Health Care Appropriations Subcommittee

February 2, 2016
10:30 AM – 1:00 PM
Webster Hall (212 Knott)

Meeting Packet

Steve Crisafulli
Speaker

Matt Hudson
Chair

The Florida House of Representatives

Appropriations Committee

Health Care Appropriations Subcommittee

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AGENDA
10:30 AM – 1:00 PM
Webster Hall

I. Call to Order/Roll Call

II. CS/HB 563—Temporary Cash Assistance Program by Gaetz

III. CS/HB 941—Department of Health by Gonzalez

IV. HB 1245—Medicaid Provider Overpayments by Peters

V. HB 1277—Licensure of Foreign-Trained Physicians by Campbell

VI. HB 1313—Low-THC Cannabis for Medical Use by Brodeur

VII. HB 1335—Long-term Care Prioritization by Magar

VIII. HB 1411—Termination of Pregnancies by Burton

IX. Closing/Adjourn

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HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 563 Temporary Cash Assistance Program
SPONSOR(S): Children, Families & Seniors Subcommittee, Gaetz
TIED BILLS: **IDEN./SIM. BILLS:** SB 750

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	8 Y, 4 N, As CS	Langston	Brazzell
2) Health Care Appropriations Subcommittee		Pridgeon	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Florida's Temporary Cash Assistance (TCA) Program provides cash assistance to needy families with children that meet the technical, income, and asset eligibility requirements. The purpose of the TCA Program is to help families become self-supporting while allowing children to remain in their own homes.

The Department of Children and Families makes the eligibility determination for TCA. To be eligible for the TCA Program, among other things, applicants must be U.S. citizens or qualified non-citizens, reside in Florida, and have a gross income of less than 185% of the Federal Poverty Level. When calculating eligibility, the earned income of a child who attends high school or the equivalent, and is 19 years of age and younger, is disregarded. When determining eligibility for the family members who meet citizenship requirements in a family that also has illegal or ineligible noncitizen members, only a pro-rata share of the illegal or ineligible noncitizen family member's income is counted.

CS/HB 563 amends s. 414.095(3)(d), F.S., to count all of a noncitizen's income when determining a household's income eligibility. The bill treats the income of U.S. citizens and noncitizens (legal, ineligible, or illegal) who are mandatory family members the same for TCA eligibility.

The bill also amends s. 414.095(11)(b), F.S., to clarify that the earned income of a child who attends high school or the equivalent is disregarded only if that child is under the age of 19, rather than 19 years old or younger. This change aligns the definition of a "child" with the definition of a "minor child" in s. 414.0252(8), F.S.

The bill is estimated to have a positive fiscal impact on the TCA program of $239,518 within the Department of Children and Families and no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Temporary Assistance for Needy Families (TANF)

Under the federal welfare reform legislation of 1996, the Temporary Assistance for Needy Families (TANF) program replaced the welfare programs known as Aid to Families with Dependent Children, the Job Opportunities and Basic Skills Training program, and the Emergency Assistance program. The law ended federal entitlement to assistance and instead created TANF as a block grant that provides states, territories, and tribes federal funds each year. These funds cover benefits, administrative expenses, and services targeted to needy families. TANF became effective July 1, 1997, and was reauthorized in 2006 by the Deficit Reduction Act of 2005. States receive block grants to operate their individual programs and to accomplish the goals of the TANF program.

Florida's Temporary Cash Assistance Program

The Temporary Cash Assistance (TCA) Program provides cash assistance to families with children under the age of 18 or under age 19[1] if full time high school students, that meet the technical, income, and asset requirements. The purpose of the TCA Program is to help families become self-supporting while allowing children to remain in their own homes.

Cash assistance is available to two categories of families: work-eligible (full-family cases) and child-only. The TCA Program also provides monthly cash assistance to relatives who meet eligibility rules and have custody of a child under age 18 who has been court-ordered dependent by a Florida court and placed in their home though the relative caregiver program. The majority of cash assistance benefits are provided to child-only and relative caregiver cases.

Administration

Various state agencies and entities work together through a series of contracts or memorandums of understanding to administer the TCA Program.

- The Department of Children and Families (DCF) is the recipient of the federal TANF block grant. DCF monitors eligibility and disperses benefits.
- CareerSource Florida, formerly Workforce Florida, Inc.,[2] is the state's workforce policy and investment board. CareerSource Florida has planning and oversight responsibilities for all workforce-related programs.
- The Department of Economic Opportunity (DEO) is the designated agency for workforce programs, funding and personnel, and implements the policy created by CareerSource.[3] DEO is responsible for financial and performance reports ensuring compliance with federal and state measures and also provides training and technical assistance to Regional Workforce Boards.

[1] Parents, children and minor siblings who live together must apply together. Additionally, pregnant women may also receive TCA, either in the third trimester of pregnancy if unable to work, or in the 9th month of pregnancy.
[2] On May 22, 2013, the WFI Board of Directors unanimously approved the brand charter, name, and logo establishing "CareerSource Florida" as the single, statewide unified brand for Florida's workforce system. This universal brand will apply directly to WFI, RWBs and One-Stop Career Centers, creating aligned brand names and logos system-wide (i.e. Workforce Florida Inc. is now CareerSource Florida and Gulf Coast Workforce Development Board is now CareerSource Gulf Coast).
[3] S. 445.007(13), F.S.

- Regional Workforce Boards (RWBs) provide a coordinated and comprehensive delivery of local workforce services. There are 24 RWBs in service delivery areas that are closely aligned with the community college system. The RWBs focus on strategic planning, policy development and oversight of the local workforce investment system within their respective areas and contract with one-stop career centers. The contracts with the RWBs are performance- and incentive-based.

Eligibility Determination

A person must pass all eligibility rules to receive TCA benefits. The initial application for TANF is processed by DCF. The application may be submitted in person, online or through the mail. DCF determines eligibility for the TCA program. To be eligible for the TCA Program, among other things, applicants must:

- Be U.S. citizens or qualified non-citizens;
- Reside in Florida;
- Have a gross income of less than 185% of the Federal Poverty Level (FPL);[4] and
- Have a countable income that is not higher than the payment standard for the family size.

The earned income of a child who attends high school or the equivalent, and is 19 years of age and younger, is disregarded. The total income of U.S. citizens is counted in determining a family's eligibility. Ineligible noncitizens may not receive benefits, however, their family members who meet the citizenship requirement may be eligible. When determining eligibility for those family members who meet citizenship requirements, only a pro-rata share of the illegal or ineligible noncitizen family member's income is counted.[5]

Additionally, some applicants must participate in work activities unless they qualify for an exemption. Exemptions from the work requirement are available for:

- An individual who receives benefits under the Supplemental Security Income program or the Social Security Disability Insurance program.
- An adult who is not defined as a work-eligible individual under federal law.
- A single parent of a child under 3 months of age, except that the parent may be required to attend parenting classes or other activities to better prepare for raising a child.
- An individual who is exempt from the time period pursuant to s. 414.105, F.S.

If no exemptions from work requirements apply, DCF refers the applicant to DEO.[6] Upon referral the participant must complete an in-take application and undergo assessment by RWB staff which includes:

- Identifying barriers to employment.
- Identifying the participant's skills that will translate into employment and training opportunities.
- Reviewing participant's work history.
- Identifying whether a participant needs alternative requirements due to domestic violence, substance abuse, medical problems, mental health issues, hidden disabilities, learning disabilities or other problems which prevent the participant from engaging in full-time employment or activities.

[4] For 2015, 185% of the FPL for a family of two is $ 29,470.50 (or $ 2,455.88 per month); for a family four it is $ 44,862.50 (or $ 3,738.54 per month).
[5] S. 414.095(3)(d), F.S.
[6] This is an electronic referral through a system interface between DCF's computer system and DEO's computer system. Once the referral has been entered into the DEO system the information may be accessed by any of the RWBs or One-Stop Career Centers.

