chapter 468 to provide medical or other health care services, including, but not limited to, patient assessment, diagnosis, consultation, treatment, or remote monitoring; the transfer of medical or health data; patient and professional health-related education; the delivery of public health services; and health care administration functions.

Section 3 - amends the definition of "discount medical plan" under s. 636.202(1), F.S., to provide that telehealth products defined under s. 456.51, F.S., are not included in the definition.

Section 4 - The act is effective July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Florida does not currently have a statutory definition for telehealth or telemedicine. Florida TaxWatch has discussed in its report, *Moving Telehealth Forward: The High Costs of Paying Later* the lack of certainty in Florida around telehealth has led to confusion among providers on billing and payment options.[39] Florida Tax Watch

[39] Florida Tax Watch, *Moving Telehealth Forward: The High Costs of Paying Later*, p. 2, (August 2015). www.floridataxwatch.org.

estimated that with more timely access to care through telehealth, a one percent reduction in hospital charges alone could save $1 billion through hospitalization avoidance costs.[40]

The average estimated cost of a telehealth visit is $40 to $50 compared to the average in-person visit of $136-$176.[41] With an estimated savings of approximately $126 per telehealth visit ,the report also showed that the participating vendor was able to resolve the patient's issue approximately 83 percent of the time; 60 percent of the time with a prescription.[42] When asked where the patient would have gone to receive care if not via telehealth, the most likely site of care was urgent care (45.8 percent), physician office (30.9 percent), do nothing (12.3 percent), emergency room (5.6 percent) or other clinics (5.4 percent).[43] Other than doing nothing, all of these options would have cost more than the cost of the telehealth visit ranging from the emergency room ($943 - $1,595) to other clinics ($57 - $83).[44]

C. Government Sector Impact:

The AHCA is required to use existing resources to support activities of the task force.

The Medicaid program may also be impacted with the definition of standard of care for telehealth to the extent that it may differ from the definition currently used by the program. Higher utilization of telehealth services may result in cost savings in other areas of the Medicaid program if the Florida Medicaid program experiences similar results as seen in other state Medicaid programs, such as New York, Texas and California where telehealth reimbursement parity is mandated.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 408.61 and 456.51.

IX. Additional Information:

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

[40] Id at 5.
[41] Dale H. Yamamoto, *Assessment of the Feasibility and Cost of Replacing In-Person Care with Acute Care Telehealth Services*, http://www.connectwithcare.org/wp-content/uploads/2014/12/Medicare-Acute-Care-Telehealth-Feasibility.pdf p. 2, (last visited Jan. 14, 2016).
[42] Id at 5.
[43] Id.
[44] Id at 6.

CS by Health Policy on January 26, 2016:
The CS makes three modifications to the bill:

- Adds consideration of opportunities for interstate cooperation to the list of items to be reviewed and evaluated by the Telehealth Task Force;
- Includes respiratory therapists to the definition of a telehealth practitioner; and
- Modifies the definition of a "discount medical plan" under s. 636.202, F.S., to specifically exclude telehealth products defined under s. 456.51, F.S.

B. Amendments:

None.

424232

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2016	.	
	.	
	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment

Between lines 72 and 73
insert:
(f) Consideration of opportunities for interstate cooperation in telehealth.

925172

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2016	.	
	.	
	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment

Delete line 98
and insert:
IV or V of chapter 468 to provide medical or other health care

397758

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2016	.	
	.	
	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Between lines 103 and 104
insert:

Section 3. Subsection (1) of section 636.202, Florida Statutes, is amended to read

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

(1) "Discount medical plan" means a business arrangement or contract in which a person, in exchange for fees, dues, charges, or other consideration, provides access for plan members to providers of medical services and the right to receive medical

397758

services from those providers at a discount. The term "discount medical plan" does not include any product regulated under chapter 627, chapter 641, or part I of this chapter, or any telehealth product defined under s. 456.51, F.S.

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

And the title is amended as follows:

Delete line 17

and insert:

defining the term "telehealth"; amending s. 636.202, F.S.; excluding telehealth products from the definition of "discount medical plan"; providing an effective

By Senator Bean

4-00356C-16 20161686__

A bill to be entitled

An act relating to telehealth; creating s. 408.61, F.S.; creating the Telehealth Task Force within the Agency for Health Care Administration; requiring the agency to use existing and available resources to administer and support the task force; providing for the membership of the task force; requiring the task force to compile and analyze certain data and to conduct a comparative analysis of health insurance coverage available for telehealth services and for in-person treatment; providing meeting requirements; requiring the task force to submit a report to the Governor and Legislature by a certain date; providing for the repeal of the section; creating s. 456.51, F.S.; authorizing certain licensed or certified health care professionals to provide telehealth services; defining the term "telehealth"; providing an effective date.

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

Section 1. Section 408.61, Florida Statutes, is created to read:

408.61 Telehealth Task Force.—

(1) The Telehealth Task Force is created within the agency. The agency shall use existing and available resources to administer and support the activities of the task force under this section.

(2) Members of the task force shall serve without compensation and are not entitled to reimbursement for per diem or travel expenses. The task force shall consist of the following 19 members:

4-00356C-16 20161686__

(a) The Secretary of Health Care Administration or his or her designee, who shall serve as the chair of the task force.

(b) The State Surgeon General or his or her designee.

(c) Three representatives of hospitals or facilities licensed under chapter 395, three representatives of health insurers that offer coverage of telehealth services, two representatives of organizations that represent health care facilities, and two representatives of entities that create or sell telehealth products, all appointed by the Secretary of Health Care Administration.

(d) Five health care practitioners, each of whom practices in a different area of medicine, and two representatives of organizations that represent health care practitioners, all appointed by the State Surgeon General.

(3) The task force shall compile and analyze data and information on the following:

(a) The frequency and extent of the use of telehealth technology and equipment by health care practitioners and health care facilities nationally and in this state.

(b) The costs and cost savings associated with using telehealth technology and equipment.

(c) The types of telehealth services available.

(d) The extent of available health insurance coverage for telehealth services. The task force shall conduct a comparative analysis of such coverage to available coverage for in-person services. The analysis must include:

1. Covered medical or other health care services.

2. A description of payment rates for such telehealth services and whether they are below, equal to, or above payment

rates for in-person services.

3. Annual and lifetime dollar maximums on coverage for telehealth and in-person services.

4. Copayment, coinsurance, and deductible amounts; policy year, calendar year, lifetime, or other durational benefit limitations; and maximum benefits for telehealth and in-person services.

5. Any unique conditions imposed as a prerequisite to obtaining coverage for telehealth services.

(e) Barriers to implementing the use of, using, or accessing telehealth services.

(4) The task force shall convene its first meeting by September 1, 2016, and shall meet as often as necessary to fulfill its responsibilities under this section. Meetings may be conducted in person, by teleconference, or by other electronic means.

(5) The task force shall submit a report by June 30, 2017, to the Governor, the President of the Senate, and the Speaker of the House of Representatives which includes its findings, conclusions, and recommendations.

(6) This section is repealed effective December 1, 2017.

Section 2. Section 456.51, Florida Statutes, is created to read:

456.51 Telehealth.—

(1) A health care practitioner, a person certified under part III of chapter 401, or a person certified under part IV of chapter 468 who is practicing within the scope of his or her license or certification may provide telehealth services. A practitioner or person who is not a physician, but who provides

telehealth services within the scope of his or her license or certification, may not be considered to be practicing medicine without a license.

(2) As used in this section, the term "telehealth" means the use of synchronous or asynchronous telecommunications technology by a health care practitioner, a person certified under part III of chapter 401, or a person certified under part IV of chapter 468 to provide medical or other health care services, including, but not limited to, patient assessment, diagnosis, consultation, treatment, or remote monitoring; the transfer of medical or health data; patient and professional health-related education; the delivery of public health services; and health care administration functions.

Section 3. This act shall take effect July 1, 2016.

The Florida Senate

Committee Agenda Request

To: Senator Aaron Bean, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 19, 2016

I respectfully request that **Senate Bill #1686**, relating to Telehealth, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Aaron Bean

Senator Aaron Bean
Florida Senate, District 4

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-16
Meeting Date

1686
Bill Number (if applicable)

424232
Amendment Barcode (if applicable)

Topic TELEHEALTH

Name LAYNE SMITH

Job Title DIRECTOR, STATE GOVT. RELATIONS

Address 4500 SAN PABLO ROAD
Street

Phone 904-953-7334

JACKSONVILLE FL 32224
City *State* *Zip*

Email Smith-layne@mayo.edu

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing MAYO CLINIC

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-16
Meeting Date

SB 1686
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Jeff Scott

Job Title _____

Address 1430 Piedmont Dr. E.
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 224-6496

Email jscott@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Medical 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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

1686
Bill Number (if applicable)

Topic TELEHEALTH

Amendment Barcode (if applicable)

Name JACK McRAY

Job Title

Address 200 W. COLLEGE ST. #304
Street

Phone 850-577-5187

TLH FL 32301
City *State* *Zip*

Email jmcray@aarp.org

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing AARP

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.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

1168
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Niland

Job Title _____

Address 1000 Riverside Ave
Street
Jacksonville, FL 32204
City *State* *Zip*

Phone 904-233-3051

Email nlandlaw@aol.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Chapter, American College of Physicians

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-16
Meeting Date

1686
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name David Poole

Job Title Dir. Leg. Affairs

Address 1825 County Club Dr
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-766-3323

Email david.poole@aidshealth.org

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

Waive Speaking: [ ] In Support [ ] Against
(The Chair will read this information into the record.)

Representing AIDS Healthcare Foundation

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.

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

S-001 (10/14/14)

9:00 AM
412 K

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-2016
Meeting Date

SB 1686
Bill Number (if applicable)

Topic TELEHEALTH

Amendment Barcode (if applicable)

Name STEPHEN R. WINN

Job Title EXECUTIVE DIRECTOR

Address 2544 BLAIRSTONE PINES DR
Street
TALLAHASSEE FL 32301
City *State* *Zip*

Phone 878-7364

Email

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

Waive Speaking: [X] In Support [ ] Against
(The Chair will read this information into the record.)

Representing FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

Appearing at request of Chair: [ ] Yes [ ] 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.

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

SB 1682
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Larry Gonzalez

Job Title General Counsel

Address 223 S. Gadsden St.
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850-570-6307

Email lawgonz@earthlink.net

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

SB 1686
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Larry Gonzalez

Job Title General Counsel

Address 223 S. Gadsden
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850-570-6307

Email langonzalez@earthlink.net

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Occupational Therapy 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 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1504
INTRODUCER:	Senator Bean
SUBJECT:	Credit for Relevant Military Service
DATE:	January 24, 2016 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Pre-meeting**
2.			AGG	
3.			AP	

I. Summary:

SB 1504 authorizes the Department of Health (DOH) to waive fees and issue licenses to active duty U.S. military personnel who are within 6 months of an honorable discharge; and issue temporary licenses to military spouses, in health care professions that do not require licenses in other states. The applicant must provide evidence of military training or experience substantially equivalent to that required in Florida, and obtain a passing score on a national standards organization exam, if one is required. The bill also eliminates the requirement for a military spouse who has been issued a temporary dental license to practice under the indirect supervision of a Florida dentist.

The bill requires the Construction Industry and Electrical Contractor's Licensing Boards and the Department of Agriculture and Consumer Services (DACS), to provide methods for honorably discharged veterans to satisfy the licensure requirements for a specific contractor's license or for licenses as private investigators, private security officers, and recovery agents, respectively, by receiving credit for their substantially similar military training and education. The boards and the DACS are to identify overlaps and gaps, between the licensure requirements and the veteran's military training and education in their respective areas of jurisdiction. They are to assist in identifying training programs to fill those gaps. The Department of Business and Professional Regulation (DBPR), in conjunction with the boards, and the DACS are to provide an annual report to the Senate President, Speaker of the House of Representatives, and the Governor detailing the results of the boards' efforts and recommendations for improvement and the DACS efforts and recommendations for improvement.

SB 1504 requires the Department of Highway Safety and Motor Vehicles, and the Department of Military Affairs, to create a commercial drivers' license testing pilot program to provide testing opportunities to qualified members of the North Florida National Guard.

II. Present Situation:

Health Care Practitioner Licensure

The DOH is responsible for the regulation of health practitioners and health care facilities in Florida for the preservation of the health, safety, and welfare of the public. The Division of Medical Quality Assurance (MQA), working in conjunction with 22 boards and six councils, licenses and regulates seven types of health care facilities, and more than 200 license types, in over 40 health care professions.[1] Any person desiring to be a licensed health care professional in Florida must apply to the DOH, MQA in writing.[2] Most health care professions are regulated by a board or council in conjunction with the DOH and all professions have different requirements for initial licensure and licensure renewal.[3]

Military Health Care Practitioners

Section 456.024, F.S., provides that any member of the U.S. Armed Forces who has served on active duty in the military, reserves, National Guard, or in the United States Public Health Service, as a health care practitioner, is also eligible for licensure in Florida. The DOH is required to waive fees and issue these individuals a license if they submit a completed application and proof of the following:

- A honorable discharge within six months before or after, the date of submission of the application;[4]
- An active, unencumbered license issued by another state, the District of Columbia, or a U.S. possession or territory, with no disciplinary action taken against it in the five years preceding the date of submission of the application;
- An Affidavit that he or she is not, at the time of submission, the subject of a disciplinary proceeding in a jurisdiction in which he or she holds a license or by the United States Department of Defense for reasons related to the practice of the profession for which he or she is applying;
- Documentation of actively practicing his or her profession for the three years preceding the date of submission of the application; and
- A completed fingerprint card for a background screening, if required for the profession for which he or she is applying.[5]

Florida offers an expedited licensure process to facilitate veterans seeking licensure in a health care profession in Florida through its Veterans Application for Licensure Online Response System (VALOR).[6] In order to qualify, a veteran must apply for the license within 6 months

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[1] Florida Dep't of Health, Medical Quality Assurance, *Annual Report and Long Range Plan, 2014-2015*, p.6, *available at:* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1415.pdf
[2] Section 456.013, F.S.
[3] *See* chs. 401, 456-468, 478, 480, 483, 484, 486, 490, and 491, F.S.
[4] A form DD-214 or an NGB-22 is required as proof of honorable discharge. Department of Health, *Veterans*, http://www.floridahealth.gov/licensing-and-regulation/armed-forces/veterans/index.html (last visited Dec. 15, 2015).
[5] *Id.* The Military Veteran Fee Waiver Request Form, also must be submitted with the application for licensure to receive waiver of fees and is available on the DOH website.
[6] Florida Dep't of Health, *Veterans*, http://www.floridahealth.gov/licensing-and-regulation/armed-forces/veterans/index.html, (last visited Dec. 15, 2015).

before, or 6 months after, he or she is honorably discharged from the Armed Forces; and there is no application fee, licensure fee, or unlicensed activity fee.[7]

A board, or the department if there is no board, may also issue a temporary health care professional license to the spouse of an active duty member of the Armed Forces upon submission of an application form and fees. The applicant must hold a valid license for the profession issued by another state, the District of Columbia, or a possession or territory of the United States and may not be the subject of any disciplinary proceeding in any jurisdiction relating to the practice of a regulated health care profession in Florida. A spouse who is issued a temporary professional license to practice as a dentist under this authority must practice under the indirect supervision of a Florida dentist.

Construction and Electrical Contractors

The DBPR is the agency charged with licensing and regulating various businesses and professionals in the state. The Division of Professions is responsible for the licensing 415,000 professions including construction contractors,[8] electrical contractors and alarm system contractors. The Construction Industry Licensing Board licenses and regulates the construction industry and the Electrical Contractor's Licensing Board licenses and regulates alarm system and electrical contractors. Licenses for these professions may be either Certified or Registered Licenses. Certified licenses are statewide and allow the contractor to work anywhere in Florida. Registered licenses are limited to certain local jurisdictions and only allow a contractor to work in the cities or counties where the contractor holds a certificate of competency.[9]

Section 489.111(2)(c), F.S., provides the experience and education requirements for all construction contractor applicants, without exception for military veterans. These requirements include four years of experience in the category applied for, with one year as a supervisor. Applicants may apply up to three years of college credit toward the experience requirements. The Construction Industry Licensing Board reviews applicant experience when necessary to determine if the experience is within the category applied for.

Section 489.511(1)(b)3.c., F.S., provides that an applicant for an electrical or alarm system contractor license may use technical experience in electrical or alarm system work with the military or a governmental entity to meet the minimum 6 year experience requirement.

Section 489.511(1)(b)3.e., F.S., provides for technical education to be used in conjunction with experience to meet the 6 year experience requirements, and technical training received in the military is acceptable under this provision. The Electrical Contractors' Licensing Board reviews all applications to determine if the required training and experience has been met.

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[7] *Id.*

[8] Section 489.105, F.S., divides contractors into Division I and Division II contractors. Division I contractors include general, building, and residential contractors. Division II contractors include sheet metal, roofing, 3 classes of air conditioning, mechanical, commercial and residential pool, 3 types of pool, plumbing, underground excavating, solar, pollutant storage, and specialty contractors.

[9] Dep't of Business and Professional Regulation, Construction Industry Licensing Board, *Definition of Occupation and Class Codes*, available at: http://www.myfloridalicense.com/DBPR/pro/cilb/codes.html, (last visited Jan. 21, 2016).

Ex-Military Construction and Electrical Contractors

Section 455.213, F.S., requires the DBPR to waive the initial licensing fee, the initial application fee, and the initial unlicensed activity fee for an honorably discharged military veteran, or his or her spouse at the time of discharge, if he or she applies for a license within five years after discharge.

Section 455.02, F.S., provides that any member of the military on active duty in the military, who at the time he or she became active was in good standing with any DBPR administrative board,[10] he or she will be kept in good standing, without registering, paying fees or dues, or performing any act required for continued licensure, as long as the service member remains on active duty and does not engage in his or her profession in the private sector for profit.

Section 455.02, F.S., also provides that the DBPR may issue a temporary license to the spouse of an active duty member of the military if the spouse provides the following:

- Application fee;
- Proof of his or her marriage to an active duty military member;
- Proof of a valid professional license in another state, the District of Columbia, any U.S. possession or territory, or any foreign jurisdiction;
- Proof of active duty military orders that the applicant and his or her spouse are both assigned to duty in Florida; and
- A complete set of the applicant's fingerprints to be submitted to the Department of Law Enforcement and the Federal Bureau of Investigation for state and federal criminal background check, at the applicant's expense.

The temporary license expires six months after the date of issuance and is not renewable.

Licensing of Private Investigators, Private Security Officers and Recovery Agents

Private investigators, private security officers, and recovery agents are regulated by the DACS under, ch. 493, F.S., and Rule 5N-1, Florida Administrative Code (F.A.C.), which sets out the requirements for a person or business to obtain and renew the various types of licenses. In 2015, the DACS, Division of Licensing, regulated 26 different licenses under ch. 493, F.S.: six private investigator, seven private security officer, seven recovery agent, and six firearm; for a total of 1,668,339 licensees in Florida.[11]

Section 493.6106, F.S., provides that applicants for licenses as a private investigator, security officer or recovery agent must:

- Be 18 years of age;
- A U.S. citizen, legal resident or have authority to work by the U.S. Citizenship and Immigration Services (USCIS);

[10] See s. 20,165(4)(a), F.S., for a complete list of a complete list of all boards and programs established within the Division of Professions.

[11] Florida DACS, Division of Licensing, *Number of Licensees by Type As of December 31, 2015*, available at: http://www.freshfromflorida.com/content/download/7471/118627/Number_of_Licensees_By_Type.pdf, (last visited January 22, 2016).

- Have no disqualifying criminal history;
- Be of good moral character; and
- Have no history of incompetency, mental illness, or history of use of illegal drugs or alcoholism, unless evidence is presented showing successful completion of a rehabilitation program, or current mental competency, as appropriate.

Those applicants must provide to the DACS, among other things, an application with the following:

- Name;
- Date of birth;
- Social Security number;[12]
- Place of Birth;
- A statement of all criminal convictions, including dispositions, and adjudications withheld;
- A statement of whether he or she has been adjudicated incapacitated or committed to a mental institution;
- A statement regarding any history of illegal drug use or alcohol abuse;
- One full-face, color photograph; and
- A full set of prints on the division's fingerprint card or submitted electronically via a personal inquiry waiver and the appropriate fees.[13]

The DACS currently requires returning veterans and their spouses to pay application fees, fingerprint fees, and all other applicable fees when applying for licenses under ch. 493, F.S., as private investigators, security officers or recovery agents.

Commercial Drivers' License Examination Process

The Florida Department of Highway Safety and Motor Vehicles (DHSMV) administers all driving tests. All applicants for a commercial driver license are required to have an Operator's License and pass the vision and hearing tests. Applicants must be at least 18 years of age. If they are under 21, they will be restricted to intrastate operation only. Oral exams may be given in English or Spanish with the exception of skills test or Hazmat exams. Interpreters may not be used.[14]

[12] The DACS will not disclose an applicant's social security number without consent of the applicant to anyone outside the DACS unless required by law. *See* Chapter 119, F. S., 15 U.S.C., ss. 1681 et seq., 15 U.S.C. ss. 6801 et seq., 18 U.S.C. ss. 2721 et seq., Pub. L. No. 107-56 (USA Patriot Act of 2001), and Presidential Executive Order 13224.

[13] *See also* Fla. Dept. of Agriculture and Consumer Affairs, *Private Investigator Handbook*, p.11, available at: https://licensing.freshfromflorida.com/forms/P-00093_PrivateInvestigatorHandbook.pdf; *Security Officer Handbook*, p. 16, available at: https://licensing.freshfromflorida.com/forms/P-00092_SecurityOfficerHandbook.pdf; *Recovery Agent Handbook*, at p. 9, https://licensing.freshfromflorida.com/forms/P-00094_RecoveryAgentHandbook.pdf, (Last visited January 22, 2016).

[14] Fla. Dept. of Highway Safety and Motor Vehicles, *How do I obtain my Commercial Driver License (CDL)?, available at:* http://www.flhsmv.gov/ddl/cdl.html, (Last visited January 22, 2016).

There are three types of CDL licenses in Florida: Class A, Class B, and Class C. Which license is required is dependent upon the weight and type of the vehicle to be operated, and the materials being transported.[15]

Active duty military or veterans requesting to be issued a CDL due to qualifications of experience while serving on military duty must:

- Pass all required knowledge[16] and endorsement exams for the CDL license class and endorsements they are applying to obtain; and
- Present the Certification for Waiver of Skill Test for Military Personnel form completed by their commanding officer or designee while on active duty or within 90 days of separation from service.[17]

Military are only exempt from taking the skills exams. The process must be completed, and the CDL issued, within 120 days of separation from service. The Certification for Waiver of Skill Test form for Military Personnel can be provided to the candidate.[18]

The portion of the examination which tests an applicant's safe driving ability is to be administered by the DHSMV or by an entity authorized by the DHSMV to administer such examination, pursuant to s. 322.56, F.S. Such examination is to be administered at a location approved by the DHSMV. A person who seeks to retain a hazardous-materials endorsement must, upon renewal, pass the test for such endorsement as specified in s. 322.57(1)(e), F.S., if the person has not taken and passed the hazardous-materials test within two years preceding his or her application for a commercial driver license in this state.[19]

Effect of Proposed Changes:

Initial Licensure Requirements

Military Health Care Practitioners [20]

SB 1504 amends s. 456.024, F.S., to authorize the DOH to waive fees and issue health care licenses to active duty U.S. military personnel who apply either 6 months before, or 6 months after, an honorable discharge, in professions that do not require licensure in other states,[21] if the applicant can provide evidence of training or experience equivalent to that required in Florida, and proof of a passing score on a national standards organization exam, if one is required in Florida.

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[15] Fla. Dept. of Highway Safety and Motor Vehicles, "*How do I obtain my Commercial Driver License (CDL)?" available at:* http://www.flhsmv.gov/ddl/cdl.html, (Last visited January 22, 2016).
[16] *See* s. 322.12(4), F.S.
[17] See supra note 15.
[18] *See* supra note 15.
[19] *See* supra note 16.
[20] See section 1 of the bill.
[21] Professions not licensed in all states: Respiratory therapists (and assistants), Clinical Laboratory Personnel, Medical Physicists, Opticians, Athletics trainers, Electrologists, Nursing home administrators, Midwives, Orthotists (and assistants), Prosthetists (and assistants), Pedorthotists (and assistants), Orthotic fitters (and assistants), Certified chiropractic physician assistants, Pharmacy Technicians.

The DOH may also issue temporary licenses to active duty military spouses, in professions that do not require licensure in other states,[22] if the applicant can provide evidence of training or experience equivalent to that required in Florida, and proof of a passing score on a national standards organization exam, if one is required in Florida. The applicant must pay the required application fee.

The bill also eliminates the requirement that a military spouse who has been issued a temporary dental license practice under the indirect supervision of a Florida dentist.

Ex-Military Construction and Electrical Contractors

SB 1504 creates ss. 489.1131 and 489.5161, F.S., and requires the Construction Industry Licensing Board and Electrical Contractor's Licensing Board, to provide methods for honorably discharged veterans to satisfy the licensure requirements for a specific contractor's license by receiving credit to the fullest extent possible towards their licensing requirements for their substantially similar military training and education. The boards are to identify the overlaps, and the gaps, between the licensure requirements and the veteran's military training and education. They are to assist in identify training programs to fill those gaps.

Beginning October 1, 2017, the DBPR, in conjunction with the boards, is to provide an annual report titled, "Construction and Electrical Contracting Veteran Application Statistics", to the Senate President, Speaker of the House of Representatives, and the Governor detailing the following for both ss. 489.1131, and 489.5161, F.S.:

- The number of applicants who identified themselves as veterans;
- The number of veterans whose application for a license was approved;
- The number of veterans whose application for a license was denied, including the reasons for denial;
- Data on the application processing times for veterans;
- The boards' efforts to assist veterans in identifying programs that offer training and education needed to meet the requirements for licensure;
- The boards' identification of the most common overlaps and gaps between requirements for licensure and the military training and education received and completed by the veteran applicants; and
- Recommendations on ways to improve the DBPR's ability to meet the needs of veterans which would effectively address the challenges that veterans face when separating from military service and seeking a license regulated by the department pursuant to ch. 489, Part I and Part II, F.S.

Ex-Military Private Investigators, Private Security Officers and Recovery Agents

SB 1504 creates s. 493.61035, F.S., and requires the DACS to provide a method for honorably discharged veterans to satisfy the licensure requirements for licenses as private investigators, private security officers, and recovery agents by receiving credit to the fullest extent possible toward the requirements for licensure for their substantially similar military training and education. The DACS is to identify the overlaps, and the gaps, between the license requirements

[22] *Id.*

and the veteran's military training and education. The DACS is to assist in identify training programs to fill the gaps.

Beginning October 1, 2017, the DACS is to provide an annual report to the Senate President, Speaker of the House of Representatives, and the Governor detailing the following for s. 493.61035, F.S.:

- The number of applicants who identified themselves as veterans;
- The number of veterans whose application for a license was approved;
- The number of veterans whose application for a license was denied, including the reasons for denial;
- Data on the application processing times for veterans;
- The DACS's efforts to assist veterans in identifying programs that offer training and education needed to meet the requirements for licensure;
- The DACS's identification of the most common overlaps and gaps between requirements for licensure and the military training and education received and completed by the veteran applicants; and
- Recommendations on ways to improve the DACS's ability to meet the needs of veterans which would effectively address the challenges that veterans face when separating from military service and seeking a license regulated by the department pursuant to ch. 493, F.S.

Commercial Drivers' License Testing Piolet Program for North Florida National Guard

SB 1504 requires the Department of Highway Safety and Motor Vehicles (DHSMV) and the Department of Military Affairs, beginning July 1, 2017, to jointly conduct a pilot program to provide onsite commercial driver license testing opportunities to qualified members of the Florida National Guard pursuant to the DHSMV commercial driver license skills test waiver under s. 322.12, F.S described previously.[23] Testing must be held at a Florida National Guard Armory, an Armed Forces Reserve Center, or the Camp Blanding Joint Training Center. The pilot program shall be accomplished using existing funds appropriated to the departments.

The DHSMV and the Department of Military Affairs shall submit, by June 30, 2018, a report on the pilot program to the President of the Senate and the Speaker of the House of Representatives.

The bill has an effective date of July 1, 2016.

III. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

[23] *See* supra note 15.

C. Trust Funds Restrictions:

None.

IV. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill may increase the number of veterans and their spouses receiving health care licenses; and increase the number of veterans receiving contractor, private investigator, private security, and Recovery agent licenses.

C. Government Sector Impact:

Rulemaking would be required by the DOH, DBPR and DACS to develop veteran specific application processes and define what military education and training is substantially similar to current license requirements. Tracking mechanisms would need to be put in place for veterans' applications, approvals, denials, and the reasons for the denials. There would also be costs associated with preparing the annual reports required by the DBPR, and DACS. There will be no additional costs to the DHSMV and the Department of Military Affairs as their funding is to come from existing funds.

V. Technical Deficiencies:

None.

VI. Related Issues:

SB 914 (2016) included a similar amendment to s. 456.024, F.S. When that bill was heard in committee, it was amended to recognize regional standards organization exams since not all professional have national exams. An amendment may be advisable for consistency.

VII. Statutes Affected:

This bill substantially amends section 456.024 of the Florida Statutes,

This bill creates the following sections of the Florida Statutes: 489.1131, 489.5161, and 493.61035, F.S.

This bill creates an undesignated section of Florida law.

VIII. Additional Information:

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

None.

B. Amendments:

None.

By Senator Bean

4-01387-16 20161504__

A bill to be entitled

An act relating to credit for relevant military service; amending s. 456.024, F.S.; providing for the issuance of a license to practice under certain conditions to a military health care practitioner in a profession for which licensure in a state or jurisdiction is not required to practice in the military; providing for the issuance of a temporary professional license under certain conditions to the spouse of an active duty member of the Armed Forces of the United States who is a health care practitioner in a profession for which licensure in a state or jurisdiction may not be required; deleting the requirement that an applicant who is issued a temporary professional license to practice as a dentist must practice under the indirect supervision of a licensed dentist; creating s. 489.1131, F.S.; requiring the Construction Industry Licensing Board to provide a method by which honorably discharged veterans may apply for licensure; providing for extension of credit toward licensing requirements for substantially similar military training and education; requiring identification and notification of overlaps and gaps between license requirements and the military training and education received by the applicant; requiring the Department of Business and Professional Regulation to provide an annual report to the Governor and Legislature; providing requirements for the annual report; creating s. 489.5161, F.S.; requiring the Electrical Contractors' Licensing Board to provide a method by which honorably discharged veterans may apply for licensure; providing for extension of credit

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toward licensing requirements for substantially similar military training and education; requiring identification and notification of overlaps and gaps between license requirements and the military training and education received by the applicant; requiring the Department of Business and Professional Regulation to annually report to the Governor and Legislature; providing requirements for the annual report; creating s. 493.61035, F.S.; requiring the Department of Agriculture and Consumer Services to adopt rules providing a method by which honorably discharged veterans may apply for licensure pursuant to ch. 493, F.S.; providing for extension of credit toward licensing requirements for substantially similar military training and education; requiring identification and notification of overlaps and gaps between license requirements and the military training and education received by the applicant; requiring an annual report to the Governor and Legislature; providing requirements for the annual report; requiring the Department of Highway Safety and Motor Vehicles and the Department of Military Affairs to create a commercial driver license testing pilot program; providing an effective date.

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

Section 1. Paragraph (a) of subsection (3) and paragraphs (a) and (j) of subsection (4) of section 456.024, Florida

Statutes, are amended to read:

456.024 Members of Armed Forces in good standing with administrative boards or the department; spouses; licensure.—

(3) A person who serves or has served as a health care practitioner in the United States Armed Forces, United States Reserve Forces, or the National Guard or a person who serves or has served on active duty with the United States Armed Forces as a health care practitioner in the United States Public Health Service is eligible for licensure in this state. The department shall develop an application form, and each board, or the department if there is no board, shall waive the application fee, licensure fee, and unlicensed activity fee for such applicants. For purposes of this subsection, "health care practitioner" means a health care practitioner as defined in s. 456.001 and a person licensed under part III of chapter 401 or part IV of chapter 468.

(a) The board, or department if there is no board, shall issue a license to practice in this state to a person who:

1. Submits a complete application.

2. Receives an honorable discharge within 6 months before, or will receive an honorable discharge within 6 months after, the date of submission of the application.

3. Holds an active, unencumbered license issued by another state, the District of Columbia, or a possession or territory of the United States and who has not had disciplinary action taken against him or her in the 5 years preceding the date of submission of the application or is a military health care practitioner in a profession for which licensure in a state or jurisdiction is not required to practice in the military, who

provides evidence of military training or experience substantially equivalent to the requirements for licensure in this state in that profession, and who obtained a passing score on the appropriate examination of a national standards organization when required for licensure in this state.

4. Attests that he or she is not, at the time of submission, the subject of a disciplinary proceeding in a jurisdiction in which he or she holds a license or by the United States Department of Defense for reasons related to the practice of the profession for which he or she is applying.

5. Actively practiced the profession for which he or she is applying for the 3 years preceding the date of submission of the application.

6. Submits a set of fingerprints for a background screening pursuant to s. 456.0135, if required for the profession for which he or she is applying.

The department shall verify information submitted by the applicant under this subsection using the National Practitioner Data Bank.

(4)(a) The board, or the department if there is no board, may issue a temporary professional license to the spouse of an active duty member of the Armed Forces of the United States who submits to the department:

1. A completed application upon a form prepared and furnished by the department in accordance with the board's rules;

2. The required application fee;

3. Proof that the applicant is married to a member of the

Armed Forces of the United States who is on active duty;

4. Proof that the applicant holds a valid license for the profession issued by another state, the District of Columbia, or a possession or territory of the United States~~,~~ and is not the subject of any disciplinary proceeding in any jurisdiction in which the applicant holds a license to practice a profession regulated by this chapter or is a health care practitioner in a profession for which licensure in a state or jurisdiction may or may not be required, who provides evidence of training or experience substantially equivalent to the requirements for licensure in this state in that profession, and who obtained a passing score on the appropriate examination of a national standards organization when required for licensure in this state; and

5. Proof that the applicant's spouse is assigned to a duty station in this state pursuant to the member's official active duty military orders~~; and~~

~~6. Proof that the applicant would otherwise be entitled to full licensure under the appropriate practice act, and is eligible to take the respective licensure examination as required in Florida~~.

~~(j) An applicant who is issued a temporary professional license to practice as a dentist pursuant to this section must practice under the indirect supervision, as defined in s. 466.003, of a dentist licensed pursuant to chapter 466.~~

Section 2. Section 489.1131, Florida Statutes, is created to read:

489.1131 Credit for relevant military training and education.-

(1) The board shall provide a method by which honorably discharged veterans may apply for licensure. The method must include:

(a) Extension of credit to the fullest extent possible toward the requirements for licensure for military training or education received and completed during service in the Armed Forces of the United States if the training or education is substantially similar to the training or education required for licensure.

(b) Identification of overlaps and gaps between the requirements for licensure and the military training and education received and completed by the veteran applicants and subsequent notification to the applicant of the overlaps and gaps.

(c) Assistance in identifying programs that offer training and education needed to meet requirements for licensure.

(2) Notwithstanding any other provision of law, beginning October 1, 2017, and annually thereafter, in conjunction with the board, the department is directed to prepare and submit a report titled "Construction and Electrical Contracting Veteran Applicant Statistics" to the President of the Senate, the Speaker of the House of Representatives, and the Governor. The report must include statistics and information relating to this section and s. 489.5161 which detail:

(a) The number of applicants who identified themselves as veterans;

(b) The number of veterans whose application for a license was approved;

(c) The number of veterans whose application for a license

was denied, including the reasons for denial;

(d) Data on the application processing times for veterans;

(e) The boards' efforts to assist veterans in identifying programs that offer training and education needed to meet the requirements for licensure;

(f) The boards' identification of the most common overlaps and gaps between requirements for licensure and the military training and education received and completed by the veteran applicants; and

(g) Recommendations on ways to improve the department's ability to meet the needs of veterans which would effectively address the challenges that veterans face when separating from military service and seeking a license regulated by the department pursuant to chapter 489, part I.

Section 3. Section 489.5161, Florida Statutes, is created to read:

489.5161 Credit for relevant military training and education.-

(1) Each board shall provide a method by which honorably discharged veterans may apply for licensure. The method shall include:

(a) Extension of credit to the fullest extent possible toward the requirements for licensure for military training or education received and completed during service in the Armed Forces of the United States if the training or education is substantially similar to the training or education required for licensure.

(b) Identification of overlaps and gaps between the requirements for licensure and the military training and

education received and completed by veteran applicants and subsequent notification to the applicant of the overlaps and gaps.

(c) Assistance in identifying programs that offer training and education needed to meet requirements for licensure.

(2) Notwithstanding any other provision of law, beginning October 1, 2017, and annually thereafter, in conjunction with the board, the department is directed to prepare and submit a report titled "Construction and Electrical Contracting Veteran Applicant Statistics" to the President of the Senate, the Speaker of the House of Representatives, and the Governor. The report shall include statistics and information relating to this section and s. 489.1131 detailing:

(a) The number of applicants who identified themselves as veterans;

(b) The number of veterans whose application for a license was approved;

(c) The number of veterans whose applications for a license were denied, including data on the reasons for denial;

(d) Data on the application processing times for veterans;

(e) The boards' efforts to assist veterans in identifying programs that offer training and education needed to meet the requirements for licensure;

(f) The boards' identification of the most common overlaps and gaps between the requirements for licensure and the military training and education received and completed by the veteran applicants; and

(g) Recommendations on ways to improve the department's ability to meet the needs of veterans which would effectively

address the challenges that veterans face when separating from military service and seeking a license regulated by the department pursuant to chapter 489, part II.

Section 4. Section 493.61035, Florida Statutes, is created to read:

493.61035 Credit for relevant military training and education.—

(1) The department shall provide a method by which honorably discharged veterans may apply for licensure. The method must include:

(a) Extension of credit to the fullest extent possible toward the requirements for licensure for military training or education received and completed during service in the Armed Forces of the United States if the training or education is substantially similar to the training or education required for licensure.

(b) Identification of overlaps and gaps between the requirements for licensure and the military training and education received and completed by the veteran applicants and subsequent notification to the applicant of the overlaps and gaps.

(c) Assistance in identifying programs that offer training and education needed to meet requirements for licensure.

(2) Notwithstanding any other provision of law, beginning October 1, 2017, and annually thereafter, the department is directed to prepare and submit a report to the President of the Senate, the Speaker of the House of Representatives, and the Governor. In addition to any other information the Legislature may require, the report must include statistics and relevant

information that detail:

(a) The number of applicants who identified themselves as veterans;

(b) The number of veterans whose application for a license was approved;

(c) The number of veterans whose application for a license was denied, including the reasons for denial;

(d) Data on the application processing times for veterans;

(e) The department's efforts to assist veterans in identifying programs that offer training and education needed to meet the requirements for licensure;

(f) The department's identification of the most common overlaps and gaps between the requirements for licensure and the military training and education received and completed by the veteran applicants; and

(g) Recommendations on ways to improve the department's ability to meet the needs of veterans which would effectively address the challenges that veterans face when separating from military service and seeking a license for a profession or occupation regulated by the department pursuant to chapter 493.

Section 5. National Guard commercial motor vehicle driver license testing pilot program.—

(1) Beginning July 1, 2017, the Department of Highway Safety and Motor Vehicles and the Department of Military Affairs shall jointly conduct a pilot program to provide onsite commercial driver license testing opportunities to qualified members of the Florida National Guard pursuant to the Department of Highway Safety and Motor Vehicles commercial driver license skills test waiver under s. 322.12, Florida Statutes. Testing

must be held at a Florida National Guard Armory, an Armed Forces Reserve Center, or the Camp Blanding Joint Training Center. The pilot program shall be accomplished using existing funds appropriated to the departments.

(2) By June 30, 2018, the Department of Highway Safety and Motor Vehicles and the Department of Military Affairs shall jointly submit a report on the pilot program to the President of the Senate and the Speaker of the House of Representatives.

Section 6. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2016.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1604
INTRODUCER:	Health Policy Committee and Senator Grimsley
SUBJECT:	Drugs, Devices, and Cosmetics
DATE:	January 26, 2016 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Fav/CS**
2.			AGG	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1604 updates the Florida Drug and Cosmetic Act (Act) to bring it into conformity with the federal Food, Drug and Cosmetic Act (federal act). Recent amendments to the federal act preempted Florida's regulatory structure. The bill replaces provisions relating to pedigree papers with federal requirements for a transaction history, transaction information, or transaction statement for certain recordkeeping for the manufacture and distribution of prescription drugs. Certain activities are exempted from the definition of wholesale distribution in order to conform regulatory oversight in Florida to the federal regulatory scheme.

The bill provides for administrative efficiencies and cost savings for initial permitting and permit renewal for prescription drug wholesale distributors and out-of-state prescription drug wholesale distributors by eliminating the distinction between primary and secondary wholesalers and the supplemental information required of a secondary wholesaler for permitting, allowing certain key personnel to submit an affidavit that information submitted on a previous personal statement remains unchanged, modifying the requirement for a surety bond, and authorizing the Department of Business and Professional Regulation (DBPR) to contract with a vendor or enter into interagency agreements for electronic fingerprinting.

The bill establishes a nonresident prescription drug repackager permit, along with the requirement to obtain such a permit if a repackager located outside the state distributes its repackaged prescription drugs into the state. This repackager is also required to comply with provisions applicable to prescription drug manufacturers. The DBPR must establish a virtual

prescription drug manufacturer permit and a virtual out-of-state prescription drug manufacturer permit for manufacturers that do not physically manufacture and possess their prescription drugs.

The DBPR is also authorized to issue nondisciplinary citations for violations of the Act for which there is no substantial threat to the public health, safety, or welfare.

II. Present Situation:

The Florida Drug and Cosmetic Act (Act) is found in ch. 499, F.S. The 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. The DBPR is responsible for regulating and enforcing the Act and is specifically charged with administering and enforcing the Act to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[1]

In 2003, the Legislature enacted the Prescription Drug Protection Act,[2] which put in place strong 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.[3] 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.

The Prescription Drug and Protection Act required prescription drug wholesalers to provide pedigree papers (a transaction history for tracing a prescription drug through the market) for the wholesale distribution of prescription drugs, strengthened permitting requirements for prescription drug wholesale distributors, especially for wholesale distributors that did not purchase directly from drug manufacturers (referred to as secondary wholesalers), and established significant criminal penalties for prescription drug violations related to counterfeiting and diversion.

In 2013, The Drug Quality and Security Act (DQSA) amended the federal act. The DQSA established a uniform national policy for product tracing and other requirements relating to the prescription drug supply chain. The DQSA expressly preempted states from establishing or continuing in effect any requirements for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirement applicable under DQSA. The preemption also included prohibiting states from establishing or continuing any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements of DQSA.[4]

[1] *See* s 499.002, F.S.
[2] *See* ch. 2003-155, L.O.F.
[3] The report is available at: http://myfloridalegal.com/grandjury17.pdf (last visited Jan. 24, 2016).
[4] *See* sec. 585 of the Food, Drug, and Cosmetic Act.

III. Effect of Proposed Changes:

Section 1 amends s. 499.003, F.S., to revise definitions to conform to the changes made to the Florida Drug and Cosmetic Act in this bill. New definitions are provided for: "active pharmaceutical ingredient"[5] and "affiliate." The following definitions are repealed: "affiliated group," "authenticate," "drop shipment," "normal distribution chain," "pedigree paper," "primary wholesale distributor," and "secondary wholesale distributor." The following definitions are substantially revised:

- "Distribute" means to sell, purchase, trade, deliver, handle, store, or receive. The term does not mean to administer or dispense. Deleted from the definition is the concept of offering to perform any of these activities and the method of distribution, i.e., by passage of title, physical movement, or both. The exemption for billing and invoicing activities is also deleted from the definition, but is addressed as an exception to the definition of wholesale distribution.
- "Manufacturer" is reworded to more accurately describe co-licensed partners and private label distributors. Third party logistics (TPL) providers are deleted from the definition.
- "Wholesale distribution" is clarified that the term includes both the distribution to a person and the receipt by a person, of a prescription drug, other than the consumer or patient. The exceptions to wholesale distribution are expanded and revised. Drug shortages not caused by a public health emergency are not deemed an emergency medical reason for the distribution of a prescription drug by a retail pharmacy. This provision is found in rule, but is now specifically addressed in statute. New exclusions from the definition of wholesale distribution include:
  - Intracompany distribution between members of an affiliate or within a manufacturer;
  - Distribution of a prescription drug by the manufacturer of that prescription drug;
  - Distribution of a prescription drug by a third-party logistics (TPL)provider in accordance with state and federal law if the TPL provider does not own the drug;
  - Distribution of, or offer to distribute, a prescription drug by an repackager that is registered under the federal act that owned or possessed the drug and which repackaged it;
  - The purchase or other acquisition by a dispenser, hospital, or other health care entity for use by that dispenser, hospital, or other health care entity;
  - Distribution of a prescription drug for the purpose of repacking the drug owned by a hospital for the hospital's use or other health care entity that is under common control with the hospital;
  - Distribution of minimal quantities of prescription drugs by a retail pharmacy for office use in compliance with the Florida Pharmacy Act and its rules;
  - Distribution of an intravenous prescription drug that is intended for replenishment of fluids and electrolytes, or to maintain the equilibrium of water and minerals in the body;
  - Distribution of a prescription drug that is intended for irrigation or sterile water;
  - Distribution of exempt medical convenience kits;
  - Transport by a common carrier if it does not own the prescription drug;
  - Saleable returns when conducted by a dispenser;
  - Facilitating the distribution of a prescription drug by providing solely administrative services;

[5] The definition of "active pharmaceutical ingredient" is moved from within the definition of definition of "drug."