Once the assessment is complete, the staff member and participant create the Individual Responsibility Plan (IRP). The IRP includes:

- The participant's employment goal;
- The participant's assigned activities;
- Services provided through program partners, community agencies and the workforce system;
- The weekly number of hours the participant is expected to complete; and
- Completion dates and deadlines for particular activities.

DCF does not disperse any benefits to the participant until it receives confirmation from DEO or the RWB that the participant has registered and attended orientation.

Effect of the Bill

Counting Income for TCA Eligibility

Noncitizens' Income

The bill amends s. 414.095(3)(d), F.S., to count all of a noncitizen's income, not only a pro-rata share. The income of U.S. citizens and noncitizens (legal, ineligible, or illegal) who are mandatory family members would be treated equally and this would increase families' countable income. Families where the increase in considered income places them above the threshold for receiving benefits would no longer be eligible and would stop receiving TCA benefits. This change will affect an estimated 149 households per month.[7]

Earned Income by a Child

The bill amends s. 414.095(11)(b), F.S., to clarify that the earned income of a child who attends high school or the equivalent is disregarded only if that child is under the age of 19, rather than 19 years old or younger. This change aligns the definition of a "child" with the definition of a "minor child" in s. 414.0252(8), F.S.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 414.095, F.S., relating to determining eligibility for temporary cash assistance.
Section 2: Reenacts s. 414.045, F.S., relating to cash assistance program.
Section 3: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

[7] Id.

2. Expenditures:

The bill will reduce annual TCA expenditures through reduced payments to households that contain an illegal or ineligible noncitizen with income. 149 households per month would be impacted by this change. The estimated savings from this change is $239,518 annually[8].

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Approximately 149 households, monthly, will no longer be eligible to receive TCA as a result of the changes to the non-citizen income calculations.

D. FISCAL COMMENTS:

The Social Service Estimating conference pursuant to s. 216.136, F.S determines the annual need and forecasted expenditures for the TCA program.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 20, 2016, the Children, Families, and Seniors Subcommittee adopted an amendment that narrowed the scope of the bill to focus solely on the eligibility determination, and what income is counted, for TCA. The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

[8] Department of Children and Families, *2016 Agency Legislative Bill Analysis-CS/HB 563*, January 28, 2016 (on file with Health Care Appropriations Subcommittee staff).

A bill to be entitled

An act relating to the temporary cash assistance program; amending s. 414.095, F.S.; revising the consideration of income from illegal noncitizen or ineligible noncitizen family members in determining eligibility for temporary cash assistance; reenacting s. 414.045(1), F.S., relating to the cash assistance program, to incorporate the amendment made by the act to s. 414.095, F.S., in a reference thereto; providing an effective date.

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

Section 1. Paragraph (d) of subsection (3) and subsection (11) of section 414.095, Florida Statutes, are amended to read:

414.095 Determining eligibility for temporary cash assistance.—

(3) ELIGIBILITY FOR NONCITIZENS.—A "qualified noncitizen" is an individual who is admitted to the United States as a refugee under s. 207 of the Immigration and Nationality Act or who is granted asylum under s. 208 of the Immigration and Nationality Act; a noncitizen whose deportation is withheld under s. 243(h) or s. 241(b)(3) of the Immigration and Nationality Act; a noncitizen who is paroled into the United States under s. 212(d)(5) of the Immigration and Nationality Act, for at least 1 year; a noncitizen who is granted

conditional entry pursuant to s. 203(a)(7) of the Immigration and Nationality Act as in effect prior to April 1, 1980; a Cuban or Haitian entrant; or a noncitizen who has been admitted as a permanent resident. In addition, a "qualified noncitizen" includes an individual who, or an individual whose child or parent, has been battered or subject to extreme cruelty in the United States by a spouse, a parent, or other household member under certain circumstances, and has applied for or received protection under the federal Violence Against Women Act of 1994, Pub. L. No. 103-322, if the need for benefits is related to the abuse and the batterer no longer lives in the household. A "nonqualified noncitizen" is a nonimmigrant noncitizen, including a tourist, business visitor, foreign student, exchange visitor, temporary worker, or diplomat. In addition, a "nonqualified noncitizen" includes an individual paroled into the United States for less than 1 year. A qualified noncitizen who is otherwise eligible may receive temporary cash assistance to the extent permitted by federal law. The income or resources of a sponsor and the sponsor's spouse shall be included in determining eligibility to the maximum extent permitted by federal law.

(d) The income of an illegal noncitizen or ineligible noncitizen who is a mandatory member of a family~~, less a pro rata share for the illegal noncitizen or ineligible noncitizen,~~ counts <u>in full</u> in determining a family's eligibility to participate in the program.

(11) DISREGARDS.—

(a) As an incentive to employment, the first $200 plus one-half of the remainder of earned income shall be disregarded. In order to be eligible for earned income to be disregarded, the individual must be:

1. A current participant in the program; or

2. Eligible for participation in the program without the earnings disregard.

(b) A child's earned income shall be disregarded if the child is a family member, attends high school or the equivalent, and is younger than 19 years of age ~~or younger~~.

Section 2. For the purpose of incorporating the amendment made by this act to section 414.095, Florida Statutes, in a reference thereto, subsection (1) of section 414.045, Florida Statutes, is reenacted to read:

414.045 Cash assistance program.—Cash assistance families include any families receiving cash assistance payments from the state program for temporary assistance for needy families as defined in federal law, whether such funds are from federal funds, state funds, or commingled federal and state funds. Cash assistance families may also include families receiving cash assistance through a program defined as a separate state program.

(1) For reporting purposes, families receiving cash assistance shall be grouped into the following categories. The department may develop additional groupings in order to comply

with federal reporting requirements, to comply with the data-reporting needs of the board of directors of CareerSource Florida, Inc., or to better inform the public of program progress.

(a) Work-eligible cases.—Work-eligible cases shall include:

1. Families containing an adult or a teen head of household, as defined by federal law. These cases are generally subject to the work activity requirements provided in s. 445.024 and the time limitations on benefits provided in s. 414.105.

2. Families with a parent where the parent's needs have been removed from the case due to sanction or disqualification shall be considered work-eligible cases to the extent that such cases are considered in the calculation of federal participation rates or would be counted in such calculation in future months.

3. Families participating in transition assistance programs.

4. Families otherwise eligible for temporary cash assistance which receive diversion services, a severance payment, or participate in the relocation program.

(b) Child-only cases.—Child-only cases include cases that do not have an adult or teen head of household as defined in federal law. Such cases include:

1. Children in the care of caretaker relatives, if the caretaker relatives choose to have their needs excluded in the calculation of the amount of cash assistance.

2. Families in the Relative Caregiver Program as provided in s. 39.5085.

3. Families in which the only parent in a single-parent family or both parents in a two-parent family receive supplemental security income (SSI) benefits under Title XVI of the Social Security Act, as amended. To the extent permitted by federal law, individuals receiving SSI shall be excluded as household members in determining the amount of cash assistance, and such cases shall not be considered families containing an adult. Parents or caretaker relatives who are excluded from the cash assistance group due to receipt of SSI may choose to participate in work activities. An individual whose ability to participate in work activities is limited who volunteers to participate in work activities shall be assigned to work activities consistent with such limitations. An individual who volunteers to participate in a work activity may receive child care or support services consistent with such participation.

4. Families in which the only parent in a single-parent family or both parents in a two-parent family are not eligible for cash assistance due to immigration status or other limitation of federal law. To the extent required by federal law, such cases shall not be considered families containing an adult.

5. To the extent permitted by federal law and subject to appropriations, special needs children who have been adopted pursuant to s. 409.166 and whose adopting family qualifies as a

needy family under the state program for temporary assistance for needy families. Notwithstanding any provision to the contrary in s. 414.075, s. 414.085, or s. 414.095, a family shall be considered a needy family if:

a. The family is determined by the department to have an income below 200 percent of the federal poverty level;

b. The family meets the requirements of s. 414.095(2) and (3) related to residence, citizenship, or eligible noncitizen status; and

c. The family provides any information that may be necessary to meet federal reporting requirements specified under Part A of Title IV of the Social Security Act.

Families described in subparagraph 1., subparagraph 2., or subparagraph 3. may receive child care assistance or other supports or services so that the children may continue to be cared for in their own homes or in the homes of relatives. Such assistance or services may be funded from the temporary assistance for needy families block grant to the extent permitted under federal law and to the extent funds have been provided in the General Appropriations Act.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 941 Licensure of Health Care Professionals
SPONSOR(S): Health Quality Subcommittee; Gonzalez
TIED BILLS: **IDEN./SIM. BILLS:** SB 918

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

SUMMARY ANALYSIS

The bill provides alternative eligibility criteria for a military member seeking licensure as a health care practitioner in this state. The bill also extends the alternative eligibility criteria, and other current licensure eligibility criteria for military applicants, to the spouses of active duty military personnel who apply for a license as a health care practitioner. The bill removes law that allows military spouses to obtain temporary licensure to conform to the new full-licensure eligibility provisions in the bill for active duty military spouses. The bill allows military health care practitioners who are practicing under a military platform, which is a training agreement with a nonmilitary health care provider, to be issued a temporary certificate to practice in this state.

The bill removes the requirement that certain health care practitioners complete pre-licensure courses on HIV/AIDS and medical errors. The bill amends various statutes to reflect the Department of Health's (DOH's) integration of an electronic continuing education (CE) tracking system with its licensure renewal system. The bill eliminates methods, such as affidavits and audits, to prove compliance with CE requirements.

The bill provides a mechanism for the DOH to eliminate a deficit cash balance in the Medical Quality Assurance Trust Fund, associated with a licensed profession, by allowing the DOH to suspend charging the profession for operational and administrative costs, and permitting the DOH to transfer certain unused funds to help eliminate the deficit.

Upon the death, incapacitation, or abandonment of patient records by a health care practitioner, the DOH may be required to secure such records. The bill permits the DOH to contract with a third party to provide such services and requires boards to obtain the approval of the DOH when appointing a custodian of medical records.

The bill allows certificates for emergency medical technicians (EMTs) and paramedics to remain in an inactive status for up to two renewal periods rather than expiring after 180 days, and exempts out-of-state or military-trained EMTs or paramedics from a certification examination requirement if the EMT or paramedic is nationally certified or registered.

The bill deletes a provision that allows individuals with certain felonies, individuals terminated for cause from any state's Medicaid program, or individuals listed on the U.S. Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities, to obtain a license in Florida. This will prevent individuals who are denied licensure renewal based on one of these offenses from re-applying and obtaining a new license.

The bill repeals the Council on Certified Nursing Assistants and the Advisory Council of Medical Physicists, as these entities are no longer actively meeting and their duties can be fulfilled by other entities within the DOH.

The bill eliminates the DOH's annual inspections of dispensing practitioners' facilities, but retains its ability to inspect the facilities on an as needed basis.

The bill requires state-funded biomedical research grant programs to report certain information to the Governor and Legislature. The bill also allows the balance of any appropriation from the General Revenue fund for the Ed and Ethel Moore Alzheimer's Disease Research Program to be carried forward for up to 5 years if such funds have been obligated.

The bill may have an insignificant, positive impact on the DOH.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

James and Esther King Biomedical Research Program

In 1999, the Legislature created the Florida Biomedical Research Program in the Department of Health (DOH), to support research initiatives that address the health care problems affecting Floridians, such as cancer, cardiovascular disease, stroke, and pulmonary disease.[1] The law also created the Biomedical Research Advisory Council (BRAC) to advise the State Surgeon General on the direction and scope of the state's biomedical research program.[2] The responsibilities of the BRAC include:

- Advising on program priorities, emphases, and overall program budget;
- Participating in periodic program evaluation;
- Assisting in developing guidelines for fairness, neutrality, principles of merit, and quality in the conduct of the program;
- Assisting in developing linkages to nonacademic entities such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials;
- Developing guidelines, criteria, and standards for the solicitation, review, and award of research grants and fellowships; and
- Developing and providing oversight regarding mechanisms for disseminating research results.[3]

At its inception, the program was intended to be supported by funds from the Lawton Chiles Endowment Fund,[4] but an appropriation amount was not specified in statute.[5] Funds appropriated to the program must be used to award grants and fellowships, for research relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, and administrative expenses.[6]

In 2001, the Legislature amended the purpose of the program, stating that the intent for the program was to provide an annual and perpetual source of funding to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease.[7] In 2003, the Florida Biomedical Research Program was renamed the "James and Esther King Biomedical Research Program" (King Program).[8]

Each fiscal year, $25 million from the revenue deposited into the Health Care Trust Fund pursuant to ss. 210.011(9) and 210.276(7), F.S., is reserved for research of tobacco-related or cancer-related illnesses. Of the revenue deposited in the Health Care Trust Fund, $25 million is transferred to the Biomedical Research Trust Fund within the DOH. Subject to annual appropriations in the General Appropriations Act, $5 million must be appropriated to the King Program.[9]

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[1] Chapter 99-167, Laws of Fla.
[2] Section 215.5602(3), F.S. The Biomedical Research Advisory Council consists of 11 members including, the chief executive officer of the Florida Division of the American Cancer Society, the chief executive officer of the Greater Southeast Affiliate of the American Heart Association, the chief executive officer of the American Lung Association of Florida, four members appointed by the Governor, two members appointed by the President of the Senate, and 2 members appointed by the Speaker of the House of Representatives.
[3] Section 215.5602(4), F.S.
[4] Section 215.5601(1)(d), F.S.
[5] *Supra* note 1.
[6] Section 215.5602(2), F.S.
[7] Chapter 2001-73, Laws of Fla.
[8] Chapter 2013-50, Laws of Fla.
[9] Section 215.5602(12), F.S.

In 2013, the Legislature created new reporting requirements within the King Program for entities that perform cancer research and receive an appropriation from the General Appropriations Act to perform biomedical research or to pay for research-related functions or operations. The report is required to be submitted to the President of the Senate and the Speaker of the House of Representatives by December 15 of each year and must:[10]

- Describe the general use of the state funds;
- Specify the research, if any, funded by the appropriation;
- Describe any fixed capital outlay project funded by the appropriation, the need for the project, how the project will be utilized, and the timeline for the status of the project, if applicable; and
- Identify any federal or private grants or donations generated as a result of the appropriation or activities funded by the appropriation, if applicable and traceable.[11]

Bankhead-Coley Program

In 2006, the Legislature created the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program) within the DOH. The purpose of the Bankhead-Coley Program was to advance progress towards cures for cancer through grant awards. The funds are distributed as grants to researchers seeking cures for cancer, with emphasis given to the efforts that significantly expand cancer research capacity in the state.[12] The goals of the Bankhead-Coley Program are to significantly expand cancer research and treatment in the state by:

- Identifying ways to attract new research talent and attendant national grant-producing researchers to cancer research facilities in this state;
- Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;
- Funding, through available resources, proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
- Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines to facilitate the full spectrum of cancer investigations;
- Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research;
- Aiding other multidisciplinary, research-support activities;
- Improving research and treatment through greater participation in clinical trials networks; and
- Reducing the impact of cancer on disparate groups.[13]

Each fiscal year, $25 million from the revenue deposited into the Health Care Trust Fund pursuant to ss. 210.011(9) and 210.276(7), F.S., is reserved for research of tobacco-related or cancer-related illnesses. Of the revenue deposited in the Health Care Trust Fund, $25 million is transferred to the Biomedical Research Trust Fund within the DOH. Subject to annual appropriations in the General Appropriations Act, $5 million must be appropriated to the Bankhead-Coley Program.[14]

In 2013, the Legislature created new reporting requirements for any entity which performs or is associated with cancer research or care that receives a specific appropriation for biomedical research, research-related functions, operations or other supportive functions, or expansion of operations in the General Appropriations Act, including entities receiving funds pursuant to the Bankhead-Coley

[10] *Id.*
[11] *Supra* note 8.
[12] Section 381.922(1), F.S.
[13] Section 381.922(2), F.S.
[14] Section 215.5602(12), F.S.