  - Distribution of a specially-priced or donated prescription drug by a charitable organization to a licensed health care practitioner, health care clinic permitted pursuant to the Act, or to the DOH or other governmental health care entity for providing emergency medical services, if the distributor and recipient receive no direct or indirect financial benefit other than tax benefits for charitable contributions; and
  - Distribution of a medical gas in compliance with part III of the Act.
- "Wholesale distributor" means a person other than a manufacturer, a manufacturer's co-licensed partner, a TPL provider, or a repackager, who is engaged in wholesale distribution.

Sections 2, 3, 4, and 20 amend s. 499.005, F.S., relating to prohibited acts; s. 499.0051, F.S., relating to criminal acts, s. 499.006, F.S., relating to adulterated drug or device, and s. 921.0022, F.S., relating to the criminal punishment code, respectively, to substitute the use of transaction history, transaction information, or transaction statement in lieu of pedigree papers to conform to federal requirements, the federal pre-emption of individual state regulation pertaining to certain recordkeeping for the manufacture and distribution of prescription drugs, and changes made by this bill.

Section 5 amends s. 499.01, F.S., relating to permits to:

- Add a nonresident prescription drug repackager permit. This permit is required for any person located outside Florida but within the U.S. or its territories that repackages prescription drugs and distributes them into Florida. This permittee is required to comply with all provisions and rules that are applicable to prescription drug manufacturers and must be registered as a drug establishment with the federal Food and Drug Administration (FDA).
- Require the DBPR to adopt rules for issuing a virtual prescription drug manufacturer permit and virtual nonresident prescription drug manufacturer permit to a person that manufactures prescription drugs but does not make or take physical possession of any prescription drugs, for example when a contract manufacturer is used. Because these manufacturers do not possess prescription drugs, the DBPR is authorized to exempt them by rule from certain establishment, security, and storage requirements.
- Delete the $100,000 security bond requirement for prescription drug wholesalers and out-of-state prescription drug wholesaler; however a similar, less costly requirement is added to s. 499.012, F.S.
- Require an out-of-state prescription drug wholesaler, a TPL provider, or a nonresident prescription drug manufacturer distributing prescription drug active pharmaceutical ingredients into the state for the manufacture of an approved drug or biologic, which is not licensed by its resident state, to be licensed or registered under the federal act and for the recipient in Florida to maintain documentation of the supplier's compliance;
- Conform requirements of various permits to the repeal of the pedigree paper requirements.
- Remove the restriction that the exemption from permitting for a nonresident prescription drug manufacturer to distribute prescription drug active pharmaceutical ingredients for research is applicable only if the distributions are in limited quantities, require that the label of a prescription drug active pharmaceutical ingredient bear specific caution statement terminology, and require that a prescription drug manufacturer that obtains an active pharmaceutical ingredient from an exempt manufacturer maintain certain records detailing the specific clinical trials or biostudies for which the ingredient was obtained;

- Exempt a restricted prescription drug distributor that repackages and distributes a prescription drug to a not-for-profit rural hospital from compliance with current state and federal current good manufacturing practices relating to repackaging. Alternate provisions are made for the labeling of those prescription drugs.

Section 6 amends s. 499.012, F.S., relating to permit application requirements to:

- Clarify that a prescription drug manufacturer permit may be issued to the same address as a licensed nuclear pharmacy, even if the nuclear pharmacy holds a special sterile compounding permit under the Florida Pharmacy Act.
- Authorize DBPR to issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy, even if the community pharmacy holds a special sterile compounding permit, as long as the community pharmacy is not a closed pharmacy.
- Provide that applications pending resolution of a deficiency after two years from the time the DBPR notified the applicant of the deficiency automatically expire.
- Require the DBPR to maintain trade secret information submitted in an application as trade secret.
- Authorize the issuance of 4-year permits on selected permit types identified in rule.
- Authorize the DBPR to send a permit renewal notification at least 90 days before the expiration date of all permits which conspicuously notes the expiration date of the permit and that the establishment may not operate unless the permit is renewed timely. The renewal notification will eliminate the costs associated with sending the renewal application.
- For a prescription drug wholesale distributor or out-of-state prescription drug wholesale distributor permit:
  - Require a $100 delinquent fee for a renewal application that is submitted later than 45 days prior to the permit's expiration date.
  - Substitute submission of the applicant's gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year in lieu of more extensive information pertaining to prescription drug sales during certain intermediate timeframes and annually, purchases directly from manufacturers for renewal permits, and estimated information for new applicants.
  - Allow a surety bond issued in this state or any other state to satisfy the bond requirement. The amount of the surety bond is tiered based on the applicant's annual gross receipts. A bond of $100,000 is applicable if the annual gross receipts of the applicant's previous tax year is over $10 million, or $25,000 if the annual gross receipts is $10 million or less.
  - Repeal the additional information required to be submitted by secondary wholesalers (wholesalers that did not purchase directly from manufacturers) since the concept of primary wholesale distributor and secondary wholesale distributor is eliminated in this bill.
  - Require proof of establishment inspection by the department, the FDA, or another governmental entity. The DBPR may recognize the inspection conducted by another state if that state's laws are substantially equivalent to the laws in Florida.
  - Authorize the DBPR to contract with a vendor or enter into interagency agreements to handle electronic fingerprinting.
  - Streamline the renewal requirements for the submission of a personal information statement for certain key individuals by allowing submission of a certification under oath

that the most recently submitted statement submitted to the department remains unchanged.

Section 7 amends s. 499.01201, F.S., to make conforming changes.

Section 8 amends s. 499.0121, F.S., relating to the storage and handling of prescription drugs to conform changes associated with the repeal of the pedigree paper requirements and to include standards for active pharmaceutical ingredients that apply to other prescription drugs.

Section 9 amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics to sync the expiration date of product registrations with the expiration date of the applicable manufacturing or repacking permit.

Section 13 amends s. 499.066, F.S., relating to penalties, to authorize the DBPR to adopt rules identifying low-risk violations of the act and applicable penalties, including monetary assessments and other remedial measures, for which a nondisciplinary citation may be issued. The person to whom a citation is issued may choose, in lieu of accepting the citation, to have the matter investigated more fully and processed according to the full procedures for violations of the Act in which discipline may be imposed. The low-risk violation are ones for which there is no substantial threat to the public health, safety, or welfare.

Sections 10, 11, 12, 15, 17, 18 and 19 amend s. 499.03, F.S., relating to possession of prescription drugs, s. 499.05, F.S., relating to rules, s. 499.051, F.S., relating to inspections and investigations, s. 499.89, F.S., relating to recordkeeping, s. 409.9201, F.S., relating to Medicaid fraud, s. 499.067, F.S., relating to denial, suspension or revocation of permit, certification, or registration, and s. 794.075, F.S., relating to sexual predators, respectively, to conform these sections of law to changes made in the bill.

Section 16 repeals s. 499.01212, relating to pedigree papers.

The effective date of the act is July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Updating and conforming the regulations for the distribution of prescription drugs in or into this state eliminates potential ambiguity between Florida's requirements and a uniform national approach thereby allowing for cost savings by regulated persons. Other changes to permit application submission requirements may streamline initial and renewal administrative paperwork, resulting in efficiencies in time and costs. Anecdotal information received from multiple wholesale distributors suggests that the annual submission of the renewal application consumes approximately 40 hours. Changing to a biennial renewal may generate an estimated saving industrywide of approximately $225,379.[6]

Allowing a surety bond that was obtained for licensure in another state to satisfy Florida's requirement for a surety bond for prescription drug wholesale distributors and out-of-state wholesale distributors will generate a cost saving of $100,000 per qualifying permit. The tiered surety bond requirement also helps small businesses.

C. Government Sector Impact:

CS/SB 1604 provides for administrative efficiencies for the DBPR in the regulation and enforcement of the Act which will generate cost savings. The DBPR indicates that technology changes will be required to implement some of these changes, but these costs can be absorbed within existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill exempts the distribution of minimal quantities of prescription drugs by a retail pharmacy for office use in compliance with the Florida Pharmacy Act and its rules from the definition of wholesale distribution. However, the requirement for a retail pharmacy drug wholesale distributor permit is still required in s. 499.01(2)(g), F.S., for a retail pharmacy that engages in the wholesale distribution of prescription drugs to practitioners of up to 30 percent of the pharmacy's total annual prescription drug purchases. It is not apparent how these two sections of law are intended to co-exist and additional legislative direction may be warranted.

Lines 1584-1593 exempt a restricted prescription drug distributor that repackages and distributes a prescription drug to a not-for-profit rural hospital from compliance with *all* current state and

[6] *See* DBPR, *Senate Bill 1604 Analysis*, p. 13, (on file with the Senate Committee on Health Policy).

federal current good manufacturing practices relating to repackaging. This may be overly broad and might create unreasonable risks for persons receiving those drugs in the rural hospital. Also, this provision may be read as exempting compliance with current good manufacturing practices for all repacked and distributed prescription drugs to all health care entities if at least one of the recipients is a rural hospital.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 499.003, 499.005, 499.0051, 499.006, 499.01, 499.012, 499.01201, 499.0121, 499.015, 499.03, 499.05, 499.051, 499.066, 499.82, 499.89, 409.9201, 499.067, 794.075, and 921.0022.

This bill repeals section 499.01212 of the Florida Statutes.

IX. 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 Policy on January 26, 2016:.
The CS corrects a reference to a prescription drug manufacturer distributing their prescription drugs as opposed to engaging in the wholesale distribution of those drugs to comport with the federal act. The CS also reinstates the mandatory registration of cosmetic products manufactured in this state.

B. Amendments:

None.


864912

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2016	.	
	.	
	.	
	.	

The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment

Delete line 930
and insert:
prescription drug manufacturer may engage in ~~wholesale~~

669120

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2016	.	
	.	
	.	
	.	

The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete lines 2419 - 2476

and insert:

Section 9. Subsection (4) of section 499.015, Florida Statues, is amended to read:

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

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any

669120

product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs, devices, or cosmetics covered by this part until he or she complies with the requirements of 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 67 - 73

and insert:

499.015, F.S.; providing for the expiration, renewal, and issuance of certain drug, device, and cosmetic product registrations; providing for product

By Senator Grimsley

21-01087-16 20161604__

A bill to be entitled

An act relating to drugs, devices, and cosmetics; amending s. 499.003, F.S.; providing, revising, and deleting definitions for purposes of the Florida Drug and Cosmetic Act; amending s. 499.005, F.S.; revising prohibited acts related to the distribution of prescription drugs; conforming a cross-reference; amending s. 499.0051, F.S.; prohibiting the distribution of prescription drugs without delivering a transaction history, transaction information, and transaction statement; providing penalties; deleting provisions and revising terminology related to pedigree papers, to conform to changes made by the act; amending s. 499.006, F.S.; conforming provisions; amending s. 499.01, F.S.; requiring nonresident prescription drug repackagers to obtain an operating permit; authorizing a manufacturer to engage in the wholesale distribution of prescription drugs; providing for the issuance of virtual prescription drug manufacturer permits and virtual nonresident prescription drug manufacturer permits to certain persons; providing exceptions from certain virtual manufacturer requirements; requiring a nonresident prescription drug repackager permit for certain persons; deleting surety bond requirements for prescription drug wholesale distributors; requiring that certain persons obtain an out-of-state prescription drug wholesale distributor permit requiring certain third party logistic providers to be licensed; requiring research and development labeling on certain prescription drug active pharmaceutical ingredient packaging; requiring certain manufacturers

21-01087-16 20161604__

to create and maintain certain records; requiring certain prescription drug distributors to provide certain information to health care entities for which they repackage prescription drugs; amending s. 499.012, F.S.; providing for issuance of a prescription drug manufacturer permit or retail pharmacy drug wholesale distributor permit when an applicant at the same address is a licensed nuclear pharmacy or community pharmacy; providing for the expiration of deficient permit applications; requiring trade secret information submitted by an applicant to be maintained as a trade secret; authorizing the quadrennial renewal of permits; providing for calculation of fees for such permit renewals; revising procedures and application requirements for permit renewals; providing for late renewal fees; allowing a permittee who submits a renewal application to continue operations; removing certain application requirements for renewal of a permit; requiring bonds or other surety of a specified amount; requiring proof of inspection of establishments used in wholesale distribution; authorizing the Department of Business and Professional Regulation to contract for the collection of electronic fingerprints under certain circumstances; providing information that may be submitted in lieu of certain application requirements for specified permits and certifications; removing provisions relating to annual renewal and expiration of permits; conforming cross-references; amending s.

499.01201, F.S.; conforming provisions; amending s. 499.0121, F.S.; revising prescription drug recordkeeping requirements; requiring inventories and records of transactions for active pharmaceutical ingredients; conforming provisions; amending s. 499.015, F.S.; removing cosmetics from registration requirements; authorizing voluntary registration of cosmetics; providing application and fee requirements for cosmetics; restricting those persons who may register a product with the department; providing for the expiration, renewal, and issuance of certain product registrations; providing for product registration fees; amending ss. 499.03, 499.05, and 499.051, F.S.; conforming provisions to changes made by the act; amending s. 499.066, F.S.; authorizing the issuance of nondisciplinary citations; authorizing the department to adopt rules designating violations for which a citation may be issued; authorizing the department to recover investigative costs pursuant to the citation; specifying a time limitation for issuance of a citation; providing for service of a citation; amending s. 499.82, F.S.; revising the definition of "wholesale distribution" for purposes of medical gas requirements; amending s. 499.89, F.S.; conforming provisions; repealing s. 499.01212, F.S., relating to pedigree papers; amending ss. 409.9201, 499.067, 794.075, and 921.0022, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Section 499.003, Florida Statutes, is amended to read:

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

(1) "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 animals.

(2)~~(1)~~ "Advertisement" means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

(3) "Affiliate" means a business entity that has a relationship with another business entity in which, directly or indirectly:

(a) The business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both business entities.

~~(2) "Affiliated group" means 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.~~

(4)~~(3)~~ "Affiliated party" means:

(a) A director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant;

(b) A person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant;

(c) A person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or

(d) The five largest natural shareholders that own at least 5 percent of the permittee or applicant.

(5)~~(4)~~ "Applicant" means a person applying for a permit or certification under this part.

~~(5) "Authenticate" means to affirmatively verify upon receipt of a prescription drug that each transaction listed on the pedigree paper has occurred.~~

~~(a) A wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit.~~

~~(b) Authentication of a prescription drug included in a sealed, medical convenience kit shall be limited to verifying the transaction and pedigree information received.~~

(6) "Certificate of free sale" means a document prepared by the department which certifies a drug, device, or cosmetic, that is registered with the department, as one that can be legally sold in the state.

(7) "Chain pharmacy warehouse" means a ~~wholesale~~ distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such drugs between members of an affiliate ~~to a member of its affiliated group~~.

(8) "Closed pharmacy" means a pharmacy that is licensed under chapter 465 and purchases prescription drugs for use by a limited patient population and not for wholesale distribution or sale to the public. The term does not include retail pharmacies.

(9) "Color" includes black, white, and intermediate grays.

(10) "Color additive" means, with the exception of any material that has been or hereafter is exempt under the federal act, a material that:

(a) Is a dye pigment, or other substance, made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or

(b) When added or applied to a drug or cosmetic or to the human body, or any part thereof, is capable alone, or through reaction with other substances, of imparting color thereto.

(11) "Contraband prescription drug" means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means any prescription drug for which

a transaction history, transaction information, or transaction statement ~~pedigree paper~~ does not exist, or for which the transaction history, transaction information, or transaction statement ~~pedigree paper~~ in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter.

(12) "Cosmetic" means an article, with the exception of soap, that is:

(a) Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or

(b) Intended for use as a component of any such article.

(13) "Counterfeit drug," "counterfeit device," or "counterfeit cosmetic" means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.

(14) "Department" means the Department of Business and Professional Regulation.

(15) "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other

similar or related article, including its components, parts, or accessories, which is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof,

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

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

and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(16) "Distribute" or "distribution" means to sell, purchase, trade, deliver, handle, store, or receive ~~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 billing and invoicing activities that commonly follow a wholesale distribution transaction~~.

~~(17) "Drop shipment" means the sale of a prescription drug from a manufacturer to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003.~~

(17)~~(18)~~ "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 nondrug 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.~~

(18)~~(19)~~ "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 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.

(19)~~(20)~~ "Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

(20)~~(21)~~ "Freight forwarder" means a person who receives prescription drugs which are owned by another person and designated by that person for export, and exports those prescription drugs.

(21)~~(22)~~ "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

(22)~~(23)~~ "Health care facility" means a health care facility licensed under chapter 395.

(23)~~(24)~~ "Hospice" means a corporation licensed under part IV of chapter 400.

(24)~~(25)~~ "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(25)~~(26)~~ "Immediate container" does not include package liners.

(26)~~(27)~~ "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this

part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(27) ~~(28)~~ "Labeling" means all labels and other written, printed, or graphic matters:

(a) Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b) Accompanying or related to such drug, device, or cosmetic.

(28) ~~(29)~~ "Manufacture" means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic.

(29) ~~(30)~~ "Manufacturer" means:

(a) A person who holds a New Drug Application, an Abbreviated New Drug Application, a Biologics License Application, or a New Animal Drug Application approved under the federal act or a license issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262, for such drug or biologics, or if such drug or biologics is not the subject of an approved application or license, the person who manufactured the drug or biologics ~~prepares, derives, manufactures, or produces a drug, device, or cosmetic~~;

(b) A co-licensed partner of the person described in paragraph (a) who obtains the drug or biologics directly from a person described in paragraph (a), paragraph (c), or this paragraph ~~The holder or holders of a New Drug Application (NDA),~~

~~an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023~~;

(c) An affiliate of a person described in paragraph (a), paragraph (b), or this paragraph that receives the drug or biologics directly from a person described in paragraph (a), paragraph (b), or this paragraph ~~A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged~~; or

(d) A person who manufactures a device or a cosmetic. ~~A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations;~~

~~(c) A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all of its affiliated~~

~~group members to the department; or~~

~~(f) A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).~~

The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(30) ~~(31)~~ "Medical convenience kit" means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2).

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

(32) ~~(33)~~ "New drug" means:

(a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of that drug; or

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under certain conditions, has been recognized for use under such conditions, but which drug has not, other than in those investigations, been used to a material extent or for a material time under such conditions.

~~(34) "Normal distribution chain" means a wholesale distribution of a prescription drug in which the wholesale distributor or its wholly owned subsidiary purchases and receives the specific unit of the prescription drug directly from the manufacturer and distributes the prescription drug directly, or through up to two intracompany transfers, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003. For purposes of this subsection, the term "intracompany" means any transaction or transfer between any parent, division, or subsidiary wholly owned by a corporate entity.~~

(33) ~~(35)~~ "Nursing home" means a facility licensed under part II of chapter 400.

(34) ~~(36)~~ "Official compendium" means the current edition of the official United States Pharmacopoeia and National Formulary, or any supplement thereto.

~~(37) "Pedigree paper" means a document in written or electronic form approved by the department which contains information required by s. 499.01212 regarding the sale and distribution of any given prescription drug.~~

(35) ~~(38)~~ "Permittee" means any person holding a permit issued under this chapter ~~pursuant to s. 499.012~~.

(36) ~~(39)~~ "Person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this

state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

(37) ~~(40)~~ "Pharmacist" means a person licensed under chapter 465.

(38) ~~(41)~~ "Pharmacy" means an entity licensed under chapter 465.

(39) ~~(42)~~ "Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing in the establishment in which the prepackaging occurred.

(40) ~~(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 act or s. 465.003(8), s. 499.007(13), subsection (31) ~~(32)~~, or subsection (47) ~~(52)~~, 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.

(41) ~~(44)~~ "Prescription drug label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug before it is dispensed ~~prior to its dispensing~~ to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

(42) ~~(45)~~ "Prescription label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a

practitioner authorized by law to prescribe.

~~(46) "Primary wholesale distributor" means any wholesale distributor that:~~

~~(a) Purchased 90 percent or more of the total dollar volume of its purchases of prescription drugs directly from manufacturers in the previous year; and~~

~~(b)1. Directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or~~

~~2. Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.~~

~~(c) For purposes of this subsection, "directly from manufacturers" means:~~

~~1. Purchases made by the wholesale distributor directly from the manufacturer of prescription drugs; and~~

~~2. Transfers from a member of an affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if:~~

~~a. The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year; and~~

~~b. The wholesale distributor discloses to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group agrees in writing to provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.~~

(43)~~(47)~~ "Proprietary drug," or "OTC drug," means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

(44)~~(48)~~ "Repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(45)~~(49)~~ "Repackager" means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(46)~~(50)~~ "Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

~~(51) "Secondary wholesale distributor" means a wholesale distributor that is not a primary wholesale distributor.~~

(47)~~(52)~~ "Veterinary prescription drug" means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(48)~~(53)~~ "Wholesale distribution" means the distribution of a prescription drug to a person ~~drugs to persons~~ other than a consumer or patient, or the receipt of a prescription drug by a person other than the 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)(h) ~~499.01(2)(g)~~:

1. The purchase or other acquisition by a hospital or other 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 distribution ~~sale, purchase, or trade~~ of a prescription drug or an offer to distribute ~~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 distribution ~~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 distribution ~~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 distribution ~~sale, purchase, trade, or other transfer~~ of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

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. 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. 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.

f. 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.

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1. The distribution ~~sale, purchase, or trade~~ of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2. The distribution ~~sale, purchase, or trade~~ of a prescription drug or ~~an~~ offer to distribute ~~sell, purchase, or trade~~ a prescription drug for emergency medical reasons, which may include~~. For purposes of this subparagraph, The term "emergency medical reasons" includes~~ transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage. For purposes of this subparagraph, a drug shortage not caused by a public health emergency does not constitute an emergency medical reason.