Program. The report is required to be submitted to the President of the Senate and the Speaker of the House of Representatives by December 15 of each year and must:

- Describe the general use of the state funds;
- Specify the research, if any, funded by the appropriation;
- Describe any fixed capital outlay project funded by the appropriation, the need for the project, how the project will be utilized, and the timeline for the status of the project, if applicable; and
- Identify any federal or private grants or donations generated as a result of the appropriation or activities funded by the appropriation, if applicable and traceable.[15]

Ed and Ethel Moore Alzheimer's Disease Research Program

The Florida Legislature created the Ed and Ethel Moore Alzheimer's Disease Research Program in 2014 (Moore Program).[16] The Moore Program is housed in the DOH and is administered by an 11 member board known as the Alzheimer's Disease Research Grant Advisory Board (Alzheimer's Disease Board). The program's purpose is to fund research leading to prevention of, or a cure for, Alzheimer's disease.[17]

The Alzheimer's Disease Board must submit recommendations for funding of research proposals to the State Surgeon General by December 15 of each year. Upon receiving consultation from the Alzheimer's Disease Board, the State Surgeon General is authorized to award grants on the basis of scientific merit. Applications for research funding may be submitted by any university or established research institute in the state, and all qualified investigators in the state must have equal access and opportunity to compete for research funding. The implementation of the program is subject to legislative appropriation. Statute specifies certain types of applications to be considered for funding, including:

- Investigatory-initiated research grants;
- Institutional research grants;
- Pre-doctoral and post-doctoral research fellowships; and
- Collaborative research grants, including those that advance the finding of cures through basic or applied research.[18]

In 2014, the Legislature appropriated $3,000,000 in general revenue funds to the Moore Program. By default, general revenue appropriations that remain unspent at the end of a fiscal year revert to the state.[19] However, the legislature may supersede this provision by passing a law that specifically authorizes the appropriation to be carried forward. The program awarded eleven grants ranging from $112,500 to $500,000, which fully expended the $3,000,000 appropriation for fiscal year 2014 - 2015.[20]

The Alzheimer's Disease Board is required to annually submit a fiscal-year progress report on the research program to the Governor, President of the Senate, Speaker of the House of Representatives, and the State Surgeon General by February 15. The report must include:

- A list of research projects supported by grants or fellowships awarded under the program;
- A list of recipients of program grants or fellowships;
- A list of publications in peer-reviewed journals involving research supported by grants or fellowships awarded under the program;
- The state ranking and total amount of Alzheimer's disease research funding currently flowing into the state from the National Institute of Health;

[15] *Supra* note 8.
[16] Chapter 2014-163, Laws of Fla.
[17] Section 381.82, F.S.
[18] *Id.*
[19] Section 216.301, F.S.
[20] Alzheimer's Disease Research Grant Advisory Board, *Annual Report 2014-2015*, pg. 4.

- New grants for Alzheimer's disease research which were funded based on research supported by grants or fellowships awarded under the program;
- Progress toward programmatic goals, particularly in the prevention, diagnosis, treatment, and cure of Alzheimer's disease; and
- Recommendations to further the mission of the program.[21]

Initial Licensure of Health Care Practitioners

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners.[22] The MQA works in conjunction with 22 boards and 6 councils to license and regulate 7 types of health care facilities and more than 40 health care professions.[23] Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory and licensure authority for the MQA.

Military Health Care Practitioners

An individual who serves or has served as a health care practitioner in the U.S. Armed Forces, U.S. Reserve Forces, or the National Guard on active duty or has served on active duty with the U.S. Armed Forces as a health care practitioner in the U.S. Public Health Service, is eligible for licensure in Florida.[24] The DOH is required to waive the application fee, licensure fee, and unlicensed fee for such applicants. The applicant will be issued a license to practice in Florida if the applicant submits a completed application, and:

- Receives an honorable discharge within the 6 months before or after submission of the application;
- Holds an active, unencumbered license issued by another state, the District of Columbia, or a U.S. territory or possession, with no disciplinary action taken against it in the 5 years preceding the date of application;
- 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 U.S. Department of Defense for a reason related to the practice of the profession for which he or she is applying;
- Has actively practiced the profession for which he or she is applying for the 3 years preceding the date of application; and
- Submits to a background screening, if required for the profession for which he or she is applying, and does not have any disqualifying offenses.[25]

The DOH offers the Veterans Application for Licensure Online Response System (VALOR) to provide expedited licensing for honorably discharged veterans with an active license in another state.[26] To qualify for VALOR, a veteran must apply for a license six months before or after his or her honorable discharge from the U.S. Armed Forces.[27]

Federal law authorizes a health care professional employed by the United States Armed Forces to practice his or her health profession in the District of Columbia or any state or territory of the United

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[21] Section 381.82(4), F.S.
[22] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.
[23] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2014-2015*, 3, *available at* http://mqawebteam.com/annualreports/1415/#6 (last visited Jan. 8, 2016).
[24] Section 456.024, F.S.
[25] Section 456.024(3)(a), F.S.
[26] *See* Department of Health, *Veterans*, *available at* http://www.floridahealth.gov/licensing-and-regulation/armed-forces/veterans/index.html (last visited Jan. 8, 2016).
[27] *Id.*

States if the health care professional has a current license to practice his profession and is performing authorized duties for the Department of Defense.[28] Military health care practitioners practice in private health care settings through the authority of a memorandum of understanding, a training affiliation agreement, or external resourcing sharing agreement entered into between the United States Department of Defense and the private health care entity.[29] One state, Nevada, explicitly authorizes hospitals to enter into such agreements with the military and exempts the military practitioners from Nevada's licensure requirements, if certain criteria are met by the practitioner.[30] Currently, under Florida law, a military health care practitioner would have to be licensed in Florida to practice in a private health care setting under such an agreement.