3. The distribution ~~transfer~~ of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

~~4. The revocation of a sale or the return of a prescription~~

~~drug to the person's prescription drug wholesale supplier.~~

4.~~5.~~ The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

5.~~6.~~ The distribution ~~transfer~~ of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

6.~~7.~~ The distribution ~~transfer~~ of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that distributes ~~transfers~~ prescription drugs pursuant to this subparagraph must reconcile all drugs distributed ~~transferred~~ and returned and resolve any discrepancies in a timely manner.

(c) Intracompany distribution of any drug between members of an affiliate or within a manufacturer.

(d) The distribution of a prescription drug by the manufacturer of the prescription drug.

(e)~~(c)~~ The distribution of prescription drug samples by

manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(f) The distribution of a prescription drug by a third-party logistics provider permitted or licensed pursuant to and operating in compliance with the laws of this state and federal law if such third-party logistics provider does not take ownership of the prescription drug.

(g) The distribution of a prescription drug, or an offer to distribute a prescription drug by a repackager registered as a drug establishment with the United States Food and Drug Administration that has taken ownership or possession of the prescription drug and repacks it in accordance with this part.

(h) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a prescription drug for use by such dispenser, hospital, or other health care entity.

(i) The distribution of a prescription drug by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drug remains with the hospital or other health care entity at all times.

(j)~~(d)~~ The distribution ~~sale, purchase, or trade~~ of blood and blood components intended for transfusion. As used in this paragraph, the term "blood" means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term "blood components" means that part

of the blood separated by physical or mechanical means.

(k) ~~(c)~~ The lawful dispensing of a prescription drug in accordance with chapter 465.

(l) ~~(f)~~ The distribution ~~sale, purchase, or trade~~ of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(m) The distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use in compliance with chapter 465 and rules adopted thereunder.

(n) The distribution of an intravenous prescription drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium or calories, such as dextrose and amino acids.

(o) The distribution of an intravenous prescription drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(p) The distribution of a prescription drug that is intended for irrigation or sterile water, whether intended for such purposes or for injection.

(q) The distribution of an exempt medical convenience kit pursuant to 21 U.S.C. s. 353(e)(4)(M).

(r) A common carrier that transports a prescription drug, if the common carrier does not take ownership of the prescription drug.

(s) Saleable drug returns when conducted by a dispenser.

(t) Facilitating the distribution of a prescription drug by providing solely administrative services, including processing of orders and payments.

(u) The distribution by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of prescription drugs donated to or supplied at a reduced price to the charitable organization to:

1. A licensed health care practitioner, as defined in s. 456.001, who is authorized under the appropriate practice act to prescribe and administer prescription drugs;

2. A health care clinic establishment permitted pursuant to chapter 499; or

3. The Department of Health or the licensed medical director of a government agency health care entity, authorized to possess prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health,

if the distributor and the receiving entity receive no direct or indirect financial benefit other than tax benefits related to charitable contributions. Distributions under this section that involve controlled substances must comply with all state and federal regulations pertaining to the handling of controlled substances.

(v) The distribution of medical gas pursuant to part III of this chapter.

(49) ~~(54)~~ "Wholesale distributor" means a ~~any~~ person, other

than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution ~~of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own label distributors; jobbers; private label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions~~.

Section 2. Subsections (21), (28), and (29) of section 499.005, Florida Statutes, are amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

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

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

(28) Failure to acquire or deliver a transaction history, transaction information, or transaction statement ~~pedigree paper~~ as required under this part and rules adopted under this part.

~~(29) The receipt of a prescription drug pursuant to a wholesale distribution without having previously received or simultaneously receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor as required under this part.~~

Section 3. Subsections (4) through (17) of section 499.0051, Florida Statutes, are renumbered as subsections (3) through (16), respectively, and subsections (1) and (2), present subsection (3), paragraphs (h) and (i) of present subsection (12), paragraph (d) of present subsection (13), and present subsection (15) of that section are amended, to read:

499.0051 Criminal acts.—

(1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE PAPERS~~.—

(a) A person~~, other than a manufacturer,~~ engaged in the ~~wholesale~~ distribution of prescription drugs who fails to deliver to another person a complete and accurate transaction history, transaction information, or transaction statement ~~pedigree papers~~ concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before ~~prior to~~, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A person engaged in the ~~wholesale~~ distribution of prescription drugs who fails to acquire a complete and accurate transaction history, transaction information, or transaction statement ~~pedigree papers~~ concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before ~~prior to~~, or

simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any person who knowingly destroys, alters, conceals, or fails to maintain a complete and accurate transaction history, transaction information, or transaction statement ~~pedigree papers~~ concerning any prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

~~(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS. Effective July 1, 2006:~~

~~(a) A person engaged in the wholesale distribution of prescription drugs who is in possession of pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

~~(b) A person in possession of pedigree papers concerning prescription drugs or contraband prescription drugs who falsely swears or certifies that he or she has authenticated the matters contained in the pedigree papers commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

(2)~~(3)~~ KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION

INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE PAPERS~~.—A person who knowingly forges, counterfeits, or falsely creates any transaction history, transaction information, or transaction statement ~~pedigree paper~~; who falsely represents any factual matter contained on any transaction history, transaction information, or transaction statement ~~pedigree paper~~; or who knowingly omits to record material information required to be recorded in a transaction history, transaction information, or transaction statement ~~pedigree paper~~, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(11)~~(12)~~ ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:

(h) The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for transaction histories, transaction information, or transaction statements ~~pedigree papers~~, invoices, or shipping documents related to prescription drugs.

(i) The possession of any drug in violation of this part, except if the violation relates to a deficiency in transaction histories, transaction information, or transaction statements ~~pedigree papers~~.

(12)~~(13)~~ REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(d) The failure to receive, maintain, or provide invoices and shipping documents~~, other than pedigree papers,~~ if applicable, related to the distribution of a prescription drug.

(15) FALSE ADVERTISEMENT.—A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesale distributor, or seller of the article to which a false advertisement relates, is not liable under subsection (11) ~~(12)~~, subsection (12) ~~(13)~~, or subsection (13) ~~(14)~~ by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, repackager, wholesale distributor, seller, or advertising agency that asked him or her to disseminate such advertisement.

Section 4. Section 499.006, Florida Statutes, is amended to read:

499.006 Adulterated drug or device.—A drug or device is adulterated, if any of the following apply:

(1) ~~If~~ It consists in whole or in part of any filthy, putrid, or decomposed substance.~~;~~

(2) ~~If~~ It has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with

filth or rendered injurious to health.~~;~~

(3) ~~If~~ It is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of this part and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess.~~;~~

(4) ~~If~~ It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health.~~;~~

(5) ~~If~~ It is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act.~~;~~

(6) ~~If~~ It purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or

purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label.~~,~~

(7) ~~If~~ It is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess.~~,~~

(8) ~~If~~ It is a drug:

(a) With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or

(b) For which any substance has been substituted wholly or in part.~~,~~

(9) ~~If~~ It is a drug or device for which the expiration date has passed.~~,~~

(10) ~~If~~ It is a prescription drug for which the required transaction history, transaction information, or transaction statement ~~pedigree paper~~ is nonexistent, fraudulent, or incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.~~,~~ ~~or~~

(11) ~~If~~ It is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesale distributor.

Section 5. Section 499.01, Florida Statutes, is amended to read:

499.01 Permits.—

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

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) A nonresident prescription drug manufacturer;

(d) A nonresident prescription drug repackager;

(e)~~(d)~~ A prescription drug wholesale distributor;

(f)~~(e)~~ An out-of-state prescription drug wholesale distributor;

(g)~~(f)~~ A retail pharmacy drug wholesale distributor;

(h)~~(g)~~ A restricted prescription drug distributor;

(i)~~(h)~~ A complimentary drug distributor;

(j)~~(i)~~ A freight forwarder;

(k)~~(j)~~ A veterinary prescription drug retail establishment;

(l)~~(k)~~ A veterinary prescription drug wholesale distributor;

(m)~~(l)~~ A limited prescription drug veterinary wholesale distributor;

(n)~~(m)~~ An over-the-counter drug manufacturer;

(o)~~(n)~~ A device manufacturer;

(p)~~(o)~~ A cosmetic manufacturer;

(q)~~(p)~~ A third party logistics provider; or

(r)~~(q)~~ A health care clinic establishment.

(2) The following permits are established:

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

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs for which the person is the

manufacturer ~~manufactured at that establishment~~ and must comply with s. 499.0121 and all other ~~of the~~ provisions of this part~~,~~ ~~except s. 499.01212,~~ and ~~the~~ rules adopted under this part~~,~~ ~~except s. 499.01212, which apply to a wholesale distributor~~. The department shall adopt rules for issuing a virtual prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

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

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(48)(j) ~~499.003(53)(d)~~ is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(b) *Prescription drug repackager permit.*—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in ~~wholesale~~ distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer ~~wholesale distributor~~.

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

(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 prescription drug manufacturer ~~wholesale distributor~~ under this part~~, except s. 499.01212~~. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

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 when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates ~~as defined in s. 499.003(30)(c)~~.

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 prescription drug distributed ~~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.

(d) *Nonresident prescription drug repackager permit.*-A nonresident prescription drug repackager permit is required for any person located outside of this state, but within the United States or its territories, that repackages prescription drugs and engages in the distribution of such prescription drugs into this state.

1. A nonresident prescription drug repackager must comply with all of the provisions of this section and the rules adopted under this section that apply to a prescription drug manufacturer.

2. A nonresident prescription drug repackager must be permitted by the department and comply with all appropriate state and federal good manufacturing practices.

3. A nonresident prescription drug repackager must be registered as a drug establishment with the United States Food and Drug Administration.

(e)~~(d)~~ *Prescription drug wholesale distributor permit.*—A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that ~~may engage in the~~ wholesale distributes such

~~distribution of~~ prescription drugs in this state. ~~A 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 Professional Regulation 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.~~ The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(f)~~(e)~~ *Out-of-state prescription drug wholesale distributor permit.*—An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, 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 Professional Regulation 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.~~ 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. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

(g)~~(f)~~ *Retail pharmacy drug wholesale distributor permit.*—A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1. The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and ~~the~~ rules

adopted under this part.

2. The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-percent maximum, the pharmacy must obtain a prescription drug wholesale distributor permit.

3. The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

4. The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.

5. All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.

(h)~~(g)~~ *Restricted prescription drug distributor permit.*—

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

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(48)(a) ~~499.003(53)(a)~~.

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

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

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

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

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

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

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

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a

licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

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

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

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved

in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

(i) ~~(h)~~ *Complimentary drug distributor permit.*—A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028.

(j) ~~(i)~~ *Freight forwarder permit.*—A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121~~, but not those set forth in s. 499.01212~~. A freight forwarder must provide the source of the prescription drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(k) ~~(j)~~ *Veterinary prescription drug retail establishment permit.*—A veterinary prescription drug retail establishment permit is required for any person that sells veterinary prescription drugs to the public but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary prescription drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary prescription drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary prescription drug retail establishment must sell a veterinary prescription drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary prescription drug.

6. A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7. Prescription drugs sold by a veterinary prescription drug retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(l) ~~(k)~~ *Veterinary prescription drug wholesale distributor permit.*—A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale distributor that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary prescription drug wholesale distributor permit. A veterinary prescription drug wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121~~, but not those set forth in s. 499.01212~~.

(m) ~~(l)~~ *Limited prescription drug veterinary wholesale distributor permit.*—Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary prescription drugs to persons:

a. Licensed as veterinarians practicing on a full-time basis;

b. Regularly and lawfully engaged in instruction in veterinary medicine;

c. Regularly and lawfully engaged in law enforcement activities;

d. For use in research not involving clinical use; or

e. For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

2. No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s.

503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, 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 Professional Regulation 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.

5. A limited prescription drug veterinary 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.

6. A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under s. ~~ss.~~ 499.0121 ~~and 499.01212, except that a limited prescription drug veterinary wholesale distributor is not required to provide a pedigree paper as required by s. 499.01212 upon the wholesale distribution of a prescription drug~~

~~to a veterinarian~~.

7. A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

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

(n) ~~(m)~~ *Over-the-counter drug manufacturer permit.*—An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.

1. An over-the-counter drug manufacturer may not possess or purchase prescription drugs.

2. A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and ~~the~~ rules adopted under that chapter.

3. An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(o) ~~(n)~~ *Device manufacturer permit.*—

1. A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:

a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or

b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).

2. A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

3. The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

(p) ~~(o)~~ *Cosmetic manufacturer permit.*—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(q) ~~(p)~~ *Third party logistics provider permit.*—A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer, ~~or~~ wholesale distributor, or dispenser, but who

does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. A third party logistics provider located outside of this state, must be licensed in the state or territory from which the prescription drug is distributed by the third party logistics provider. If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistic provider must be licensed as a third party logistics provider as required by the federal act. Each third party logistics provider permittee shall comply with s. ~~the requirements for wholesale distributors under ss.~~ 499.0121 ~~and 499.01212, with the exception of those wholesale distributions described in s. 499.01212(3)(a),~~ and other rules that the department requires.

(r) ~~(q)~~ *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 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 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.

(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 subsection 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; if available, 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 define the term "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amount of prescription drugs distributed into the state for purposes of this exemption.~~ The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a

violation of s. 499.0051(3) ~~499.0051(4)~~.

(a) The immediate package or container of a prescription drug active pharmaceutical ingredient distributed into the state that is intended for research and development under this subsection shall bear a label prominently displaying the statement: "Caution: Research and Development Only—Not for Manufacturing, Compounding, or Resale."

(b) A prescription drug manufacturer that obtains a prescription drug active pharmaceutical ingredient under this subsection for use in clinical trials and or biostudies authorized and regulated by federal law must create and maintain records detailing the specific clinical trials or biostudies for which the prescription drug active pharmaceutical ingredient was obtained.

(4)(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. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

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. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

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 s. ~~ss.~~

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 or federal license, registration, or permit that authorizes the source to distribute prescription drugs ~~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 from 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, 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(3) ~~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.

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(48)(a)3. ~~499.003(53)(a)3.~~, if:

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

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing

prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

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

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection. A prescription drug distributor that repackages and distributes prescription drugs under this subsection to a not-for-profit rural hospital, as defined in s. 395.602, is not required to comply with paragraph (c) or paragraph (d), but must provide to each health care entity for which it repackages, for each prescription drug that is repackaged and distributed, the information required by department rule for labeling prescription drugs. The prescription drug distributor shall also provide the additional current packaging and label information for the prescription drug by hard copy or by electronic means.

Section 6. Section 499.012, Florida Statutes, is amended to read:

499.012 Permit application requirements.—

(1)(a) A permit issued pursuant to this part may be issued only to a natural person who is at least 18 years of age or to

an applicant that is not a natural person if each person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

(b) An establishment that is a place of residence may not receive a permit and may not operate under this part.

(c) A person that applies for or renews a permit to manufacture or distribute prescription drugs may not use a name identical to the name used by any other establishment or licensed person authorized to purchase prescription drugs in this state, except that a restricted drug distributor permit issued to a health care entity will be issued in the name in which the institutional pharmacy permit is issued and a retail pharmacy drug wholesale distributor will be issued a permit in the name of its retail pharmacy permit.

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesale distributor, limited prescription drug veterinary wholesale distributor, or retail pharmacy drug wholesale distributor may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, even if the nuclear pharmacy holds a special sterile compounding permit under chapter 465, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art

pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy licensed under chapter 465, even if the community pharmacy holds a special sterile compounding permit under chapter 465, as long as the community pharmacy ~~which~~ does not meet the definition of a closed pharmacy in s. 499.003.

(e) A county or municipality may not issue an occupational license for ~~any licensing period beginning on or after October 1, 2003, for~~ any establishment that requires a permit pursuant to this part, unless the establishment exhibits a current permit issued by the department for the establishment. Upon presentation of the requisite permit issued by the department, an occupational license may be issued by the municipality or county in which application is made. The department shall furnish to local agencies responsible for issuing occupational licenses a current list of all establishments licensed pursuant to this part.

(2) Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state

prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(3)(a) A written application for a permit or to renew a permit must be filed with the department on forms furnished by the department. The department shall establish, by rule, the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct.

(b) Upon a determination that 2 years have elapsed since the department notified an applicant for permit, certification, or product registration of a deficiency in the application and that the applicant has failed to cure the deficiency, the application shall expire. The determination regarding the 2-year lapse of time shall be based on documentation that the department notified the applicant of the deficiency in accordance with s. 120.60.

(c) Information submitted by an applicant on an application required pursuant to this subsection which is a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information pursuant to s. 499.051(7).

(4)(a) Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor, an application for a permit must include:

1. The name, full business address, and telephone number of

the applicant;

2. All trade or business names used by the applicant;

3. The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;

4. The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and

5. The names of the owner and the operator of the establishment, including:

a. If an individual, the name of the individual;

b. If a partnership, the name of each partner and the name of the partnership;

c. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

d. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

e. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

f. Any other relevant information that the department requires.

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

(c) Any change in information required under paragraph (a) must be submitted to the department before the change occurs.

(d) The department shall consider, at a minimum, the following factors in reviewing the qualifications of persons to be permitted under this part:

1. The applicant's having been found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a violation of a law that directly relates to a drug, device, or cosmetic. A plea of nolo contendere constitutes a finding of guilt for purposes of this subparagraph.

2. The applicant's having been disciplined by a regulatory agency in any state for any offense that would constitute a violation of this part.

3. Any felony conviction of the applicant under a federal, state, or local law;

4. The applicant's past experience in manufacturing or distributing drugs, devices, or cosmetics;

5. The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distributing drugs, devices, or cosmetics;

6. Suspension or revocation by a federal, state, or local government of any permit currently or previously held by the applicant for the manufacture or distribution of any drugs, devices, or cosmetics;

7. Compliance with permitting requirements under any previously granted permits;

8. Compliance with requirements to maintain or make available to the state permitting authority or to federal, state, or local law enforcement officials those records required under this section; and

9. Any other factors or qualifications the department

considers relevant to and consistent with the public health and safety.

(5) ~~Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:~~

(a) The department shall adopt rules for the biennial renewal of permits; however, the department may issue up to a 4-year permit to selected permittees notwithstanding any other provision of law. Fees for such renewal may not exceed the fee caps set forth in s. 499.041 on an annualized basis as authorized by law.

(b) The department shall renew a permit upon receipt of the renewal application and renewal fee if the applicant meets the requirements established under this part and ~~the~~ rules adopted under this part.

(c) At least 90 days before the expiration date of a permit, the department shall forward a permit renewal notification to the permittee at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely. ~~A permit, unless sooner suspended or revoked, automatically expires 2 years after the last day of the anniversary month in which the permit was originally issued.~~

(d) A permit issued under this part may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees.

1. If a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor renewal application and fee are submitted and postmarked later than 45 days before the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee.

2. If any other ~~a~~ renewal application and fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than 60 days after the expiration date.

3. A permittee submits a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

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

(6) A permit issued by the department is nontransferable. Each permit is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily; nor is a permit valid for any establishment other than the establishment for which it was originally issued.

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

(b)1. An application for a new permit is required when a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee. The application for the new permit must be made before the date of the sale, transfer, assignment, or lease.

2. A permittee that is authorized to distribute prescription drugs may transfer such drugs to the new owner or lessee under subparagraph 1. only after the new owner or lessee has been approved for a permit to distribute prescription drugs.

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

1. Return the permit to the department;

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

The department may revoke the permit of any person that fails to comply with the requirements of this subsection.

(7) A permit must be posted in a conspicuous place on the

licensed premises.

(8) An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(a) The name, full business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(e) The names of the owner and the operator of the establishment, including:

1. If an individual, the name of the individual.

2. If a partnership, the name of each partner and the name of the partnership.

3. If a corporation:

a. The name, address, and title of each corporate officer and director.

b. The name and address of the corporation, resident agent of the corporation, the resident agent's address, and the corporation's state of incorporation.

c. The name and address of each shareholder of the corporation that owns 5 percent or more of the outstanding stock of the corporation.

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

5. If a limited liability company:

a. The name and address of each member.

b. The name and address of each manager.

c. The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f) If applicable, the name and address of each affiliate of ~~member of the affiliated group of which~~ the applicant ~~is a member~~.

(g)~~1.~~ The applicant's gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year. ~~For an application for a new permit, the estimated annual dollar volume of prescription drug sales of the applicant, the estimated annual percentage of the applicant's total company sales that are prescription drugs, the applicant's estimated annual total dollar volume of purchases of prescription drugs, and the applicant's estimated annual total dollar volume of prescription drug purchases directly from manufacturers.~~

~~2. For an application to renew a permit, the total dollar volume of prescription drug sales in the previous year, the total dollar volume of prescription drug sales made in the previous 6 months, the percentage of total company sales that were prescription drugs in the previous year, the total dollar volume of purchases of prescription drugs in the previous year, and the total dollar volume of prescription drug purchases directly from manufacturers in the previous year.~~

~~Such portions of the information required pursuant to this paragraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.~~

(h) The tax year of the applicant.

(i) A copy of the deed for the property on which applicant's establishment is located, if the establishment is owned by the applicant, or a copy of the applicant's lease for the property on which applicant's establishment is located that has an original term of not less than 1 calendar year, if the establishment is not owned by the applicant.

(j) A list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs.

(k) The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l) The name of each of the applicant's designated representatives as required by subsection (15) ~~(16)~~, together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m) Evidence of a surety bond in this state or any other state in the United States in the amount of $100,000. If the annual gross receipts of the applicant's previous tax year is $10 million or less, evidence of a surety bond in the amount of

$25,000. The specific language of the surety bond must include the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. In lieu of the surety bond, the applicant may provide other equivalent security such as an irrevocable letter of credit or a deposit in a trust account or financial institution payable to the Professional Regulation Trust Fund. The purpose of the bond or other security 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. ~~For an applicant that is a secondary wholesale distributor, each of the following:~~

~~1. A personal background information statement containing the background information and fingerprints required pursuant to subsection (9) for each person named in the applicant's response to paragraphs (k) and (l) and for each affiliated party of the applicant.~~

~~2. If any of the five largest shareholders of the corporation seeking the permit is a corporation, the name, address, and title of each corporate officer and director of each such corporation; the name and address of such corporation; the name of such corporation's resident agent, such corporation's resident agent's address, and such corporation's~~

~~state of its incorporation; and the name and address of each shareholder of such corporation that owns 5 percent or more of the stock of such corporation.~~

~~3. The name and address of all financial institutions in which the applicant has an account which is used to pay for the operation of the establishment or to pay for drugs purchased for the establishment, together with the names of all persons that are authorized signatories on such accounts. The portions of the information required pursuant to this subparagraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.~~

~~4. The sources of all funds and the amounts of such funds used to purchase or finance purchases of prescription drugs or to finance the premises on which the establishment is to be located.~~

~~5. If any of the funds identified in subparagraph 4. were borrowed, copies of all promissory notes or loans used to obtain such funds.~~

(n) For establishments used in wholesale distribution, proof of an inspection conducted by the department, the United States Food and Drug Administration, or another governmental entity charged with the regulation of good manufacturing practices related to wholesale distribution of prescription drugs, within timeframes set forth by the department in departmental rules, which demonstrates substantial compliance with current good manufacturing practices applicable to wholesale distribution of prescription drugs. The department may recognize another state's inspection of a wholesale distributor

located in that state if such state's laws are deemed to be substantially equivalent to the law of this state by the department. The department may accept an inspection by a third-party accreditation or inspection service which meets the criteria set forth in department rule.