Disqualification of Certain Applicants for Licensure

Each board, or the DOH if there is no board, must refuse to admit a candidate to any examination, and refuse to issue a license, certificate, or registration to any applicant, if the candidate, applicant, or principal, officer, agent, managing employee, or affiliated person of an applicant:

- Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, certain specified felonies;[31]
- Has been terminated for cause from any Medicaid program; or
- Is listed on the U.S. Department of Health and Human Services' List of Excluded Individuals and Entities.[32]

Any of the above-referenced disqualifications do not apply to applicants for initial licensure or certification who were enrolled in a recognized educational or training program on or before July 1, 2009, and who applied for licensure after July 1, 2012.[33]

Section 456.0635(3), F.S., requires the DOH to refuse to renew the license, certificate, or registration of an applicant that would be disqualified for an initial license based on the disqualification criteria indicated above. However, according to the DOH, when it denies a license renewal pursuant to this section, licensees who meet the exception under s. 456.0635(2), F.S., may reapply and be granted a new license.[34] By utilizing this exception, licensees that would have otherwise been disqualified have been able to regain a license to practice. When the renewal cycle ends, those licensees will once again be denied pursuant to s. 456.0635(3), F.S., but would be eligible to reapply and obtain a license under the exception.[35]

HIV and AIDS Course Requirement

As a requirement for initial licensure, midwives, radiological personnel, clinical laboratory personnel, speech-language pathologists, and audiologists, must complete an education course on HIV and AIDS. If the applicant has not taken the course at the time of licensure and upon an affidavit showing good cause, an applicant may be granted 6 months to complete this requirement.[36]

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[28] 10 U.S.C. § 1094.
[29] These military training agreements set forth the parameters under which the military practitioner may practice and may include strict supervision requirements. Such parameters and the degree of control the private health care entity has over the military health care practitioner may determine whether the federal government or the private health care entity is liable when a legal challenge is made. See, for example, *McBee v. United States*, 101 Fed.Appx. 5, 6 (5th Cir.2004), *Banks v. United States*, 623 F.Supp.2d 751 (S.D.Miss.2009), and *Starnes v. U.S.*, 139 F.3d 540, 542 (5th Cir.1998).
[30] NRS 449.2455.
[31] Section 456.0635(2), F.S., provides a tiered timeframe for these individuals to apply for a license, certificate, or registration, depending on the severity of the crime and length of time elapsed between the crime and the date of application for licensure.
[32] Section 456.0635(2), F.S.
[33] *Id.*
[34] Department of Health, *2016 Agency Legislative Bill Analysis for House Bill 941* (Dec. 15, 2015), on file with the Health Quality Subcommittee.
[35] *Id.* This provision was adopted
[36] Section 381.0034, F.S.

Medical Errors Course Requirement

Section 456.013(7), F.S., requires that every health care practitioner regulated by the DOH complete an approved 2-hour course relating to the prevention of medical errors as part of the licensure and renewal process.

Continuing Education Requirements

Compliance with continuing education (CE) requirements is a condition of renewal of license for health care practitioners. Boards, or the DOH when there is no board, require each licensee to demonstrate competency by completing CEs during each licensure cycle. The number of required CE hours varies by profession. The requirements for CEs may be found in ch. 456, F.S., professional practice acts, administrative rules, or a combination of these references. Failure to comply with CE requirements may result in disciplinary action against the licensee, in accordance with the disciplinary guidelines established by the applicable board, or the DOH if there is no board.

The DOH or boards, when applicable, monitor heath care practitioner's compliance with the CE requirements in a manner required by statute. The statutes vary as to the as to the required method to use. For example, DOH or a board, when applicable, may have to randomly select a licensee to request the submission of CE documentation;[37] require a licensees to a submit sworn affidavit or statement attesting that he or she has completed the required CE hours,[38] or perform an audit. Licensees are responsible for maintaining documentation of the CE courses completed.

In 2001, the Legislature directed the DOH to implement an electronic CE tracking system that was to be integrated into the licensure and renewal systems.[39] In the initial phase of the system, the system allowed licensees to check compliance with CE requirements but did not prevent the renewal of the license if such requirements were not met. The DOH is currently in the second phase of integration, which requires a licensee to have entered and met all CE requirements before his or her license is renewed.[40] The DOH's electronic CE system eliminates the need for submission of affidavits, audits, and other methods of proof of completion of CE requirements.

Emergency Medical Technicians and Paramedics

The DOH, Division of Emergency Operations regulates emergency medical technicians (EMTs) and paramedics. "Emergency Medical Technician" is defined under s. 401.23, F.S., to mean a person who is certified by the DOH to perform basic life support.[41] "Paramedic" means a person who is certified by the DOH to perform basic and advanced life support.[42]

The National Emergency Medical Service (EMS) Education Standards define the minimal entry-level educational competencies, clinical behaviors, and judgments that must be met by Emergency Medical Service personnel to meet national practice guidelines.[43] The National EMS Education Standards assume there is a progression in practice from the entry-level Emergency Medical Responder level to the Paramedic level. That is, licensed personnel at each level are responsible for all knowledge,

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[37] For example, see s. 457.107, F.S.
[38] For example see ss.458.347(4)(e), 466.0135(6), 466.014, and 466.032(5), F.S.
[39] Chapter 2001-277, Laws of Fla.
[40] *Supra* note 34.
[41] "Basic life support" means the assessment or treatment by a person qualified under this part through the use of techniques described in the EMT-Basic National Standard Curriculum or the National EMS Education Standards of the United States Department of Transportation and approved by the DOH. The term includes the administration of oxygen and other techniques that have been approved and are performed under conditions specified by rules of the DOH.
[42] "Advanced life support" means assessment or treatment by a person qualified under this part through the use of techniques such as endotracheal intubation, the administration of drugs or intravenous fluids, telemetry, cardiac monitoring, cardiac defibrillation, and other techniques described in the EMT-Paramedic National Standard Curriculum or the National EMS Education Standards, pursuant to rules of the DOH.
[43] National Highway Traffic Safety Administration, Emergency Medical Services, Educational Standards and NSC: National Emergency Medical Services Education Standards, available at: http://www.ems.gov/EducationStandards.htm (last visited Jan. 19, 2016).

judgments, and behaviors at their level and at all levels preceding their level. According to these standards, there are four licensure levels of EMS personnel: Emergency Medical Responder; Emergency Medical Technician; Advanced Emergency Medical Technician; and Paramedic. For example, a paramedic is responsible for knowing and doing everything identified in that specific area, as well as knowing and doing all tasks in the three preceding levels.[44]

Under Florida law, an applicant for certification or recertification as an EMT or paramedic must:

- Have completed an appropriate training program as follows:
  - For an EMT, an EMT training program approved by the DOH as equivalent to the most recent EMT-Basic National Standard Curriculum or the National EMS Education Standards of the United States Department of Transportation; or
  - For a paramedic, a paramedic training program approved by the DOH as equivalent to the most recent EMT-Paramedic National Standard Curriculum or the National EMS Education Standards of the United States Department of Transportation;
- Certify under oath that he or she is not addicted to alcohol or any controlled substance;
- Certify under oath that he or she is free from any physical or mental defect or disease that might impair the applicant's ability to perform his or her duties;
- Within 2 years after program completion have passed an examination developed or required by the DOH;
- For an EMT, hold a current American Heart Association cardiopulmonary resuscitation course card or an American Red Cross cardiopulmonary resuscitation course card or its equivalent as defined by DOH rule;
- For a paramedic, hold a certificate of successful course completion in advanced cardiac life support from the American Heart Association or its equivalent as defined by DOH rule;
- Submit the certification fee and the nonrefundable examination fee prescribed in s. 401.34, F.S., which examination fee will be required for each examination administered to an applicant; and
- Submit a completed application to the DOH, which application documents compliance with the certification requirements.[45]

Certified Nursing Assistants

The Board of Nursing regulates certified nursing assistants (CNAs). To be certified as a CNA, an applicant must meet the education and training requirements as established in statute and by rule by the Board of Nursing, and successfully pass a background screening.[46] To maintain certification, a CNA must show proof of having completed in-service training hours, which are the equivalent of CE hours for other health care professions. Currently, a CNA must complete 12 hours of in-service training each calendar year.[47] CNA certificates are issued for a biennium with a May 31st expiration date.[48]

The Council on Certified Nursing Assistants (Council) was created under the Board of Nursing to assist in the oversight of CNAs.[49] The Council's duties include recommending policy and procedures for CNAs, proposing rules to implement training and certification requirements, making recommendations to the Board of Nursing regarding matters related to the certification of CNAs, and addressing concerns and problems of CNAs in order to improve safety in the practice of CNAs.[50] The Council is composed of five members:

- Two registered nurses appointed by the chair of the Board of Nursing;

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[44] *Id.*
[45] Section 401.27, F.S.
[46] *See* s. 464.203, F.S., and Rules 64B9-15.006 and 64B9-15.008, F.A.C.
[47] Section 464.203(7), F.S., and Rule 64B9-15.011, F.A.C.
[48] Rule 64B-11.001, F.A.C. *See also* Florida Board of Nursing, *Certified Nursing Assistant (CNA) Renewal Requirements*, *available at* http://floridasnursing.gov/renewals/certified-nursing-assistant/ (last visited Jan. 6, 2016).
[49] Section 464.2085, F.S.
[50] Section 464.2085(2), F.S.