(o) ~~(n)~~ Any other relevant information that the department requires~~, including, but not limited to, any information related to whether the applicant satisfies the definition of a primary wholesale distributor or a secondary wholesale distributor~~.

(p) ~~(o)~~ Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(9)(a) Each person required by subsection (8) or subsection (15) to provide a personal information statement and fingerprints shall provide the following information to the department on forms prescribed by the department:

1. The person's places of residence for the past 7 years.

2. The person's date and place of birth.

3. The person's occupations, positions of employment, and offices held during the past 7 years.

4. The principal business and address of any business, corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on.

5. Whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding.

6. Whether, during the past 7 years, the person has been enjoined, temporarily or permanently, by a court of competent

jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning any such event.

7. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 4 ~~7~~ years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

8. A description of any felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony in this state must be reported. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

9. A photograph of the person taken in the previous 180 ~~30~~ days.

10. A set of fingerprints for the person on a form and under procedures specified by the department, together with payment of an amount equal to the costs incurred by the department for the criminal record check of the person.

11. The name, address, occupation, and date and place of birth for each member of the person's immediate family who is 18 years of age or older. As used in this subparagraph, the term "member of the person's immediate family" includes the person's

spouse, children, parents, siblings, the spouses of the person's children, and the spouses of the person's siblings.

12. Any other relevant information that the department requires.

(b) The information required pursuant to paragraph (a) shall be provided under oath.

(c) The department shall submit the fingerprints provided by a person for initial licensure to the Department of Law Enforcement for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person. The department shall submit the fingerprints provided by a person as a part of a renewal application to the Department of Law Enforcement for a statewide criminal record check, and for forwarding to the Federal Bureau of Investigation for a national criminal record check, for the initial renewal of a permit after January 1, 2004; for any subsequent renewal of a permit, the department shall submit the required information for a statewide and national criminal record check of the person. Any person who as a part of an initial permit application or initial permit renewal after January 1, 2004, submits to the department a set of fingerprints required for the criminal record check required in this paragraph are ~~shall~~ not ~~be~~ required to provide a subsequent set of fingerprints for a criminal record check to the department, if the person has undergone a criminal record check as a condition of the issuance of an initial permit or the initial renewal of a permit of an applicant after January 1, 2004. The department is authorized to contract with private vendors, or enter into interagency agreements, to collect electronic

fingerprints where fingerprints are required for registration, certification, or the licensure process or where criminal history record checks are required.

(d) For purposes of applying for renewal of a permit under subsection (8) or certification under subsection (16), a person may submit the following in lieu of satisfying the requirements of paragraphs (a), (b), and (c):

1. A photograph of the individual taken within 180 days; and

2. A copy of the personal information statement form most recently submitted to the department and a certification under oath, on a form specified by the department, that the individual has reviewed the previously submitted personal information statement form and that the information contained therein remains unchanged.

(10) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor if:

(a) The applicant has not met the requirements for the permit.

(b) The management, officers, or directors of the applicant or any affiliated party are found by the department to be incompetent or untrustworthy.

(c) The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health.

(d) The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of

successful operation of the wholesale distributor.

(e) The applicant is lacking in experience in the distribution of prescription drugs.

(f) The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g) The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

(h) The applicant, or any affiliated party, has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

(i) The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j) The applicant has furnished false or fraudulent information or material in any application made in this state or any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

(k) That a federal, state, or local government permit currently or previously held by the applicant, or any affiliated party, for the manufacture or distribution of any drugs, devices, or cosmetics has been disciplined, suspended, or revoked and has not been reinstated.

(l) The applicant does not possess the financial or

physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

(m) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

(n) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company or a mutual fund.

(o) The applicant for renewal of a permit under s. 499.01(2)(e) or (f) ~~499.01(2)(d) or (c)~~ has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p) Information obtained in response to s. 499.01(2)(e) or (f) ~~499.01(2)(d) or (c)~~ demonstrates it would not be in the best

interest of the public health, safety, and welfare to issue a permit.

(q) The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r) The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(11) Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor permit to the applicant.

~~(12) For a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:~~

~~(a) The department shall adopt rules for the annual renewal of permits. At least 90 days before the expiration of a permit, the department shall forward a permit renewal notification and renewal application to the prescription drug wholesale distributor or out-of-state prescription drug wholesale distributor at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely.~~

~~(b) A permit, unless sooner suspended or revoked,~~

~~automatically expires 1 year after the last day of the anniversary month in which the permit was originally issued. A permit may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees. If a renewal application and fee are submitted and postmarked after 45 days prior to the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee. A permittee that has submitted a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.~~

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

(12) ~~(13)~~ A person that engages in wholesale distribution of prescription drugs in this state must have a wholesale distributor's permit issued by the department, except as noted in this section. Each establishment must be separately permitted except as noted in this subsection.

(a) A separate establishment permit is not required when a permitted prescription drug wholesale distributor consigns a prescription drug to a pharmacy that is permitted under chapter 465 and located in this state, provided that:

1. The consignor wholesale distributor notifies the department in writing of the contract to consign prescription drugs to a pharmacy along with the identity and location of each consignee pharmacy;

2. The pharmacy maintains its permit under chapter 465;

3. The consignor wholesale distributor, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of s. ~~ss.~~ 499.0121 ~~and 499.01212~~ with respect to the consigned drugs and maintains records documenting the transfer of title or other completion of the wholesale distribution of the consigned prescription drugs;

4. The distribution of the prescription drug is otherwise lawful under this chapter and other applicable law;

5. Open packages containing prescription drugs within a pharmacy are the responsibility of the pharmacy, regardless of how the drugs are titled; and

6. The pharmacy dispenses the consigned prescription drug in accordance with the limitations of its permit under chapter 465 or returns the consigned prescription drug to the consignor wholesale distributor. In addition, a person who holds title to prescription drugs may transfer the drugs to a person permitted or licensed to handle the reverse distribution or destruction of drugs. Any other distribution by and means of the consigned prescription drug by any person, not limited to the consignor wholesale distributor or consignee pharmacy, to any other person is prohibited.

(b) A wholesale distributor's permit is not required for the one-time transfer of title of a pharmacy's lawfully acquired prescription drug inventory by a pharmacy with a valid permit

issued under chapter 465 to a consignor prescription drug wholesale distributor, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesale distributor if the permitted pharmacy and the permitted prescription drug wholesale distributor comply with all of the provisions of paragraph (a) and the prescription drugs continue to be within the permitted pharmacy's inventory for dispensing in accordance with the limitations of the pharmacy permit under chapter 465. A consignor drug wholesale distributor may not use the pharmacy as a wholesale distributor through which it distributes the prescription drugs to other pharmacies. Nothing in this section is intended to prevent a wholesale distributor from obtaining this inventory in the event of nonpayment by the pharmacy.

(c) A separate establishment permit is not required when a permitted prescription drug wholesale distributor operates temporary transit storage facilities for the sole purpose of storage, for up to 16 hours, of a delivery of prescription drugs when the wholesale distributor was temporarily unable to complete the delivery to the recipient.

(d) The department shall require information from each wholesale distributor as part of the permit and renewal of such permit, as required under this section.

(13)~~(14)~~ Personnel employed in wholesale distribution must have appropriate education and experience to enable them to perform their duties in compliance with state permitting requirements.

(14)~~(15)~~ The name of a permittee or establishment on a prescription drug wholesale distributor permit or an out-of-

state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any indicia that the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(15) ~~(16)~~ (a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

(b) To be certified as a designated representative, a natural person must:

1. Submit an application on a form furnished by the department and pay the appropriate fees.

2. Be at least 18 years of age.

3. Have at least 2 years of verifiable full-time:

a. Work experience in a pharmacy licensed in this state or another state, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs;

b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state; or

c. Managerial experience with the United States Armed Forces, where the person's responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or

other logistics services pertaining to prescription drugs.

4. Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year.

5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

(c) The department may deny an application for certification as a designated representative or may suspend or revoke a certification of a designated representative pursuant to s. 499.067.

(d) A designated representative:

1. Must be actively involved in and aware of the actual daily operation of the wholesale distributor.

2. Must be employed full time in a managerial position by the wholesale distributor.

3. Must be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence.

4. May serve as a designated representative for only one wholesale distributor at any one time.

(e) A wholesale distributor must notify the department when a designated representative leaves the employ of the wholesale

distributor. Such notice must be provided to the department within 10 business days after the last day of designated representative's employment with the wholesale distributor.

(f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

Section 7. Section 499.01201, Florida Statutes, is amended to read:

499.01201 Agency for Health Care Administration review and use of statute and rule violation or compliance data.—Notwithstanding any other provision ~~provisions~~ of law ~~to the contrary~~, the Agency for Health Care Administration may not:

(1) Review or use any violation or alleged violation of s. 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that section ~~those sections~~, as a ground for denying or withholding any payment of a Medicaid reimbursement to a pharmacy licensed under chapter 465; or

(2) Review or use compliance with s. 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that section ~~those sections~~, as the subject of any audit of Medicaid-related records held by a pharmacy licensed under chapter 465.

Section 8. Paragraph (d) of subsection (4) and subsection (6) of section 499.0121, Florida Statutes, are amended to read:

499.0121 Storage and handling of prescription drugs;

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

(4) EXAMINATION OF MATERIALS AND RECORDS.—

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. ~~This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37).~~

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs, including active pharmaceutical ingredients, as are necessary for the protection of the public health.

(a) ~~Wholesale~~ Distributors of prescription drugs and active pharmaceutical ingredients must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and active pharmaceutical ingredients. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

1. The source of the prescription drugs or active pharmaceutical ingredients, including the name and principal address of the seller or transferor, and the address of the

location from which the prescription drugs were shipped;

2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs or active pharmaceutical ingredients;

3. The name, strength, dosage form, and quantity of the prescription drugs received and distributed or disposed of;

4. The dates of receipt and distribution or other disposition of the prescription drugs or active pharmaceutical ingredients; and

5. Any financial documentation supporting the transaction.

(b) Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records, whichever period is longer.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.

(d) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain records that

include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.

~~(c) When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.~~

Section 9. Subsections (1), (3), (4), and (6) of section 499.015, Florida Statutes, are amended to read:

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

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

(b) Any person who manufactures, packages, repackages, labels, or relabels a cosmetic in this state may voluntarily register such cosmetic biennially with the department. A person registering a cosmetic must submit a completed application to register the cosmetic, pay a fee in accordance with the fee schedule provided by s. 499.041, comply with the provisions of this section, and must list each separate and distinct cosmetic at the time of registration.

(c) ~~(b)~~ The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(d) A person may not register a product with the department if that person is not legally authorized to manufacture, package, repackage, label, or relabel the product in this state.

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

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this

section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs, devices, or cosmetics covered by this part until he or she complies with the requirements of this section.

(6) The department may only issue a certificate of free sale for any product that is ~~required to be~~ registered under this part.

Section 10. Subsection (1) of section 499.03, Florida Statutes, is amended to read:

499.03 Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—

(1) A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to s. 499.003(32) ~~499.003(33)~~, or prescription drug as defined in s. 499.003(40) ~~499.003(43)~~, unless the possession of the drug has been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

(a) A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice;

(b) A licensed practitioner authorized by law to prescribe

prescription drugs or any person under the licensed practitioner's supervision while acting within the scope of the licensed practitioner's practice;

(c) A qualified person who uses prescription drugs for lawful research, teaching, or testing, and not for resale;

(d) A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;

(e) An officer or employee of a federal, state, or local government; or

(f) A person that holds a valid permit issued by the department pursuant to this part which authorizes that person to possess prescription drugs.

Section 11. Paragraphs (i) through (p) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

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

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s. 499.82.

~~(j) Procedures and forms relating to the pedigree paper requirement of s. 499.01212.~~

(j)~~(k)~~ The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.

(k)~~(l)~~ Information required from each retail establishment pursuant to s. 499.012(3) or s. 499.83(2)(c), including

requirements for prescriptions or orders.

(l)~~(m)~~ The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s. 499.82(14).

~~(n) Alternatives to compliance with s. 499.01212 for a prescription drug in the inventory of a permitted prescription drug wholesale distributor as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.~~

(m)~~(o)~~ Wholesale distributor reporting requirements of s. 499.0121(14).

(n)~~(p)~~ Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).

Section 12. Subsection (7) of section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.—

(7) The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed. However, trade secret information contained therein as defined by s. 812.081(1)(c) shall remain confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution, as long as the information is retained by the department. This subsection does not prohibit the department from using such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other

regulatory agency. However, the receiving agency shall keep such records confidential and exempt as provided in this subsection. ~~In addition, this subsection is not intended to prevent compliance with the provisions of s. 499.01212, and the pedigree papers required in that section shall not be deemed a trade secret.~~

Section 13. Subsection (8) is added to section 499.066, Florida Statutes, to read:

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

(8)(a) The department shall adopt rules to permit the issuance of remedial, nondisciplinary citations. A citation shall be issued to the person alleged to have committed a violation and contain the person's name, address, and license number, if applicable, a brief factual statement, the sections of the law allegedly violated, and the monetary assessment and or other remedial measures imposed. The citation must clearly state that the person may choose, in lieu of accepting the citation, to have the department rescind the citation and conduct an investigation pursuant to s. 499.051. If the person does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation becomes a final order and does not constitute discipline.

(b) The department shall adopt rules designating violations for which a citation may be issued. The rules shall designate as citable those violations for which there is no substantial threat to the public health, safety, or welfare.

(c) The department is entitled to recover the costs of investigation, in addition to any penalty provided according to

department rule, as part of the penalty levied pursuant to the citation.

(d) A citation must be issued within 12 months after the filing of the complaint that is the basis for the citation.

(e) Service of a citation may be made by personal service or certified mail, restricted delivery, to the person at the person's last known address of record with the department or to the person's Florida registered agent.

(f) The department has authority to, and shall adopt rules to, designate those violations for which a person is subject to the issuance of a citation and designate the monetary assessments and or other remedial measures that must be taken for those violations. The department has continuous authority to amend its rules adopted pursuant to this section.

Section 14. Subsection (14) of section 499.82, Florida Statutes, is amended to read:

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

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

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

(b) Activities exempt from the definition of wholesale distribution in s. 499.003; or

(c) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade a medical gas for emergency medical reasons~~; or~~

~~(d) Other transactions excluded from the definition of~~

~~wholesale distribution under the federal act or regulations implemented under the federal act related to medical gas~~.

Section 15. Subsection (4) of section 499.89, Florida Statutes, is amended to read:

499.89 Recordkeeping.—

~~(4) A pedigree paper is not required for distributing or dispensing medical gas.~~

Section 16. Section 499.01212, Florida Statutes, is repealed.

Section 17. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

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

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined in, or described in s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47) ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

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

Section 18. Paragraph (b) of subsection (1) of section 499.067, Florida Statutes, is amended to read:

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

(1)

(b) The department may deny an application for a permit or certification, or suspend or revoke a permit or certification, if the department finds that:

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

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

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

4. The applicant, permittee, or person certified under s. 499.012(15) ~~s. 499.012(16)~~ demonstrates any of the conditions enumerated in s. 499.012.

5. The applicant, permittee, or person certified under s. 499.012(15) ~~s. 499.012(16)~~ has committed any violation of this chapter.

Section 19. Subsection (1) of section 794.075, Florida Statutes, is amended to read:

794.075 Sexual predators; erectile dysfunction drugs.—

(1) A person may not possess a prescription drug, as defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of treating erectile dysfunction if the person is designated as a sexual predator under s. 775.21.

Section 20. Paragraphs (d), (f), (i), and (j) of subsection (3) of section 921.0022, Florida Statutes, are amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(d) LEVEL 4

Florida Statute	Felony Degree	Description
316.1935(3)(a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
499.0051(1)	3rd	Failure to maintain or deliver transaction history, transaction information, or transaction statements ~~pedigree papers~~.
~~499.0051(2)~~	~~3rd~~	~~Failure to authenticate pedigree papers.~~
499.0051(5) ~~499.0051(6)~~	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
517.07(1)	3rd	Failure to register securities.
517.12(1)	3rd	Failure of dealer, associated person, or issuer of securities to register.
784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, etc.
784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
784.075	3rd	Battery on detention or commitment facility staff.
784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
784.081(3)	3rd	Battery on specified official or employee.
784.082(3)	3rd	Battery by detained person on visitor or other detainee.
784.083(3)	3rd	Battery on code inspector.
784.085	3rd	Battery of child by throwing, tossing, projecting, or

		expelling certain fluids or materials.
787.03(1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
787.04(2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
787.04(3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
787.07	3rd	Human smuggling.
790.115(1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
790.115(2)(b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
790.115(2)(c)	3rd	Possessing firearm on school

		property.
800.04(7)(c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
810.02(4)(a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
810.02(4)(b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
810.06	3rd	Burglary; possession of tools.
810.08(2)(c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
812.014(2)(c)3.	3rd	Grand theft, 3rd degree $10,000 or more but less than $20,000.
812.014 (2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
812.0195(2)	3rd	Dealing in stolen property by

		use of the Internet; property stolen $300 or more.
817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
817.568(2)(a)	3rd	Fraudulent use of personal identification information.
817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
837.02(1)	3rd	Perjury in official proceedings.
837.021(1)	3rd	Make contradictory statements in official proceedings.
838.022	3rd	Official misconduct.
839.13(2)(a)	3rd	Falsifying records of an individual in the care and

		custody of a state agency.
839.13(2)(c)	3rd	Falsifying records of the Department of Children and Families.
843.021	3rd	Possession of a concealed handcuff key by a person in custody.
843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.
893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d),

		(2)(a), (2)(b), or (2)(c)4. drugs).
914.14(2)	3rd	Witnesses accepting bribes.
914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
918.12	3rd	Tampering with jurors.
934.215	3rd	Use of two-way communications device to facilitate commission of a crime.

(f) LEVEL 6

Florida Statute	Felony Degree	Description
316.027(2)(b)	2nd	Leaving the scene of a crash involving serious bodily injury.
316.193(2)(b)	3rd	Felony DUI, 4th or subsequent

		conviction.
400.9935(4)(c)	2nd	Operating a clinic, or offering services requiring licensure, without a license.
499.0051(2) ~~499.0051(3)~~	2nd	Knowing forgery of transaction history, transaction information, or transaction statement ~~pedigree papers~~.
499.0051(3) ~~499.0051(4)~~	2nd	Knowing purchase or receipt of prescription drug from unauthorized person.
499.0051(4) ~~499.0051(5)~~	2nd	Knowing sale or transfer of prescription drug to unauthorized person.
775.0875(1)	3rd	Taking firearm from law enforcement officer.
784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
784.041	3rd	Felony battery; domestic

		battery by strangulation.
784.048(3)	3rd	Aggravated stalking; credible threat.
784.048(5)	3rd	Aggravated stalking of person under 16.
784.07(2)(c)	2nd	Aggravated assault on law enforcement officer.
784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
784.081(2)	2nd	Aggravated assault on specified official or employee.
784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
784.083(2)	2nd	Aggravated assault on code inspector.
787.02(2)	3rd	False imprisonment; restraining

		with purpose other than those in s. 787.01.
790.115(2)(d)	2nd	Discharging firearm or weapon on school property.
790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
794.05(1)	2nd	Unlawful sexual activity with specified minor.
800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older

		but less than 16 years of age; offender less than 18 years.
800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
810.145(8)(b)	2nd	Video voyeurism; certain minor victims; 2nd or subsequent offense.
812.014(2)(b)1.	2nd	Property stolen $20,000 or more, but less than $100,000, grand theft in 2nd degree.
812.014(6)	2nd	Theft; property stolen $3,000 or more; coordination of others.
812.015(9)(a)	2nd	Retail theft; property stolen $300 or more; second or subsequent conviction.

812.015(9)(b)	2nd	Retail theft; property stolen $3,000 or more; coordination of others.
812.13(2)(c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
817.4821(5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
825.102(1)	3rd	Abuse of an elderly person or disabled adult.
825.102(3)(c)	3rd	Neglect of an elderly person or disabled adult.
825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
825.103(3)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than $10,000.
827.03(2)(c)	3rd	Abuse of a child.
827.03(2)(d)	3rd	Neglect of a child.

827.071(2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
836.05	2nd	Threats; extortion.
836.10	2nd	Written threats to kill or do bodily injury.
843.12	3rd	Aids or assists person to escape.
847.011	3rd	Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.
847.012	3rd	Knowingly using a minor in the production of materials harmful to minors.
847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.

944.35(3)(a)2.	3rd	Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community supervision, resulting in great bodily harm.
944.40	2nd	Escapes.
944.46	3rd	Harboring, concealing, aiding escaped prisoners.
944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.

(i) LEVEL 9

Florida Statute	Felony Degree	Description
316.193 (3)(c)3.b.	1st	DUI manslaughter; failing to render aid or give information.

327.35 (3)(c)3.b.	1st	BUI manslaughter; failing to render aid or give information.
409.920 (2)(b)1.c.	1st	Medicaid provider fraud; $50,000 or more.
499.0051(8) ~~499.0051(9)~~	1st	Knowing sale or purchase of contraband prescription drugs resulting in great bodily harm.
560.123(8)(b)3.	1st	Failure to report currency or payment instruments totaling or exceeding $100,000 by money transmitter.
560.125(5)(c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding $100,000.
655.50(10)(b)3.	1st	Failure to report financial transactions

		totaling or exceeding $100,000 by financial institution.
775.0844	1st	Aggravated white collar crime.
782.04(1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
782.04(3)	1st,PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, aggravated fleeing or eluding with serious bodily injury or death, and other specified felonies.
782.051(1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).
782.07(2)	1st	Aggravated manslaughter of an elderly person or disabled adult.

787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
787.02(3)(a)	1st,PBL	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
787.06(3)(c)1.	1st	Human trafficking for labor and services of an unauthorized alien child.
787.06(3)(d)	1st	Human trafficking using

		coercion for commercial sexual activity of an unauthorized adult alien.
787.06(3)(f)1.	1st,PBL	Human trafficking for commercial sexual activity by the transfer or transport of any child from outside Florida to within the state.
790.161	1st	Attempted capital destructive device offense.
790.166(2)	1st,PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
794.011(2)	1st	Attempted sexual battery; victim less than 12 years of age.
794.011(2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.

794.011(4)(a)	1st,PBL	Sexual battery, certain circumstances; victim 12 years of age or older but younger than 18 years; offender 18 years or older.
794.011(4)(b)	1st	Sexual battery, certain circumstances; victim and offender 18 years of age or older.
794.011(4)(c)	1st	Sexual battery, certain circumstances; victim 12 years of age or older; offender younger than 18 years.
794.011(4)(d)	1st,PBL	Sexual battery, certain circumstances; victim 12 years of age or older; prior conviction for specified sex offenses.
794.011(8)(b)	1st,PBL	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
794.08(2)	1st	Female genital mutilation; victim younger than 18 years of age.
800.04(5)(b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
812.13(2)(a)	1st,PBL	Robbery with firearm or other deadly weapon.
812.133(2)(a)	1st,PBL	Carjacking; firearm or other deadly weapon.
812.135(2)(b)	1st	Home-invasion robbery with weapon.
817.535(3)(b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; property owner is a public officer or employee.

817.535(4)(a)2.	1st	Filing false claim or other unauthorized document; defendant is incarcerated or under supervision.
817.535(5)(b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; owner of the property incurs financial loss as a result of the false instrument.
817.568(7)	2nd, PBL	Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.
827.03(2)(a)	1st	Aggravated child abuse.
847.0145(1)	1st	Selling, or otherwise transferring custody or control, of a minor.

847.0145(2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
859.01	1st	Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.
893.135	1st	Attempted capital trafficking offense.
893.135(1)(a)3.	1st	Trafficking in cannabis, more than 10,000 lbs.
893.135 (1)(b)1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
893.135 (1)(c)1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
893.135	1st	Trafficking in

(1)(c)2.d.		hydrocodone, 200 grams or more, less than 30 kilograms.
893.135 (1)(c)3.d.	1st	Trafficking in oxycodone, 100 grams or more, less than 30 kilograms.
893.135 (1)(d)1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
893.135 (1)(e)1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
893.135 (1)(f)1.c.	1st	Trafficking in amphetamine, more than 200 grams.
893.135 (1)(h)1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
893.135 (1)(j)1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.

893.135 (1)(k)2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
896.101(5)(c)	1st	Money laundering, financial instruments totaling or exceeding $100,000.
896.104(4)(a)3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding $100,000.

(j) LEVEL 10

Florida Statute	Felony Degree	Description
499.0051(9) ~~499.0051(10)~~	1st	Knowing sale or purchase of contraband prescription drugs resulting in death.
782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.

782.07(3)	1st	Aggravated manslaughter of a child.
787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
787.01(3)(a)	Life	Kidnapping; child under age 13, perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
787.06(3)(g)	Life	Human trafficking for commercial sexual activity of a child under the age of 18 or mentally defective or incapacitated person.
787.06(4)(a)	Life	Selling or buying of minors into human trafficking.
794.011(3)	Life	Sexual battery; victim 12 years or older,

		offender uses or threatens to use deadly weapon or physical force to cause serious injury.
812.135(2)(a)	1st,PBL	Home-invasion robbery with firearm or other deadly weapon.
876.32	1st	Treason against the state.

Section 21. This act shall take effect July 1, 2016.

The Florida Senate

Committee Agenda Request

To: Senator Aaron Bean, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 14, 2016

I respectfully request that **Senate Bill #1518**, relating to Adult Cardiovascular Services and **Senate Bill #1604** relating to Drugs, Devices, and Cosmetics be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Denise Grimsley

Senator Denise Grimsley
Florida Senate, District 21

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/2016
Meeting Date

1604
Bill Number (if applicable)

Topic SB 1604 - Bill as amended

Amendment Barcode (if applicable)

Name Matilde Miller Matilda Miller

Job Title Chief of Staff

Address 1921 N. Monroe St.
Street

Phone (850) 487-4827

Tallahassee FL 32399
City *State* *Zip*

Email matilde.miller@myfloridalicense.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing DBPR

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

SB 1604
Bill Number (if applicable)

Topic Drugs, Devices & Cosmetics

Amendment Barcode (if applicable)

Name Larry Gonzalez

Job Title General Counsel

Address 223 S. Gadsden St
Street

Tallahassee, FL 32301
City *State* *Zip*

Phone 850-570-6307

Email lawgon2@earthlink.net

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

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 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SPB 7056
INTRODUCER:	Health Policy Committee
SUBJECT:	Long-term Care Managed Care Prioritization
DATE:	January 26, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall		**HP Submitted as Committee Bill**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

SPB 7056 addresses the long-term care Medicaid managed care program and revises ss. 409.962 and 409.949, F.S., relating to eligibility, enrollment and prioritization for the program.

SPB 7056 requires the Department of Elderly Affairs (DOEA) to maintain a statewide wait list for enrollment for the community-based services portion of the long-term care managed care program and to prioritize individuals for potential enrollment using a frailty-based screening tool that generates a priority score. The DOEA must develop the screening tool by rule. The DOEA is also required to make publicly available on its website the specific methodology used to calculate an individual's priority score. The bill requires individuals to be rescreened at least annually or upon notification of a significant change in the individual's circumstances.

When the DOEA Comprehensive Assessment and Review for Long-Term Care Services program (CARES) is notified of available enrollment capacity by the Agency for Health Care Administration (AHCA), a pre-release assessment is conducted of individuals based on the priority scoring process. If capacity is limited for individuals with identical priority scores, the individual with the oldest date of placement on the wait list will receive priority for pre-release assessment.

If found financially and clinically eligible, the individual may be enrolled in the long-term care managed care program.

An individual may also be terminated from the long-term care managed care program wait list. Once terminated, an individual would be required to initiate a new request for placement on the wait list and any previous priority consideration is disregarded.

SPB 7056 identifies certain populations that are provided priority enrollment for home and community based services through the long-term care managed care program, and that do not have to complete the screening or wait-list process as long as all other program eligibility requirements are met. These individuals are:

- Individuals who are 18, 19, and 20 years of age who have chronic, debilitating diseases or conditions of one or more physiological or organ systems which generally make the individual dependent upon 24-hour-per-day medical, nursing, or health supervision or intervention; and
- Nursing facility residents requesting to transition into the community who have resided in Florida-licensed skilled nursing facility for at least 60 consecutive days.

The bill authorizes the DOEA and the AHCA to adopt rules to implement the bill.

Both the DOEA and the AHCA estimate no fiscal impact. The effective date of the bill July 1, 2016.

II. Present Situation:

Florida Medicaid

The Medicaid program is a partnership between the federal and state governments to provide medical care to low income children and disabled persons. Each state operates its own Medicaid program under a state plan that must be approved by the federal Centers for Medicare and Medicaid Services (CMS). The state plan outlines Medicaid eligibility standards, policies, and reimbursement methodologies.

Florida Medicaid is administered by the AHCA and is financed with federal and state funds. The Department of Children and Families (DCF) determines eligibility for the Medicaid program and transmits that information to the AHCA. The AHCA is designated as the single state Medicaid agency and has the lead responsibility for the overall program.[1]

Over 3.9 million Floridians are currently enrolled in Medicaid[2] with a projected caseload of 4.2 million for 2016-2017.[3] The Medicaid program's estimated expenditures for the 2015-2016

[1] *See* s. 409.963, F.S.
[2] Agency for Health Care Administration, *Report of Medicaid Eligibles* (November 30, 2015) *available at* http://ahca.myflorida.com/medicaid/Finance/data_analytics/eligibles_report/docs/age_assistance_category_2015-11-30.pdf (last visited Jan. 21, 2016).
[3] Agency for Health Care Administration, Senate Health and Human Services Appropriations Subcommittee Presentation, *Florida Medicaid* (October 20, 2015), slide 6, http://ahca.myflorida.com/medicaid/recent_presentations/Florida_Medicaid_to_Senate_HHS_Appropriations_2015-10-20.pdf (last visited Jan. 21, 2016).

fiscal year are $25.7 billion.[4] The current traditional federal share is 60.51 percent with the state paying 39.49 percent for Medicaid enrollees.[5] Florida has the fourth largest Medicaid population in the country.[6]

Medicaid currently covers:

- 20 percent of Florida's population;
- 27 percent of Florida's children;
- 62.2 percent of Florida's births; and
- 69 percent of Florida's nursing homes days.[7]

The structure for each state's Medicaid program is different and each state's share of expenditures is largely determined by the federal government. Federal law and regulations set the minimum amount, scope, and duration of services offered in the program, among other requirements. Eligibility for Medicaid is based on a number of factors, including age, household or individual income, and assets. State Medicaid benefits are provided in statute under s. 409.903, F.S. (Mandatory Payments for Eligible Persons) and s. 409.904, F.S. (Optional Payments for Eligible Persons).

Applicants for Medicaid must be United States citizens or qualified noncitizens, must be Florida residents, and must provide social security numbers for data matching. While self-attestation is permitted for a number of data elements on the application, most components are matched through the Federal Data Services Hub.[8] Applicants must also agree to cooperate with Child Support Enforcement during the application process.[9]

Federal Poverty Guidelines for 2015[10] Annual Income (rounded)				
Family Size	**100%**	**133%**	**150%**	**200%**
1	$11,770	$15,654	$17,655	$23,540
2	$15,930	$21,187	$23,895	$31,860
3	$20,090	$26,720	$30,135	$40,180
4	$24,250	$32,252	$36,375	$48,500

[4] Office of Economic and Demographic Research, *Fiscal Analysis in Brief - 2015 Legislative Sessions, Including Special Session A* (August 2015), chart 3, p. 3 *available at* http://edr.state.fl.us/Content/revenues/reports/fiscal-analysis-in-brief/FiscalAnalysisinBrief2015.pdf (last visited Jan. 21, 2015).
[5] Office of Economic and Demographic Research, *Social Services Estimating Conference - Official FMAP Estimate* (February 2015), http://edr.state.fl.us/Content/conferences/medicaid/fmap.pdf (last viewed Jan. 21, 2016). The SSEC has also created a "real time" FMAP blend" for the Statewide Medicaid Managed Care Program which is 60.43% for SFY 2015-16.
[6] Agency for Health Care Administration, Health and Human Services Appropriations Committee Presentation, *Agency for Health Care Administration - An Overview* (January 22, 2015), slide 9, http://www.flsenate.gov/PublishedContent/Committees/2014-2016/AHS/MeetingRecords/MeetingPacket_2759.pdf (last visited Jan. 21, 2016).
[7] Id at 10.
[8] Florida Dep't of Children and Families, *Family-Related Medicaid Programs Fact Sheet*, p. 3 (January 2015), http://www.dcf.state.fl.us/programs/access/docs/Family-RelatedMedicaidFactSheet.pdf (last visited Jan. 21, 2016).
[9] Id.
[10] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Medicaid and CHIP Program Information - 2015 Federal Poverty Level Charts* http://www.medicaid.gov/medicaid-chip-program-information/by-topics/eligibility/downloads/2015-federal-poverty-level-charts.pdf (last visited Jan. 21, 2016).

Minimum eligibility coverage thresholds are established in federal law for certain population groups, such as children, as well as minimum benefits and maximum cost sharing. The minimum benefits include items such as physician services, hospital services, home health services, and family planning.[11] States can add benefits, pending federal approval. Florida has added benefits, including prescription drugs, adult dental services, and dialysis.[12] For children under age 21, the benefits must include the Early and Periodic Screening, Diagnostic and Treatment services, which are those health care and diagnostic services and treatment and measures that may be needed to correct or ameliorate defects or physical and mental illnesses and conditions discovered by screening services, consistent with federal law.[13]

Statewide Medicaid Managed Care

In 2011, the Legislature established the Statewide Medicaid Managed Care (SMMC) Program as part IV of ch. 409, F.S.[14] The SMMC has two components: the Long Term Care Managed Care (LTC) program and the Managed Medical Assistance (MMA) program. The SMMC is an integrated, comprehensive, managed care program for Medicaid enrollees that manages the delivery of primary and acute care in 11 regions.

To implement the two components and receive federal Medicaid funding, the AHCA received federal authorization through two different Medicaid waivers from the CMS. The first component authorized was the LTC's 1915(b) and (c) waivers on February 1, 2013. The waivers for the LTC program are effective July 1, 2013, through June 30, 2016, and operate concurrently.[15]

Initial enrollment into the LTC began August 1, 2013, and finished March 1, 2014. As of January 1, 2016, 90,841 individuals were enrolled in both the nursing home portion and the non-entitlement, home and community based services component of the LTC program.[16]

Long Term Care Managed Care Program (LTC)

The LTC provides services in two settings: the nursing facility and a community setting such as a recipient's home, an assisted living facility, or an adult family care home. Nursing facility services are an entitlement program for eligible enrollees; however, home and community based services are delivered through waivers and are dependent on the availability of annual funding.

[11] Section 409.905, F.S.
[12] Section 409.906, F.S.
[13] *See* Section 1905 9(r) of the Social Security Act.
[14] *See* Chapter Laws, 2011-134 and 2011-135.
[15] Letter from U.S. Department of Health and Human Services, Disabled and Elderly Health Programs Group to Justin Senior, Deputy Secretary for Medicaid, Agency for Health Care Administration (February 1, 2013) *available at* http://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/mma/Signed_approval_FL0962_new_1915c_02-01-2013.pdf (last visited Jan. 21, 2016).
[16] Agency for Health Care Administration, *SMMC LTC Enrollment by County By Plan Report* (as of January 1, 2016) *available at* http://ahca.myflorida.com/Medicaid/Finance/data_analytics/enrollment_report/index.shtml (last visited Jan. 21, 2016).

Enrollment in the home and community based services portion of the long term care managed care program is managed based on a priority system and wait list. For the 2015-2016 state fiscal year, the state is approved for 50,390 unduplicated recipients in the home and community based services portion of the program.[17]

Eligibility and Enrollment

The AHCA is the single state agency for Medicaid; however through an interagency agreement with the DOEA, the DOEA is responsible for the care evaluations for all Medicaid nursing home admissions and is Florida's federally mandated pre-admission screening program for nursing home applicants, including for the LTC.[18] The CARES program has 18 field offices across the state which are staffed with physicians, nurses, and other healthcare professionals who evaluate the level of care an individual may or may not need for waiver services. The frailty based assessment results in a priority score for the individual and individuals are then placed on the wait list based on their priority score.

To receive nursing facility care, an individual must also be determined to meet the requirements of s. 409.985(3). This subsection requires:

> The CARES program shall determine if an individual requires nursing facility care and, if the individual requires such care, assign the individual to a level of care as described in s. 409.983(4). When determining the need for nursing facility care, consideration shall be given to the nature of the services prescribed and which level of nursing or other health care personnel meets the qualifications necessary to provide such services and the availability to and access by the individual of community or alternative resources. For the purposes of the long-term care managed care program, the term "nursing facility care" means the individual:
>
> (a) Requires nursing home placement as evidenced by the need for medical observation throughout a 24-hour period and care required to be performed on a daily basis by, or under the direct supervision of, a registered nurse or other health care professional and requires services that are sufficiently medically complex to require supervision, assessment, planning, or intervention by a registered nurse because of a mental or physical incapacitation by the individual;
>
> (b) Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and care and the constant availability of medical and nursing treatment and requires services on a daily or intermittent basis that are to be performed

[17] Letter from U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services to Justin Senior, Deputy Secretary for Medicaid, Agency for Health Care Administration (June 11, 2015), *available at* http://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/LTC_Waiver_Amend_Approval_Letter_2015-03-17.pdf (last visited Jan. 21, 2016).

[18] Florida Dep't of Elderly Affairs, *Comprehensive Assessment and Review for Long-Term Care Services (CARES)*, http://elderaffairs.state.fl.us/doea/cares.php (last visited Jan. 21, 2016).

> under the supervision of licensed nursing or other health professionals because the individual is incapacitated mentally or physically; or
>
> (c) Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and care and the constant availability of medical and nursing treatment and requires limited services that are to be performed under the supervision of licensed nursing or other health professionals because the individual is mildly incapacitated mentally or physically.

Individuals are released from the wait list periodically based on the availability of funding and their priority score. Before being released; however, individuals must also meet the following eligibility requirements or participate in one of the following waivers, as applicable, to enroll in the program:

- Age 65 years or older and need nursing facility level of care;
- Age 18 years of age or older and are eligible for Medicaid by reason of a disability and need nursing facility level of care;
- Aged and Disabled Adult (A/DA) waiver;
- Consumer Directed Care Plus for individuals in the A/DA waiver;
- Assisted Living waiver;
- Nursing Home Diversion waiver;
- Frail Elder Option; or
- Channeling Services waiver.[19]

Individuals who are enrolled in the following programs may enroll in the LTC, but are not required to:

- Developmental Disabilities waiver program;
- Traumatic Brain and Spinal Injury waiver;
- Project AIDS Care waiver;
- Adult Cystic Fibrosis waiver;
- Program of All-Inclusive Care for the Elderly (PACE);
- Familial Dysautonomia waiver; or
- Model waiver.[20]

Individuals, both those who are enrolled in the LTC and those on the wait list, must be re-screened, on at least an annual basis or whenever there is a significant change in circumstances, such as change in caregivers or medical condition.[21]

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[19] Agency for Health Care Administration, *A Snapshot of the Florida Medicaid Long-term Care Program*, http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/LTC/SMMC_LTC_Snapshot.pdf (last visited Jan. 21, 2016).
[20] Id.
[21] Application for §1915(c) Home and Community-Based Services Waiver (Effective July 1, 2013), pp. 45-46, http://www.fdhc.state.fl.us/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/mma/LTC_1915c_Application.pdf (last visited Jan. 22, 2016).

Aging Resource Centers

The Aging Resource Centers (ARCs) provide information to elders and adults who request long-term care services and make referrals to lead agencies for vulnerable adults in need of other services. Under contract with the Department of Elderly Affairs, the ARCs coordinate all initial screenings to determine prioritization for long-term care services, provide choice counseling for nursing facility placements, assist with informal resolution of member grievances with Medicaid long-term managed care plans, and provide enrollment and coverage information to Medicaid managed long-term care enrollees.

The ARCs are also responsible for services funded through these programs:
- Community care for the elderly;
- Home care for the elderly;
- Contracted services;
- Alzheimer's disease initiative; and
- Older American's Act.[22]

The ARCs serve as a "one-stop" shop for all elder services as elders can receive a single financial determination for all services, including Medicaid, food stamps, and Supplemental Security Income. [23] Minimum standards of operation and responsibilities for the ARCs are provided in s. 430.2053, F.S., and in administrative rules under Chapter 58B-1, F.A.C.

Delivery System and Benefits

The AHCA conducted a competitive procurement to select providers in each of the 11 regions. Contracts were awarded to health maintenance organizations and provider service networks. Six non-specialty plans are currently contracted, including one provider service network that is available in all 11 regions and one health maintenance organization that is in 10 regions.[24] Recipients receive choice counseling services to assist them in selecting the plan that will best meet their needs.

Each plan under the LTC is required to provide a minimum level of services. These services include:
- Adult companion care;
- Adult day health care;
- Assisted living;
- Assistive care services;
- Attendant care;
- Behavioral management;
- Care coordination and case management;
- Caregiver training;
- Home accessibility training;
- Home-delivered meals;
- Homemaker;

[22] *See* s. 430.2053(9), F.S.
[23] *See* s. 430.2053(9), F.S.
[24] *Supra* note 20.

- Hospice;
- Intermittent and skilled nursing;
- Medical equipment and supplies;
- Medication administration;
- Medicaid management;
- Nursing facility;
- Nutritional assessment/risk reduction;
- Personal care;
- Personal emergency response system;
- Respite care;
- Therapies; and
- Non-emergency transportation.[25]

A LTC managed care plan may elect to offer expanded benefits to its enrollees. Some of the approved expanded benefits for the LTC include:

- Cellular phone service;
- Dental services;
- Emergency financial assistance;
- Hearing evaluation;
- Mobile personal emergency response system;
- Non-medical transportation;
- Over-the-counter medication and supplies;
- Support to transition out of a nursing facility;
- Vision services; and
- Wellness grocery discount.[26]

The LTC managed care plan enrollees who are not eligible for Medicare receive their medical services through an MMA plan. Some of the same plans participate in both programs and in the same regions, and a recipient may choose the same plan, but is not required to do so.

III. Effect of Proposed Changes:

Section 1 adds four definitions to s. 409.963, F.S., relating to the long-term care managed care program (LTC):

- "Authorized representative" means an individual who has the legal authority to make decisions on behalf of a Medicaid recipient or potential Medicaid recipient in matters related to the managed care plan or the screening or eligibility process;
- "Rescreening" means the use of a screening tool to conduct annual screenings or screenings due to a significant change which determine an individual's placement and continuation on the wait list;

[25] *See* s. 409.98, F.S.

[26] Agency for Health Care Administration, MMA - Model Contract - Attachment I - Scope of Services (Effective date 11/1/15) p. 5, http://ahca.myflorida.com/medicaid/statewide_mc/pdf/Contracts/2015-11-01/Attachment_I-Scope_of_Services_2015-11-01.pdf (last visited Jan. 21, 2016).

- "Screening" means the use of an information collection tool to determine a priority score for placement on the wait list;
- "Significant change" means change in an individual's health status after an accident or illness; an actual or anticipated change in the individual's living situation; a change in the caregiver relationship; loss of or damage to the individual's home, or deterioration of his or her home environment; or loss of the individual's spouse or caregiver.

Section 2 amends s. 409.979, F.S., to clarify the existing eligibility process for the home and community based services through the LTC. The bill establishes that Medicaid recipients must meet prerequisite criteria for eligibility and be determined eligible by the CARES preadmission screening program at the DOEA to require nursing facility care as defined in s. 409.985(3), F.S.

The bill clarifies that offers for enrollment in the LTC will be made subject to the availability of funds and based on wait-list prioritization. Before making any enrollment offers, the AHCA and the DOEA are required to determine that sufficient funds are available to support such enrollment.

The DOEA is directed to maintain a statewide wait list for enrollment into the program for home and community based services through the LTC. Individuals will be prioritized for enrollment through a frailty-based screening tool that results in a priority score. The priority score is used to determine the release order for individuals from the wait list for potential enrollment. If capacity is limited for individuals with the same priority score, the individual with the oldest date of placement on the wait list receives priority for release.

Aging Resource Center personnel certified by the DOEA shall perform the screening or rescreening for those requesting enrollment in the home and community-based services through the LTC.

To be placed on the wait list, an individual requesting the long-term care services or the individual's authorized representative must participate in an initial screening or rescreening. A rescreening of the individual must occur annually or upon notification of a significant change in an individual's circumstances.