- A licensed practical nurse appointed by the chair of the Board of Nursing; and
- Two CNAs appointed by the State Surgeon General.[51]

Historically, the Council met every 2 months in conjunction with the Board of Nursing at a cost of $40,000 per year.[52] However, the Council has not held a face-to-face meeting since 2013, and beginning in 2014, the Council meets only by telephone conference call on an as needed basis. The Board of Nursing and the Council support abolishment of the Council.[53]

Costs of Licensure Regulation

It is the intent of the Legislature that the costs associated with regulating health care professions and health care practitioners be borne by the licensees and the licensure applicants.[54] Further, it is the intent that no profession operate with a negative cash balance.[55] The boards, in consultation with the DOH, or the DOH if there is no board, is required to set licensure renewal fees by rule and which must:

- Be based on revenue projections;
- Be adequate to cover all expenses related to that board identified in the DOH's long-range plan;[56]
- Be reasonable, fair, and not serve as a barrier to licensure;
- Be based on potential earnings from working under the scope of the license;
- Be similar to fees imposed on similar licensure types; and
- Not be more than 10 percent greater than the actual cost to regulate that profession for the previous biennium.[57]

The chairpersons of the boards and councils must meet annually to review the long-range policy plan and the current and proposed fee schedules.[58] The chairpersons are required to make recommendations for any necessary statutory changes relating to fees and fee caps, which are to be included in the DOH's annual report to the Legislature.

All funds collected by the DOH from fees, fines, or costs awarded to the agency by a court are paid into the Medical Quality Assurance Trust Fund.[59] The DOH is prohibited from expending funds from one profession to pay expenses incurred on behalf of another profession, except that the Board of Nursing may pay for costs incurred in the regulation of CNAs.[60]

The DOH may adopt rules for advancing funds to a profession operating with a negative cash balance.[61] However, the advancement may not exceed two consecutive years and the regulated profession must pay interest at the current rate earned on trust funds used by the DOH to implement ch. 456, F.S. The interest earned is allocated to the various funds in accordance with the allocation of investment earnings. Each board, or the DOH if there is no board, may assess and collect a one-time fee from each active and inactive licensee, in an amount necessary to eliminate a cash deficit in the

[51] Section 464.2085(1), F.S.
[52] *Supra* note 34.
[53] *Id.*
[54] Section 456.025(1), F.S.
[55] Section 456.025(3), F.S.
[56] Pursuant to s. 456.005, F.S., the long-range policy plan is used to facilitate efficient and cost-effective regulation by evaluating whether the DOH is operating efficiently and effectively and if there is a need for a board or council to assist in cost-effective regulation; how and why the various professions are regulated; whether is a need to continue regulation and to what degree; whether or not consumer protection is adequate and how it can be approved; whether there is consistency between the various practice acts; and whether unlicensed activity is adequately enforced.
[57] *Supra* note 54.
[58] Section 456.025(2), F.S.
[59] Section 456.025(8), F.S.
[60] *Id.*
[61] *Supra* note 54.

profession, or if there is no deficit, to maintain the financial integrity of the profession.[62] Only one such assessment may be made in any 4-year period.

According to the DOH, four one-time assessments have been imposed in the past 10 years, for the following professions:

- Electrolysis in fiscal year 2005-2006, in the amount of $1,306;
- Nursing Home Administrators in fiscal year 2005-2006, in the amount of $200;
- Dentistry in fiscal year 2007-2008, in the amount of $250; and
- Midwifery in fiscal year 2008-2009, in the amount of $250.[63]

Three professions operate in a chronic deficit. Each of these professions is at its statutory fee cap, and according to the DOH, the licensure base is not large enough to generate enough revenue to cover expenditures.[64] The professions and the deficit amount under which they operate are:

Profession	Cash Balance	Renewal Fee	Statutory Fee Cap	Total Licenses
Dentistry	$ (2,144,333)	$ 300	$ 300	14,285
Electrologists	$ (638,545)	$ 100	$ 100	1,591
Midwifery	$ (900,155)	$ 500	$ 500	206

If the boards or the DOH were to impose a one-time assessment to eliminate the deficit and result in solvency through FY 19-20, the amount per licensee would be:

- Dentistry - $450 per active/inactive licensee;
- Electrolysis - $900 per active/inactive licensee; and
- Midwifery - $5,500 per active/inactive licensee.[65]

Patient Records

Upon the death or incapacitation of a practitioner or abandonment of medical records by a practitioner, the board, or the DOH if there is no board, may temporarily or permanently appoint a custodian of records.[66] The records custodian is required to comply with all recordkeeping requirements of s. 456.057, F.S., including maintaining the confidentiality of patient records except upon written authorization by the patient or by operation of law.

According to the DOH, 10 times per year or more, patient records are abandoned, mostly due to the death or incarceration of a practitioner, and patients are unable to access their medical records.[67] The DOH attempts to secure the records but does not have the resources available to assume control and release the records to the patients.[68]

Dispensing Practitioner Facility Inspections

The DOH is required to inspect any facility where a dispensing practitioner dispenses medicinal drugs, in the same manner and frequency as it inspects pharmacies, to determine whether the practitioner is in compliance with all applicable statutes and rules.[69] In its annual inspection of the facility, the DOH

[62] Section 456.025(5), F.S.
[63] *Supra* note 34 at 5.
[64] *Id.*
[65] *Id.*
[66] Section 456.057(20), F.S.
[67] *Supra* note 34.
[68] *Id.*
[69] Section 465.0276(3), F.S.

reviews compliance with requirements related to registration, labeling and storing drugs, recordkeeping, and other safety, quality, and security requirements.[70]

Dispensing practitioners may not dispense Schedule II or Schedule III controlled substances, except:

- In the health care system of the Department of Corrections;
- In connection with a surgical procedure and limited to a 14-day supply;
- In an approved clinical trial;
- In a facility, licensed under s. 397.427, F.S., providing medication-assisted treatment for opiate addiction;
- In a hospice facility, licensed under part IV of chapter 400, F.S.[71]

The DOH indicates that during the last two fiscal years, it has conducted 15,062 dispensing practitioner inspections with a passing rate of 99 percent.[72]

Advisory Council of Medical Physicists

The Advisory Council of Medical Physicists (council) is a nine-member board, created in 1997, to advise the DOH in the regulation of the practice of medical physics.[73] The responsibilities of the council include recommending rules to regulate the practice of medical physics, practice standards, and CE requirements.[74]

The council fulfilled its initial statutory requirements in making recommendations for the initial development of rules, practice standards, and CE requirements, and last met in December 1998.[75] The State Surgeon General appointed new members to the council in 2015 and the council met for the first time in 17 years. The DOH estimates that a face-to-face meeting of the council is $3,535 per meeting. The DOH advises that an Advisory Council on Radiation Protection, which includes medical physicists among its members, may be used in lieu of the council for guidance on matters of practice and public safety.[76]

Effect of Proposed Changes

The bill revises the regulation of various health care practitioners and programs under the jurisdiction of the DOH.