The DOEA must adopt the screening tool that generates the priority score by rule and make publicly available on its website the specific methodology used to calculate an individual's priority score. When an individual's screening has been completed, the DOEA must inform the individual or the individual's representative that the individual has been placed on the wait list.

If the DOEA is unable to contact the individual or the individual's representative to schedule an initial screening or rescreening, a letter must be sent to the last documented address to advise the individual to contact the DOEA within the next 30 calendar days to schedule a screening or rescreening. Failure to conduct a screening or rescreening will result in the individual's termination from the screening process and the wait list.

The bill requires the CARES program to conduct a pre-release assessment of individuals after notification by the AHCA of available capacity in the long-term care managed care program. The DOEA shall release individuals from the wait list based on the priority score process and the

prerelease assessment. An individual must be both financially and clinically eligible to enroll in the LTC.

The bill directs the DOEA to terminate an individual on the wait list if the individual:

- Does not have a current priority score due to the individual's action or inaction;
- Requests to be removed from the wait list;
- Does not keep an appointment to complete the rescreening without scheduling another appointment;
- Receives an offer to begin the eligibility determination process for the long-term managed care program; or
- Begins receiving services through the long-term care managed care program.

If an individual is removed from the wait list for one of these reasons above, and subsequently requests to be placed on the wait list, the individual is required to initiate a new request for placement on the wait list and any previous placement is disregarded.

The bill provides for priority enrollment for home and community based services through the LTC for certain individuals. These individuals are not required to complete the screening or wait-list process described in this subsection if all other LTC eligibility requirements are met:

- Individuals who are 18, 19, or 20 years of age who have chronic, debilitating diseases or conditions of one or more physiological or organ systems which generally make the individual dependent upon 24-hour-per-day medical, nursing, or health supervision or intervention or
- Nursing facility residents requesting transition into the community who have resided in a Florida-licensed skilled nursing facility for at least 60 consecutive days.

SPB 7056 provides both the DOEA and the AHCA authority to adopt rules to implement the provisions of this act.

The bill removes obsolete language.

Section 3 provides the effective date of the act as July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Elder Affairs reports no fiscal impact.[27]

The Agency for Health Care Administration reports no fiscal impact.[28]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.962. 409.979.

IX. Additional Information:

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

CS by Health Policy on January 26, 2016:
The Committee Substitute names the Aging Resource Center personnel as the entity to conduct the screenings and rescreenings consistent with their current statutory duties in s. 430.2053, F.S. The CS also reinstates current law with respect to receiving long-term care services through the LTC managed care program.

A. Amendments:

None.

[27] Email from Jo Morris, Legislative Affairs Director, Department of Elder Affairs (Jan., 22, 2016) (on file with the Senate Committee on Health Policy).
[28] Conversation with Joshua Spagnola, Legislative Affairs Director, Agency for Health Care Administration (Jan. 22, 2016).

818638

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
01/26/2016	.	
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	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment

Delete line 63
and insert:
to receive long-term care services and must receive long-term

229302

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
01/26/2016	.	
	.	
	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete lines 106 - 115
and insert:
1. Pursuant to s. 430.2053, Aging Resource Center personnel certified by the Department of Elderly Affairs shall perform the screening for each individual requesting enrollment for home and community-based services through the long-term care managed care program.
2. The individual requesting the long-term care services, or the individual's authorized representative, must participate

229302

in an initial screening or rescreening for placement on the wait list. The screening or rescreening must be completed in its entirety before placement on the wait list.

3. Pursuant to s. 430.2053, Aging Resource Center personnel shall administer rescreening annually or upon notification of

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

And the title is amended as follows:

Delete line 13

and insert:

rescreening by Aging Resource Center personnel of individuals requesting long-term care

FOR CONSIDERATION By the Committee on Health Policy

588-02342A-16 20167056pb

A bill to be entitled

An act relating to long-term care managed care prioritization; amending s. 409.962, F.S.; defining terms; amending s. 409.979, F.S.; requiring the Department of Elderly Affairs to maintain a statewide wait list for enrollment for home and community-based services through the Medicaid long-term care managed care program; requiring the department to prioritize individuals for potential enrollment using a frailty-based screening tool that provides a priority score; providing for determinations regarding offers of enrollment; requiring screening and certain rescreening of individuals requesting long-term care services from the program; requiring the department to adopt by rule a screening tool; requiring the department to make a specified methodology available on its website; requiring the department to notify applicants if they are placed on the wait list; requiring the department to conduct prerelease assessments upon notification by the agency of available capacity; authorizing certain individuals to enroll in the long-term care managed care program; requiring the department to terminate an individual from the wait list under certain circumstances; providing for priority enrollment for home and community-based services; authorizing the department and the Agency for Health Care Administration to adopt rules; deleting obsolete language; providing an effective date.

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

588-02342A-16 20167056pb

Section 1. Present subsections (4) through (13) of section 409.962, Florida Statutes, are redesignated as subsections (5) through and (14), respectively, present subsection (14) of that section is redesignated as subsection (18), and new subsection (4) and subsections (15), (16), and (17) are added to that section, to read:

409.962 Definitions.—As used in this part, except as otherwise specifically provided, the term:

(4) "Authorized representative" means an individual who has the legal authority to make decisions on behalf of a Medicaid recipient or potential Medicaid recipient in matters related to the managed care plan or the screening or eligibility process.

(15) "Rescreening" means the use of a screening tool to conduct annual screenings or screenings due to a significant change which determine an individual's placement and continuation on the wait list.

(16) "Screening" means the use of an information-collection tool to determine a priority score for placement on the wait list.

(17) "Significant change" means change in an individual's health status after an accident or illness; an actual or anticipated change in the individual's living situation; a change in the caregiver relationship; loss of or damage to the individual's home or deterioration of his or her home environment; or loss of the individual's spouse or caregiver.

Section 2. Section 409.979, Florida Statutes, is amended to read:

409.979 Eligibility.—

(1) PREREQUISITE CRITERIA FOR ELIGIBILITY.—Medicaid

recipients who meet all of the following criteria are eligible to receive long-term care services and ~~must~~ receive long-term care services by participating in the long-term care managed care program. The recipient must be:

(a) Sixty-five years of age or older, or age 18 or older and eligible for Medicaid by reason of a disability.

(b) Determined by the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) preadmission screening program to require nursing facility care as defined in s. 409.985(3).

(2) ENROLLMENT OFFERS.—~~Medicaid recipients who, on the date long-term care managed care plans become available in their region, reside in a nursing home facility or are enrolled in one of the following long-term care Medicaid waiver programs are eligible to participate in the long-term care managed care program for up to 12 months without being reevaluated for their need for nursing facility care as defined in s. 409.985(3):~~

~~(a) The Assisted Living for the Frail Elderly Waiver.~~

~~(b) The Aged and Disabled Adult Waiver.~~

~~(c) The Consumer-Directed Care Plus Program as described in s. 409.221.~~

~~(d) The Program of All-inclusive Care for the Elderly.~~

~~(e) The Channeling Services Waiver for Frail Elders.~~

~~(3)~~ Subject to availability of funds, the Department of Elderly Affairs shall make offers for enrollment to eligible individuals based on a wait-list prioritization ~~and subject to availability of funds~~. Before making enrollment offers, the agency and the Department of Elderly Affairs ~~department~~ shall determine that sufficient funds exist to support additional

enrollment into plans.

(3) WAIT LIST, RELEASE, AND OFFER PROCESS.—The Department of Elderly Affairs shall maintain a statewide wait list for enrollment for home and community-based services through the long-term care managed care program.

(a) The Department of Elderly Affairs shall prioritize individuals for potential enrollment for home and community-based services through the long-term care managed care program using a frailty-based screening tool that results in a priority score. The priority score is used to set an order for releasing individuals from the wait list for potential enrollment in the long-term care managed care program. If capacity is limited for individuals with identical priority scores, the individual with the oldest date of placement on the wait list shall receive priority for release.

1. A person certified by the Department of Elderly Affairs shall perform the screening for each individual requesting enrollment for home and community-based services through the long-term care managed care program.

2. The individual requesting the long-term care services, or the individual's authorized representative, must participate in an initial screening or rescreening for placement on the wait list. The screening or rescreening must be completed in its entirety before placement on the wait list.

3. Rescreening must occur annually or upon notification of a significant change in an individual's circumstances.

4. The Department of Elderly Affairs shall adopt by rule a screening tool that generates the priority score, and shall make publicly available on its website the specific methodology used

to calculate an individual's priority score.

(b) Upon completion of the screening or rescreening process, the Department of Elderly Affairs shall notify the individual or the individual's authorized representative that the individual has been placed on the wait list.

(c) If the Department of Elderly Affairs is unable to contact the individual or the individual's authorized representative to schedule an initial screening or rescreening, it shall send a letter to the last documented address of the individual or the individual's authorized representative. The letter must advise the individual or his or her authorized representative that he or she must contact the Department of Elderly Affairs within 30 calendar days after the date of the notice to schedule a screening or rescreening and must notify the individual that failure to complete the screening or rescreening will result in his or her termination from the screening process and the wait list.

(d) After notification by the agency of available capacity, the CARES program shall conduct a prerelease assessment. The Department of Elderly Affairs shall release individuals from the wait list based on the priority scoring process and prerelease assessment results. Upon release, individuals who also are determined by the department to be financially eligible and by the Department of Elderly Affairs to be clinically eligible may enroll in the long-term care managed care program.

(e) The Department of Elderly Affairs shall terminate an individual's inclusion on the wait list if the individual:

1. Does not have a current priority score due to the individual's action or inaction;

2. Requests to be removed from the wait list;

3. Does not keep an appointment to complete the rescreening without scheduling another appointment;

4. Receives an offer to begin the eligibility determination process for the long-term care managed care program; or

5. Begins receiving services through the long-term care managed care program.

An individual whose inclusion on the wait list is terminated must initiate a new request for placement on the wait list, and any previous priority considerations must be disregarded.

(f) Notwithstanding this subsection, the following individuals are afforded priority enrollment for home and community-based services through the long-term care managed care program and do not have to complete the screening or wait-list process if all other long-term care managed care program eligibility requirements are met:

1. Individuals who are 18, 19, or 20 years of age who have chronic debilitating diseases or conditions of one or more physiological or organ systems which generally make the individual dependent upon 24-hour-per-day medical, nursing, or health supervision or intervention.

2. Nursing facility residents requesting to transition into the community who have resided in a Florida-licensed skilled nursing facility for at least 60 consecutive days.

(g) The Department of Elderly Affairs and the agency may adopt rules to implement this subsection.

Section 3. This act shall take effect July 1, 2016.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1116
INTRODUCER:	Senator Joyner
SUBJECT:	Long-acting Reversible Contraception Pilot Program
DATE:	January 20, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Favorable**
2.			AHS	
3.			FP	

I. Summary:

SB 1116 directs the Department of Health (department) to establish a long-acting reversible contraception (LARC) pilot program in Hillsborough, Palm Beach, and Pinellas counties. The department must contract with eligible family planning providers to deliver the services. A report on the effectiveness of the pilot program is due to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2018.

The bill appropriates $75,000 in nonrecurring General Revenue for the 2016-2017 fiscal year and directs the funds be equally divided among the three pilot counties.

II. Present Situation:

Long-acting reversible contraception (LARC) methods are the most effective forms of reversible birth control available with fewer than 1 in 100 women using a LARC method becoming pregnant, the same range as for sterilization.[1] LARC methods include the intrauterine device (IUD) and the birth control implant. Both methods last for several years, are reversible, and can be removed at any time.

The IUD is a small, T-shaped, plastic device that is inserted and left inside the uterus. There are two types of IUDS. The hormonal IUD releases progestin and is approved for up to five years and another is approved for up to three years. The copper IUD does not contain hormones and is approved for up to 10 years.[2]

[1] American College of Obstetricians and Gynecologists, *Frequently Asked Questions - Contraception (LARC)*, http://www.acog.org/Patients/FAQs/Long-Acting-Reversible-Contraception-LARC-IUD-and-Implant (last visited: Jan. 12, 2016).
[2] Id.

The birth control implant is a single flexible rod about the size of a matchstick that is inserted in the upper arm under the skin and releases progestin. The implant lasts for three years.

Both the IUD and the implant are placed and removed by a health care provider. There are few side effects to either method and almost all women are eligible for an IUD or implant.[3]

In the United States, approximately 3 million pregnancies per year, 50 percent of all pregnancies, are unintended.[4] Of those unintended pregnancies, half are from contraceptive failure and the other half are due to non-use of contraception.[5] Adolescents especially use contraceptive methods with high failure rates, such as condoms, withdrawal, or oral contraceptive pills.[6]

In Florida, the unintended pregnancy rate was 58 per 1,000 women in 2010 for women aged 15-44 and the teen pregnancy rate was 50 per 1,000 women.[7] The federal and state governments spent $1.3 billion on unintended pregnancies in 2010, of which $892.8 million (57%) was paid by the federal government and $427.1 million was paid by the state.[8]

While being cost-effective over the long-term, the high up-front costs of the LARC methods may be a barrier to widespread use as the wholesale cost of an IUD or implant can be as high as $850, plus the cost of insertion.[9] In February 2015, the federal Food and Drug Administration approved a new IUD, Liletta, which was developed by a nonprofit and is made available by that non-proft to public clinics for just $50.[10]

Most insurance plans under the Affordable Care Act and Medicaid cover contraception and the associated services with no out of pocket costs, those without insurance coverage may face a financial hurdle. The American College of Obstetricians and Gynecologists also recognized the high cost as a barrier to wide use of LARCs by adolescents in its *Committee on Adolescent Health Care Long-Acting Reversible Contraception Working Group* Committee Opinion document in 2014 along with lack of familiarity with or misconceptions about the methods, the lack of access, and health care providers' concerns about the safety of LARC use in adolescents (ages 9-11).[11]

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[3] Brooke Winner, et al., *Effectiveness of Long-Acting Reversible Contraception*, N ENGL J MED 366; 21, nejm.org, May 24, 2012.
[4] Brooke Winner, et al., *Effectiveness of Long-Acting Reversible Contraception*, N ENGL J MED 366; 21, nejm.org, May 24, 2012.
[5] Id.
[6] American College of Obstetricians and Gynecologists, *Committee Opinion: Adolescents and Long-Acting Reversible Contraception: Implants and Intrauterine Devices*, (October 2012), http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Adolescent-Health-Care/Adolescents-and-Long-Acting-Reversible-Contraception, (last visited: Jan. 12, 2016).
[7] Guttmacher Institute, *State Facts About Unintended Pregnancy: Florida (2014)*, http://www.guttmacher.org/statecenter/unintended-pregnancy/pdf/FL.pdf (last visited: Jan. 12, 2016.)
[8] Id.
[9] Heather D. Boonstra, *Leveling the Playing Field: The Promise of Long-Acting Reversible Contraceptives for Adolescents*, Guttmacher Policy Review, Vol. 16, p. 16, https://www.guttmacher.org/pubs/gpr/16/4/gpr160413.html (last visited: Jan. 12, 2016).
[10] Karen Weise, *Warren Buffet's Family Secretly Funded a Birth Control Revolution,* Bloomberg Business (July 30, 2015), http://www.bloomberg.com/news/articles/2015-07-30/warren-buffett-s-family-secretly-funded-a-birth-control-revolution (last visited: Jan. 12, 2016).
[11] *Supra,* Note 6 at 2.

Overall, the Committee found LARC methods to be "top-tier contraceptives based on effectiveness, with pregnancy rates of less than 1 percent per year for perfect use and typical use. Adolescents are at high risk of unintended pregnancy and may benefit from increased access to LARC methods."[12]

Current Family Planning Services

County Health Departments

The Department of Health (department) currently provides comprehensive family planning services, including providing LARC services, in all 67 Florida counties. Funding for these services is provided through a Title X federal grant, part of a Title V federal grant, and state general revenue. Funds are distributed to each county health department (CHD) by the department.

According to the department, more than 152,000 individuals received family planning services in 2014 with 71.3 percent of the clients having incomes at or below 150 percent of the federal poverty level.[13] For a family of two, 150 percent of the federal poverty level is $23,895.[14] Of those served by the department for family planning services, 44.1 percent were covered by public insurance and 27.4 percent were uninsured.

Individuals, men and women, served under this program have access to FDA-approved birth control methods and supplies, abstinence counseling, pregnancy testing, physical examinations, screenings, and HIV counseling and testing.[15] Services are provided on a sliding scale, based on family size and income with those under 100 percent of the federal poverty level, which is $11,770 for 2015, paying no fees which is $11,770 for 2015.

The majority of family planning services are delivered at CHD clinic sites. A small number of CHDs contract with outside providers for family planning services, including the three below.[16]

	Numbers of Clinical Sites, including Contracted Sites
Hillsborough CHD	11
Palm Beach CHD	10
Pinellas CHD	5

[12] *Supra*, Note 6 at 1.
[13] Florida Department of Health, *Family Planning Fact Sheet*, *http://www.floridahealth.gov/programs-and-services/womens-health/family-planning/fp-facts.html* (last visited: Jan. 12, 2016).
[14] 2015 Federal Poverty Guidelines, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/eligibility/downloads/2015-federal-poverty-level-charts.pdf (last visited: Jan. 12, 2016).
[15] Florida Department of Health, *Family Planning*, *http://www.floridahealth.gov/programs-and-services/womens-health/family-planning/index.html* (last visited: Jan. 12, 2016).
[16] Florida Department of Health, *2016 Agency Bill Analysis - SB 1116*, p.2 (Dec. 16, 2015)(on file with Senate Health Policy Committee).

In State Fiscal Year 2014-15, the CHDs provided services to 10,806 clients who were using a LARC method.[17] Of those 10,806 clients seen by the CHDs, 5,451 of these clients were new users and received the LARC during SFY 2014-15.[18] The table below illustrates the total number of services in the proposed pilot counties and statewide.

Long Acting Reversible Contraceptives (LARCs) Use by County, Florida Fiscal Year 2014-2015[19]

	Age <15-19			Age 20-45+			Total		
County	# of Clients with LARCs	# of Clients	%	# of Clients with LARCs	# of Clients	%	Total # of Clients with LARCs	Total Clients	%
Hillsborough	52	493	10.55%	726	4,748	15.29%	778	5,241	14.84%
Palm Beach	38	1,529	2.49%	842	8,139	10.35%	880	9,668	9.10%
Pinellas	15	1,714	0.88%	242	7,749	3.12%	257	9,463	2.72%
Statewide	963	24,027	4.01%	9,843	118,205	8.33%	10,806	142,232	7.60%

The department's Family Planning Program (FPP) has received level funding of approximately $4.7 million in general revenue for contraceptives over the last five years.[20] These funds are allocated to the department's Bureau of Statewide Pharmacy. Ordering higher cost contraceptives, such as LARCs is done through the FPP and paid for through funds that are separate and distinct from the finite general revenue funds.

The legislature designated a line item appropriation of $300,000 in SFY 2014-15 for the purchase of LARCs.[21] The department reports that this allocation was quickly spent by the 67 CHDs and no allocation was received in the subsequent fiscal year. The Maternal and Child Health Program at the department allocated Title V funds to the CHDs allowing them to choose from three Title V priorities, one being well woman, which would allow the CHDs to provide LARCs.[22] The three proposed pilot programs did not request their Title V funding be used for this purpose.

Florida Medicaid Program

Family planning services are also covered under Medicaid for Medicaid enrollees of child-bearing age and include reimbursement for:

- New and established patient visits;
- Required laboratory tests;
- Selection of contraceptive method, provision of supplies;
- Post examination review;

[17] Email from Bryan P. Wendel, Government Analyst II, Department of Health, to Jennifer Lloyd, Senate Health Policy Committee (Jan. 13, 2016)(on file with Senate Health Policy Committee).
[18] Id.
[19] Id.
[20] Id.
[21] Ch. 2014-51, s. 3, line 525, Laws of Fla. (line item appropriation of $300,000 for the purchase of long- acting reversible contraceptives with non-recurring general revenue funds, effective July 1, 2014).
[22] *Supra,* Note 17.

- Counseling visits;
- Supply visits;
- HIV Counseling;
- Coverage for insertion and removal of IUD;
- Services associated with decision to use long-acting injectable or implantable contraceptives; and
- Pregnancy testing.[23]

Family planning services for Medicaid eligibles are funded through Title XIX federal funds and state general revenue.

Family planning services are also provided through a family planning waiver (FPW) for women ages 14 through 55 losing Medicaid coverage at the end of their 60 days postpartum coverage and who have family income at or below 185 percent of the federal poverty level at the time of their annual redetermination or for women who have lost their Medicaid coverage. Enrollees must also not be otherwise eligible for Medicaid, Children's Health Insurance Program (CHIP), or other health insurance coverage with family planning services. Eligibility is limited to two years after losing Medicaid coverage and must be re-determined every 12 months.

The FPW was first implemented in 1998 and has been through several extension periods. The state received its most recent extension in December 2014, and was approved through December 31, 2017.[24]

Covered services are limited to those services and supplies whose primary purpose is family planning. Those services under the FPW include:

- Approved methods of contraception;
- Sexually transmitted infection (STI)/;sexually transmitted disease (STD) testing, Pap smears and pelvic exams;
- Approved sterilizations;
- Drugs, supplies, or devices related to women's health services; and
- Contraceptive management, patient education, and counseling.[25]

The FPW does not cover emergency room visits, inpatient services, or any other non-family planning related services.

Family planning services and supplies are reimbursed at the 90 percent federal matching rate; the processing of claims is at the 50 percent administrative match.[26] In 2010, the total public

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[23] Agency for Health Care Administration, *Practitioner Services Coverage and Limitations Handbook*, pp.51-55, http://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/Practitioner%20Services%20Handbook_Adoption.pdf (last visited: Jan. 12, 2016).

[24] Letter from Department of Health and Human Services, Center for Medicare and Medicaid Services to Justin Senior from Cindy Mann, http://ahca.myflorida.com/medicaid/Family_Planning/pdf/FL_FPW_Extension_CMS_Approval_Ltr_12-29-14.pdf (Dec, 29, 2014) (last visited: Jan. 12, 2016).

[25] Agency for Health Care Administration, *Extension of the Florida Medicaid Family Planning Waiver, (June 27, 2014)* p.23, *http://ahca.myflorida.com/Medicaid/Family_Planning/pdf/FPW_Extension_Request_6-27-14_final.pdf* (last visited: Jan. 12, 2016).