Florida Biomedical Research Programs

The bill creates additional reporting requirements for the Biomedical Research Advisory Council (BRAC), which relate to any biomedical research grant awarded under the James and Esther King Biomedical Research Program (King Program) or the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, or to an appropriation made to an entity performing biomedical research from the General Appropriations Act. Specifically the BRAC must report to the Governor, the State Surgeon General, the President of the Senate, and the Speaker of the House of Representatives, by December 15 each year, the following additional information:

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[70] Florida Department of Health, *Inspection Forms*, *available at* http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html (last visited Jan. 12, 2016). Click on "Dispensing Practitioners" to view the inspection checklist; the form lists the legal authority for each item.
[71] Section 465.0276(1)(b), F.S.
[72] *Supra* note 34 at 8.
[73] Section 483.901(4), F.S. Section 483.901(3)(h), F.S., defines medical physics is a branch of physics associated with the practice of medicine, and includes the fields of diagnostic radiological physics, medical nuclear radiological physics, and medical health physics.
[74] Section 483.901(5), F.S.
[75] *Supra* note 34 at 9.
[76] *Id.*

- The status of the research and whether it has concluded;
- The results or expected results of the research;
- The names of principal investigators performing the research;
- The title, citation, and summary of findings of a publication in a peer reviewed journal resulting from the research;
- The status of a patent, if any, generated from the research and an economic analysis of the impact of the resulting patent;
- A list of postsecondary educational institutions involved in the research, a description of each postsecondary educational institution's involvement in the research, and the number of students receiving training or performing research;
- A description of any fixed capital outlay project funded by the appropriation, the need for the project, how the project will be utilized, and the timeline for and status of the project, if applicable; and
- The identity of state or local government grants or donations generated as a result of the appropriation or activities funded by the appropriation, if applicable and traceable.

The bill also requires the Alzheimer's Disease Research Grant Advisory Board of the Ed and Ethel Moore Alzheimer's Disease Research Program to report the above information annually, by February 15, to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General. The bill also allows the balance of any appropriation from the General Revenue fund for the Ed and Ethel Moore Alzheimer's Disease Research Program, which has not been disbursed, but which is obligated by contract or otherwise, to be carried forward for up to 5 years after the initial appropriation. This would prevent the disruption of the funding of biomedical research that has been contractually obligated for more than a fiscal year.

Initial Licensure of Health Care Practitioners

Military and Military Spouse Health Care Practitioners

The bill authorizes the DOH to waive fees and issue a health care practitioner license to an active duty member of the military, who applies 6 months before or after an honorable discharge, in a profession for which licensure is not required in another state.[77] However, the applicant must provide evidence of military training or experience substantially equal to the requirements for licensure in Florida, and proof of a passing score on the appropriate examination of a national or regional standards organization, if required for licensure in Florida.

The bill also authorizes the DOH to issue a health care practitioner license to the spouse of an active duty military member in a profession that may not require a license in another state and allows the applicant to apply in the same manner as those military members applying for a health care practitioner license within 6 months of an honorable discharge, meaning the military spouse applicant will not be subject to application fees and will have a truncated application process. As is required for military applicants, the military spouse applicant who is not licensed in another state must provide evidence of training or experience equivalent to the requirements for licensure in Florida and provide proof of a passing score on the appropriate exam of a national or regional standards organization, if required for licensure in Florida. The bill repeals the law pertaining to temporary licensure of military spouses to conform to the new full-licensure provisions of the bill for military spouses.

The bill allows military health care practitioners who are practicing under a military platform, which is a training agreement with a nonmilitary health care provider, to be issued a temporary certificate from

[77] According to the DOH, professions not licensed in all states and jurisdictions, but are licensed in Florida, include: respiratory therapists and assistants, clinical laboratory personnel, medical physicists, opticians, athletic trainers, electrologists, nursing home administrators, midwives, orthotists and assistants, prosthetists and assistants, pedorthotists and assistants, orthotic fitters and assistants, certified chiropractic physician assistants, and pharmacy technicians. *Supra* note 34 at 3.

DOH, which authorizes the practitioner to practice in this state for up to 6 months. This would allow military health care practitioners to develop and maintain technical proficiency in their profession.

The bill includes certain safeguards to ensure military health care practitioners applying for a temporary certificate will competently and safely practice in nonmilitary health care settings. An applicant who has been convicted of a felony or misdemeanor related to the practice of a health care profession, who has had a health care provider license revoked or suspended in another jurisdiction, who has failed the Florida licensure examination for his or her profession, or who is under investigation in another jurisdiction for an act that constitutes a violation under a Florida practice act, is ineligible to apply for a temporary certificate. Upon application, the bill requires the military health care practitioner seeking a temporary certificate to:

- Submit proof that he or she will practice pursuant to a military platform;
- Submit a complete application and a nonrefundable application fee not to exceed $50;
- Hold a valid and unencumbered license to practice as a health care professional in another state, the District of Columbia, or a possession or territory of the United States, or is a military health care practitioner in a profession for which licensure in a state or jurisdiction is not required for practice in the military and who provides evidence of training and experience substantially equivalent to the requirements for licensure in this state for that profession;
- Attest that he or she is not, at the time of application, the subject of a disciplinary proceeding in another jurisdiction or by the United States Department of Defense for reasons related to the practice of the profession for which he or she is applying;
- Be determined to be competent in the profession for which they are applying for a temporary certificate; and
- Submit a set of fingerprints for a background screening, if required in this state for a profession for which he or she is applying for a temporary certificate.

Disqualification of Certain Applicants for Licensure

Current law requires the DOH to deny the initial licensure application or renewal application of any health care practitioner who has been convicted of certain felonies or excluded from participating in governmental health programs. The bill deletes a provision that allows certain felons, individuals terminated for cause from any state's Medicaid program, or individuals listed on the U.S. Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities, to obtain a license in Florida. The deletion of this provision will prevent those denied licensure renewal based on one of these offenses from re-applying and obtaining a new license based on the exemption.

HIV and AIDS Course Requirement

The bill repeals the requirement that radiological personnel, speech-language pathologists, and audiologists complete a course on HIV and AIDS prior to licensure. According to the DOH, this will accelerate the initial licensure process and reduce costs to licensees.[78] Midwives and clinical laboratory personnel must still meet this requirement for licensure.

Medical Errors Course Requirement

The bill eliminates the requirement that health care practitioners complete a 2-hour course on medical errors before a license may be issued; but maintains the requirement for biennial renewal.

Continuing Education Requirements

The bill creates s. 456.0361, F.S., and relocates the requirement that DOH establish an electronic continuing education (CE) tracking system to the newly created section of law. The bill prohibits the

[78] *Supra* note 34 at 9.

DOH from issuing a license renewal if the licensee has not complied with applicable CE requirements. The boards and the DOH may impose additional penalties, as authorized by statute or rule, for noncompliance with CE requirements. The DOH is granted rulemaking authority for implementation of this provision.

The bill simplifies the CE reporting requirements for certain practitioners to conform with the electronic CE tracking system. For acupuncturists, physician assistants, optometrists, dentists, dental hygienists, dental laboratories, hearing aid specialists, and physical therapists, the bill eliminates procedures for proving compliance with CE requirements, such as the submission of an affidavit or written statement attesting to the completion of the required CEs. The bill also eliminates the DOH's authority to request that a licensee produce documentation of his or her CEs.

Emergency Medical Technicians and Paramedics

The bill permits the certificates for emergency medical technicians (EMTs) and paramedics to remain in an inactive status for up to two renewal periods (4 years) rather than expiring after 180 days. Additionally, the bill exempts out-of-state or military-trained EMTs or paramedics from the certification examination required by the DOH if the EMT or paramedic is nationally certified or registered.