[26] Id at 32.

expenditures for family planning client services was $103.1 million which included $66 million through Medicaid and $11.5 million through Title X.[27]

III. Effect of Proposed Changes:

SB 1116 creates s. 381.00515, F.S., and the long-acting reversible contraceptive (LARC) pilot program within the Department of Health (department). The pilot program is established in Hillsborough, Palm Beach, and Pinellas counties with the purpose of improving the provision of LARC services in those counties. The department shall contract with eligible family planning providers to implement the program and the contract for LARC services must include:

- Provision of intrauterine devices and implants;
- Training for providers and staff regarding LARC devices, counseling strategies, and the management of side effects;
- Technical assistance regarding issues such as coding, billing, pharmacy rules, and clinic management because of increased use of LARC services;
- General support to expand the capacity of family planning clinics; and
- Other services the department considers necessary to ensure the health and safety of LARC participants.

The bill also directs the department to seek federal grants and funds from other sources to supplement state funds.

By January 1, 2018, the department must submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the effectiveness of the pilot program. The report must also be published on the department's website. The report must include:

- An assessment of the pilot program, including any progress made in the reduction of unintended pregnancies and subsequent births, especially among teenagers;
- An assessment on the effectiveness of the pilot program in increasing the availability of LARC services;
- The number and location of family planning providers who participated in the pilot program;
- The number of clients served by family planning providers;
- The number of times LARC services were provided by participating family planning providers;
- The average cost per client served;
- The demographics of clients served;
- The sources and amounts of funding used;
- A description of federal grants the department applied for, including the outcomes;
- An analysis of the return on investment for the provision of LARC services, including tax dollars saved on health and social services;
- A description and analysis of marketing and outreach activities conducted to promote the availability of LARC services; and
- Recommendation for improving the pilot program.

[27] *Supra,* Note 7.

For the 2016-2017 state fiscal year, $75,000 in nonrecurring funds from the General Revenue Fund is appropriated to the department for the purpose of implementing this bill. The funds are to be distributed equally among the three counties and are not to supplant or reduce any other appropriation of state funds to family planning providers or to the department for family planning services.

The bill is effective July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

A reduction in unintended pregnancies in the pilot counties may have a fiscal and operational impact on the private sector by reducing costs and business interruptions related to unplanned pregnancies on private employers and taxpayers. The average birth in Medicaid cost $14,930 in 2014.[28]

The bill also anticipates marketing and outreach efforts to promote the availability of LARC services and private business may benefit from funds or other resources spent on such a campaign.

C. Government Sector Impact:

The department has estimated expenditures of $233,955 for the 2016-2017 state fiscal year and $235,809 for the 2017-2018 state fiscal year to implement SB 1116. The funds

[28] Agency for Health Care Administration, MED 145 Deliverable 2.3 Interim Report (Family Planning Waiver) (July 29, 2015), p.17, http://ahca.myflorida.com/medicaid/Family_Planning/pdf/Final_Inteim_Report_July_29_2015.pdf (last visited: Jan. 12, 2016).

requested support 2 FTEs and the cost of a marketing campaign. The department has made the following request:

Department of Health Fiscal Note[29]		
	SFY 2016-2017	**SFY 2017-2018**
1-Sr. Mgmt Analyst II *35% Fringe calculated*	$62,614	$62,614
1-Pharmacy Tech *35% Fringe calculated* *No Expense*	$31,702	$31,702
Expense - 1 FTE *Standard DOH* *Professional package* *1 docking station*	$19,780 $147	$15,781
2 -Human Resources	$712	$712
Marketing Campaign	$125,000	$125,000
Department Total:	**$233,955**	**$235,809**

The Senior Management Analyst would be responsible for review and approval of applications, management of contracts, on-site observations and monitoring, program site reports, participation in implementation of the marketing and outreach plan and to provide information and technical assistance to the pilot program sites. This position will also be responsible for seeking out grants and preparing and posting the required report.

The state may also benefit from a reduction in costs if the pilot program results in fewer unintended pregnancies. Each Medicaid birth costs the state $14,930 while the highest priced LARC may be $800 - $1,000.[30]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 381.00515 of the Florida Statutes.

[29] *Supra,* Note 16 at 3-4.
[30] *Supra,* Note 28.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Joyner

19-00563B-16 20161116__

A bill to be entitled

An act relating to a long-acting reversible contraception pilot program; creating s. 381.00515, F.S.; requiring the Department of Health to establish a long-acting reversible contraception (LARC) pilot program in Hillsborough, Palm Beach, and Pinellas Counties; requiring the department to contract with family planning providers to implement the pilot program; requiring that such contracts include specified provisions; requiring the department to apply for grants for additional funding; requiring the department to submit a report to the Governor and the Legislature; requiring the department to publish the report on its website; specifying requirements for such report; providing an appropriation subject to certain requirements; providing legislative findings; providing an effective date.

WHEREAS, the Legislature finds that unintended pregnancies, especially among young women, carry health risks for mother and baby, and

WHEREAS, the Legislature further finds that programs that provide long-acting reversible contraceptive (LARC) methods, along with other contraceptive methods, contribute to declines in the number of unintended pregnancies and abortions, NOW, THEREFORE,

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

Section 1. Section 381.00515, Florida Statutes, is created to read:

19-00563B-16 20161116__

381.00515 Long-acting reversible contraception pilot program.—

(1) The Department of Health shall establish a long-acting reversible contraception (LARC) pilot program in Hillsborough, Palm Beach, and Pinellas Counties. The purpose of the pilot program is to improve the provision of LARC services in those counties. The department shall contract with eligible family planning providers to implement the pilot program. A contract to provide LARC services must include all of the following:

(a) Provision of intrauterine devices and implants to participants.

(b) Training for providers and staff regarding the provision of LARC devices, counseling strategies, and the management of side effects.

(c) Technical assistance regarding issues such as coding, billing, pharmacy rules, and clinic management necessitated by the increased use of LARC devices.

(d) General support to expand the capacity of family planning clinics.

(e) Marketing and outreach regarding the availability of LARC services among other currently available contraceptive services.

(f) Other services the department considers necessary to ensure the health and safety of participants who receive LARC devices.

(2) The department shall seek grants from federal agencies and other sources to supplement state funds provided for the pilot program.

(3) By January 1, 2018, the department shall submit a

report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the effectiveness of the pilot program. The department shall publish the report on its website. The report must include, but is not limited to:

(a) An assessment of the operation of the pilot program, including any progress made in reducing the number of unintended pregnancies and subsequent births, especially among teenagers.

(b) An assessment of the effectiveness of the pilot program in increasing the availability of LARC services.

(c) The number and location of family planning providers that participated in the pilot program.

(d) The number of clients served by participating family planning providers.

(e) The number of times LARC services were provided by participating family planning providers.

(f) The average cost per client served.

(g) The demographic characteristics of clients served.

(h) The sources and amounts of funding used for the pilot program.

(i) A description of federal grants the department applied for in order to provide LARC services, including the outcomes of the grant applications.

(j) An analysis of the return on investment for the provision of LARC services with regard to tax dollars saved on health and social services.

(k) A description and analysis of marketing and outreach activities conducted to promote the availability of LARC services.

(l) Recommendations for improving the pilot program.

Section 2. For the 2016-2017 fiscal year, the sum of $75,000 in nonrecurring funds is appropriated from the General Revenue Fund to the Department of Health for the purpose of implementing this act. The department shall distribute the funds equally among the three counties participating in the pilot program. These funds do not supplant or reduce any other appropriation of state funds to family planning providers or to the department for family planning services.

Section 3. The Legislature finds that this act is necessary to protect the public health, safety, and welfare.

Section 4. This act shall take effect July 1, 2016.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on Criminal and Civil Justice, *Vice Chair*
Appropriations
Health Policy
Higher Education
Judiciary
Rules

JOINT COMMITTEE:
Joint Legislative Budget Commission

SENATOR ARTHENIA L. JOYNER
Democratic Leader
19th District

January 5, 2016

Senator Aaron Bean, Chair
Senate Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Dear Chairman Bean:

This is to request that Senate Bill 1116, Long-acting Reversible Contraception Pilot Program, be placed on the agenda for the Committee on Health Policy. Your consideration of this request is greatly appreciated.

Sincerely,

Arthenia L. Joyner
State Senator, District 19

REPLY TO:
☐ 508 W. Dr. Martin Luther King, Jr. Blvd., Suite C, Tampa, Florida 33603-3415 (813) 233-4277
☐ 200 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5019 FAX: (813) 233-4280

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

THE FLORIDA SENATE

APPEARANCE RECORD

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

11/26/15
Meeting Date

1116
Bill Number (if applicable)

Topic Long acting reversible contraception

Amendment Barcode (if applicable)

Name Missy Wesolowski

Job Title Director of Governmental Affairs

Address 2300 N. Florida Mango Rd
Street

West Palm Beach FL 33409
City *State* *Zip*

Phone 561-472-9942

Email Missy@ppsenfl.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Alliance of Planned Parenthood Affiliates

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-26-16
Meeting Date

1116
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Contraception

Name Barbara DeHaven

Job Title MS

Address 625 E. Brevard St
Street

Phone 222-3969

Tallahassee
City *State* *Zip*

Email barbara.dehaven1@yahoo.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing CLASP

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

Jan 26, 2016
Meeting Date

1116
Bill Number (if applicable)

Topic Long-Acting Reversible Contraception Pilot

Amendment Barcode (if applicable)

Name Amber Kelly

Job Title Legislative Assistant

Address _____ Phone _____
Street

_____ Email _____
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Waive Speaking: ☐ In Support ☑ Against
(The Chair will read this information into the record.)

Representing Florida Family Action

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 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/26/16
Meeting Date

SB 1116
Bill Number (if applicable)

Topic Senate Bill 1116

Amendment Barcode (if applicable)

Name Roxanne Finch

Job Title Student

Address 2738 W. Tharpe St. Apt 602
Street

Tallahassee FL 32303
City *State* *Zip*

Phone (904) 392-5158

Email Roxanne.Finch95@gmail.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Roxanne Finch

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 (10/14/14)

CourtSmart Tag Report

Room: KN 412 **Case No.:** **Type:**
Caption: Senate Commitee on Health Policy **Judge:**

Started: 1/26/2016 9:03:56 AM
Ends: 1/26/2016 10:58:10 AM Length: 01:54:15

9:05:08 AM Meeting called to order
9:05:51 AM Momentarily paused by Chair Bean
9:06:19 AM Delay cont'd
9:06:20 AM Delay cont'd
9:06:45 AM Delay cont'd
9:06:48 AM Meeting called to order
9:07:01 AM Opening Remarks
9:07:18 AM Roll call
9:07:46 AM Tab 5 Senate Bill 878
9:08:15 AM Sen Sachs speaks
9:09:00 AM Layne Smith Mayo Clinic College of Medicine waves in support
9:09:23 AM Sen Sachs waives in support
9:09:35 AM Roll Call
9:09:52 AM Bill passes favorably
9:10:07 AM Sen Grimsely Tab 8 SB 1604
9:10:28 AM Bill explained
9:11:55 AM Call for Questions
9:12:08 AM AM 864912
9:12:20 AM Sen Grimsley speaks
9:12:58 AM AM 864912 adopted
9:13:12 AM Sen Grimsley speaks
9:13:38 AM Sen Grimsley speaks
9:13:41 AM Chair calls for questions
9:13:50 AM AM 669120 adopted
9:14:00 AM Larry Gonzalez waives in support
9:14:05 AM
9:14:19 AM Matilda Miller waives in support
9:14:32 AM Sen Grimsley waives close
9:14:48 AM SB 1604 passes as CS
9:15:20 AM Tab 10 SB 1116
9:15:47 AM Tab 6 SB 1686
9:15:57 AM Sen Joyner explains SB 1686
9:17:24 AM Questions
9:17:35 AM AM 424232 by Sen Joyner ammendment
9:18:03 AM Questions for Joyner
9:18:09 AM Layne Smith waives in support
9:18:19 AM Amendment 424232 /adopted
9:18:45 AM AM 925172
9:19:09 AM Questions
9:19:18 AM Questions
9:19:19 AM AM 925172
9:19:28 AM AM 391778
9:19:55 AM adopted 397758
9:20:08 AM Jeff Scott Fl Medical Associate waives in support
9:20:21 AM Jack McCrae waives in support
9:20:30 AM Jack McCrae speaks
9:21:06 AM Jack McRay speaks
9:21:20 AM Chris Newland waives in support
9:21:32 AM David Poole speaks
9:21:48 AM Steven Wynn waives in support
9:21:48 AM David Poole speaks
9:21:57 AM Larry Gonzalez waives in support

9:22:14 AM Larry Gonzalez waives in support
9:22:23 AM Sen Joyner closes
9:23:07 AM Sen Joyner closes
9:23:07 AM chair speaks
9:23:14 AM roll call for passage
9:23:23 AM CS SB 1686 passes favorbly
9:23:45 AM Tab 3 SB 818
9:24:07 AM Elizabeth Maybry speaks
9:24:28 AM Elizabeth Maybry explains
9:24:56 AM Call for discussion
9:25:41 AM AM 418914 adopted
9:26:01 AM Barbara Devane waives in support
9:26:23 AM Barbara Devane waives in support
9:26:39 AM CS SB 818 passes favorably
9:27:03 AM Tab 4 SB 764
9:27:18 AM Amy Nicotra Legislative Aid
9:27:37 AM Amy Nicotra Legislative Aid explains
9:28:22 AM Chair calls for questions
9:28:41 AM Discussion
9:28:49 AM SB 764 passes favorably
9:29:19 AM Tab 11 SB 1116
9:29:44 AM Sen Joyner explains
9:31:20 AM Call for questions
9:31:24 AM President Gaetz has a question
9:31:41 AM Sen Joyner
9:32:33 AM Chair questions
9:33:07 AM Pubic Testimony
9:33:18 AM Missy Wesolowski waives in support
9:33:28 AM Barbara Devane waives in support
9:33:42 AM Amber Kelly, Florida Family Action, waives in oppositiion
9:33:49 AM Roxanne Finch, student, spoke in support
9:35:19 AM Call for debate on the bill
9:36:10 AM Chair questions
9:36:16 AM Sen Joyner responds
9:36:53 AM Jennifer Lloyd, Health Policy Staff committee, speaks
9:37:18 AM Call for debate
9:37:30 AM Sen Joyner closes
9:37:49 AM Vice Chair Sobel questions
9:38:04 AM Sen Joyner responds
9:38:45 AM Vice Chair Sobel comments
9:38:45 AM Sen Joyner responds
9:39:04 AM Roll call
9:39:10 AM SB 1116 passes favorably
9:39:44 AM Tab 9- SB 7056 Health Policy Long Term Care
9:40:01 AM Jennifer Lloyd explains
9:41:39 AM Jennifer Lloyd explains
9:41:42 AM AM 818638 by Sen Flores. Call for questions
9:42:18 AM AM 818638 adopted
9:42:27 AM AM 229302
9:43:00 AM Robert Beck waives in support
9:43:11 AM AM 229302 adopted
9:43:21 AM Jack McRay, AARP, speaks
9:44:49 AM Jack McRay speaks to inform
9:44:50 AM Discussion and debate
9:45:00 AM Motion to debate SB 7056 introduce as a Committee Bill
9:45:27 AM SB 7056 CB Health Policy passes favorably
9:45:52 AM Tab 7 SB 1504
9:46:02 AM SB 1504 TP
9:46:09 AM Tab 1 SB 1722
9:47:00 AM Michael Rajner speaks
9:48:40 AM Michael Rajner advocate for individuals living with HIV -AIDS speaks against the bill
9:49:40 AM Michael Rajner advocate for individuals living with HIV -Aspeaks against the bill

9:49:40 AM Michael Rajner advocate for individuals living with HIV -Aspeaks against the bill
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9:49:40 AM Michael Rajner advocate for individuals living with HIV -Aspeaks against the bill
9:49:55 AM Chris Nuland,Surgeon General Confirmation, waives in support
9:50:55 AM Vice Chair Sobel speaks favorably for SB
9:51:01 AM Tab 1 SB 1722 Termination of Pregnancies
9:51:31 AM Sen Stargel explains
9:52:23 AM Vice Chair Sobel speaks
9:52:23 AM Sen Stargel explains
9:52:30 AM Sen Braynon questions
9:52:52 AM Sen Stargel responds
9:53:46 AM Sen Stargel responds
9:53:48 AM Sen Braynon questions
9:54:01 AM Sen Stargel
9:54:46 AM Sen Braynon
9:54:53 AM Staff elaborates
9:55:18 AM Pres Gaetz speaks
9:57:16 AM Pres Gaetz speaks
9:57:17 AM Sen Braynon question
9:57:47 AM Sen Stargel speaks
9:58:26 AM Vice Chair Sobel question
9:59:10 AM Sen Stargel speaks
9:59:12 AM Vice Chair Sobel questions and comments
9:59:23 AM Sen Stargel speaks
10:00:40 AM Vice Chair Sobel question
10:00:44 AM Sen Stargel comments
10:00:46 AM Vice Chair Sobel question
10:00:52 AM Sen Stargel comments
10:00:57 AM Vice Chair Sobel questions
10:01:00 AM Sen Stargel comments
10:01:32 AM Vice Chair Sobel question
10:01:48 AM Sen Stargel comments
10:02:04 AM Vice Chair Sobel comment
10:02:08 AM Sen Stargel comment
10:02:17 AM Vice Chair Sobel question
10:02:38 AM Sen Stargel comment
10:02:51 AM Vice Chair Sobel question
10:02:56 AM Sen Stargel comment
10:03:00 AM Vice Chair Sobel question
10:03:04 AM Sen Stargel comments
10:03:13 AM Vice Chair Sobel question
10:04:02 AM Vice Chair Sobel question
10:04:03 AM Sen Stargel comments
10:04:43 AM Vice Chair Sobel question
10:05:13 AM Sen Stargel comments
10:05:36 AM Chair questions
10:05:44 AM Sen Joyner question
10:05:56 AM Sen Stargel comments
10:06:02 AM Sen Joyner question
10:06:09 AM Sen Stargel comments
10:06:26 AM Sen Joyner question
10:06:45 AM Sen Stargel comments
10:07:21 AM Sen Joyner questions
10:07:37 AM Sen Stargel comments
10:08:25 AM Molly McKinstry, Agency for Health Care Admin, explains inspections
10:09:13 AM Sen Joyner questions
10:09:24 AM Molly responds
10:10:04 AM Sen Joyner comments
10:10:09 AM Pres Gaetz question for Molly
10:10:36 AM Molly responds
10:10:43 AM Sen Joyner question
10:11:05 AM Chair

10:11:11 AM Sen Joyner question
10:11:57 AM Sen Stargel responds
10:12:10 AM Sen Joyner question
10:12:18 AM Sen Stargel comments
10:12:33 AM Sen Joyner question
10:12:47 AM Sen Stargel comments
10:13:05 AM Sen Joyner question
10:13:43 AM Sen Stargel comments
10:13:47 AM Sen Joyner question
10:14:00 AM Sen Stargel comments
10:14:15 AM Chair calls for question
10:14:21 AM Sen Grimsley question
10:14:36 AM Sen Stargel comments
10:15:26 AM Sen Grimsley question
10:15:30 AM Chair Richter speaks
10:15:37 AM Sen Stargel comments
10:16:11 AM Vice Chair Sobel question
10:16:30 AM Sen Stargel comments
10:16:44 AM Vice Chair Sobel question
10:16:49 AM Sen Stargel comments
10:17:34 AM Vice Chair Sobel question
10:17:39 AM Sen Stargel comments
10:17:43 AM Sen Joyner question
10:18:19 AM Sen Stargel comments
10:18:22 AM Sen Joyner question
10:19:49 AM Sen Joyner question
10:19:52 AM Chair
10:19:59 AM Sen Joyner comment
10:20:13 AM Chair
10:20:21 AM Stargel
10:20:33 AM Sen Joyner
10:20:45 AM Josh Spagnola, AHCA , speaks to inform
10:21:08 AM Josh AHCA provides information
10:21:41 AM Sen Joyner question
10:21:55 AM Josh responds
10:22:23 AM Sen Braynon question
10:22:58 AM Josh answers
10:23:19 AM Sen Braynon question
10:23:46 AM Josh answers
10:24:04 AM Sen Braynon questions
10:24:33 AM Vice Chair Sobel holds question
10:25:25 AM Motion by Sen Galvano to vote by 10:59 a.m.
10:25:35 AM Public Testimony
10:25:52 AM Teresa Ward Florida Right to Life waives in support
10:26:39 AM Speakers waived time in support:
10:26:55 AM Speakers waives time against: Natalia Reyes; Missy Wesolowski; Yaritza Morales; Pamela Burch Fort
10:27:58 AM Speakers waives time against: Amanda Canate; Saverro Alade; Amy Datz; Chris Demesio
10:28:04 AM Speakers waives time in support: Ingrid Delgado; Bob Wilder;Bill Snyder;David Borrero;Pamela Berman
10:28:31 AM Pamela Olsen, Pastor, speaks in support
10:29:39 AM Barbara Devane, FL Now, speaks in opposition
10:31:13 AM Sen Joyner comment
10:31:27 AM Marcia Buterakos,representing Life Choices, waives in support
10:31:43 AM Gianna Bonner, student,waves in opposition
10:32:29 AM Gabriel Garcia Vera, Nat Latina Inst Repo for Health, speaks in opposition
10:33:29 AM Bill Bunkley,FL Ethics and Religious Committee, waives in support
10:33:57 AM Mariah Rivera constituent speaks in opposition
10:34:23 AM Mariah Rivera constituent speaks in opposition
10:35:18 AM Madison Podes-Tolchin, consituent, speaks in opposition
10:36:17 AM John Stemberger, FL Family policy counsel, speaks in support
10:37:54 AM John Stemberger, FL Family policy counsel, speaks in support
10:37:59 AM Amber Kelly, Legislative Asst, waives in support
10:38:10 AM Patty Burke from Gulf Breeze speaks in support

10:38:44 AM Patty Burke speaks in support cont.
10:40:24 AM Patty Burke speaks in support cont
10:40:29 AM Laurie Bartlett waives in support
10:40:40 AM Cliff Myrtil constituent speaks in opposition
10:42:03 AM Cliff Myrtil constituent speaks in opposition
10:42:13 AM Chair calls for debate
10:42:17 AM Vice Chair Sobel comment
10:44:12 AM Vice Chair Sobel comment
10:45:11 AM Sen Braynon comment
10:46:11 AM Sen Braynon comment
10:47:11 AM Sen Grimsley comment
10:48:12 AM Chair comments
10:54:02 AM Sen Joyner comment
10:55:02 AM Sen Stargel closes
10:56:53 AM Chair speaks
10:57:00 AM Roll Call on final passage on SB 1722
10:57:14 AM SB 1722 passes favorably
10:57:41 AM Sen Joyner affirmtive
10:57:54 AM Sen Grimsley comments
10:58:10 AM Meeting Adjourned