Certified Nursing Assistants

The bill repeals s. 464.2085, F.S., to abolish the Council on Certified Nursing Assistants, under the Board of Nursing. The Council currently meets by telephone conference call, on an as needed basis. Historically, the Board met every two months, in conjunction with Board of Nursing meetings, at an estimated cost of $40,000 per year. According to the DOH, the Board of Nursing, in conjunction with stakeholders, has the knowledge and experience to undertake the promulgation of rules for the CNAs. The Board of Nursing and the Council on Certified Nursing Assistants support this repeal.[79]

The bill also amends the reporting schedule for CE for CNAs from annual to biennial to align the renewal cycle for the profession.

Medical Physicists

The bill abolishes the Advisory Council of Medical Physicists (council), which was created to advise the DOH in the regulation of the practice of medical physics. The council fulfilled its initial statutory duties by making recommendations for the initial development of rules, practice standards, and CE requirements. The State Surgeon General appointed new members to the council in 2015 and council met for the first time in 17 years. The DOH estimates that a face-to-face meeting of the council is $3,535 per meeting. The DOH advises that an Advisory Council on Radiation Protection includes medical physicists among its members and that group may be used for guidance on matters of practice and public safety.[80]

Dispensing Practitioner

The bill eliminates the inspection by the DOH of the facilities of a dispensing practitioner. The dispensing practitioner must continue to comply with all applicable statutes and rules. However, a dispensing practitioner will not be subject to an inspection by the DOH within specified timeframes. The DOH retains the authority to inspect the facilities of a dispensing practitioner at such time as the DOH determines it is necessary.[81]

[79] *Supra* note 34 at 8.
[80] *Supra* note 34.
[81] *See* s. 456.069, F.S.

Costs of Regulation

The bill creates a mechanism to eliminate the cash deficit of professions that have operated in a deficit for two or more years and are at their statutory fee cap. The bill allows the DOH to waive allocated administrative and indirect operational costs until such profession has a positive cash balance. Administrative and operational costs include costs associated with:

- The director's office;
- System support;
- Communications;
- Central records; and
- Other administrative functions.

The waived costs are to be allocated to the other professions. The bill also authorizes the transfer of unused funds in the deficit profession's unlicensed activity account to help reduce the deficit.

The bill also removes from law:

- The requirement that the chairpersons of the boards and councils meet annually to review the DOH's long-range plan and the current and proposed fee schedules, and make recommendations for any necessary statutory changes relating to fees and fee caps to be included in DOH's annual report to the Legislature;
- The requirement that the DOH set license fees, on behalf of a board that fails to act timely, to cover anticipated deficits and maintain the required cash balance;
- The DOH's rulemaking authority for authorizing advances, with interest, to a profession operating with a negative case balance;
- The prohibition against using funds from the account of a profession to pay for the expenses of another profession; and
- A requirement that the DOH include in its annual report to the Legislature, a condensed report of the revenue and allocated expenses of each profession, along with the DOH's recommendations.

Patient Records

The bill permits the DOH to contract with a third party to become the custodian of medical records in the event of a practitioner's death, incapacitation, or abandonment of the medical records, under the same confidentiality and disclosure requirements imposed on a licensee. The bill requires board-appointed medical records custodians to be approved by the DOH.

The bill makes other technical and conforming changes.

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

B. SECTION DIRECTORY:

Section 1. Amends s. 215.5602, F.S., relating to the James and Esther King Biomedical Research Program.
Section 2. Amends s. 381.0043, F.S., relating to the requirement for instruction on HIV and AIDS.
Section 3. Amends s. 381.82, F.S., relating to the Ed and Ethel Moore Alzheimer's Disease Research Program.
Section 4. Amends s. 381.922, F.S., relating to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.
Section 5. Amends s. 401.27, F.S., relating to personnel; standards and certification.
Section 6. Amends s. 456.013, F.S., relating to the Department of Health and general licensing provisions.

Section 7. Amends s. 456.024, F.S., relating to members of the Armed Forces in good standing with administrative boards or the department; spouses; licensure.
Section 8. Creates s. 456.0241, F.S., relating to temporary certificates for active duty military health care practitioners.
Section 9. Amends s. 456.025, F.S., relating to fees, receipts, and disposition.
Section 10. Creates s. 456.0361, F.S., relating to compliance with continuing education requirements.
Section 11. Amends s. 456.057, F.S., relating to ownership and control of patient records; report or copies of records to be furnished; disclosure of information.
Section 12. Amends s. 456.0635, F.S., relating to health care fraud; disqualification for license, certificate, or registration.
Section 13. Amends s. 457.107, F.S., relating to renewal of licenses; continuing education.
Section 14. Amends s. 458.347, F.S., relating to physician assistants.
Section 15. Amends s. 463.007, F.S., relating to renewal of license; continuing education.
Section 16. Amends s. 464.203, F.S., relating to certified nursing assistants; certification requirement.
Section 17. Repeals s. 464.2085, F.S., relating to the Council on Certified Nursing Assistants.
Section 18. Amends s. 456.0276, F.S., relating to the dispensing practitioner.
Section 19. Amends s. 466.0135, F.S., relating to continuing education; dentists.
Section 20. Amends s. 466.014, F.S., relating to continuing education; dental hygienists.
Section 21. Amends s. 466.032, F.S., relating to registration.
Section 22. Repeals s. 468.1201, F.S., relating to the requirement for instruction on human immunodeficiency virus and acquired immune deficiency syndrome.
Section 23. Amends s. 483.901, F.S., relating to medical physicists; definitions; licensure.
Section 24. Amends s. 484.047, F.S., relating to renewal of license.
Section 25. Amends s. 486.109, F.S., relating to continuing education.
Section 26. Amends s. 499.028, F.S., relating to drug samples or complimentary drugs; starter packs; permits to distribute.
Section 27. Amends s. 921.0022, F.S., relating to the Criminal Punishment Code; offense severity ranking chart.
Section 28. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Military Health Care Practitioners

The revenues from health care practitioner licensure fees will be reduced due to the expansion of fee waivers for military spouses applying for licensure. The bill also allows the DOH to assess up to a $50 application fee and renewal fee for temporary certificates for active duty military health care professionals. The DOH has the authority to waive the fee, yet if assessed, the fee revenues generated would support the regulatory expenses of the licenses. Since the implementation of current legislation granting fee waivers for honorably discharged veterans, the department has issued 150 licenses for a total of $55,017 in unrealized revenue. Since implementation of legislation granting temporary licenses for military spouses, the department has issued 112 temporary licenses.[82]

Dispensing Practitioner Facility Inspections

The bill amends the requirement for inspecting a dispensing practitioner's location and instead allows the department to inspect at such times as the department determines it is necessary as a random, unannounced inspection or during the course of an investigation. Each registered dispensing practitioner is assessed a $100 fee at the time of registration and again upon the

[82] *Supra* note 34.

renewal of their license to cover the cost of inspections. The loss of revenue would be the result of 2,984 dispensing practitioners not being assessed the biannual fee for a calculated total annual loss in revenue of $149,200.[83]

2. Expenditures:

Military Health Care Practitioners

The DOH may experience a recurring increase in workload associated with the expanded eligibility criteria of the military fee waiver for health care professional licensure. The number of qualified applicants who will apply for licensure is indeterminate however, it is anticipated that current resources are adequate to absorb the impact.

Dispensing Practitioner Facility Inspections

The bill is anticipated to have an insignificant, positive fiscal impact on the DOH with the elimination of annual inspections of the facilities of dispensing practitioners. In Fiscal Year 2014-2015, the DOH conducted 7,800 inspections of dispensing practitioner locations at an estimated cost of approximately $75 per inspection with an annual cost savings of $597,706.[84]

Advisory Councils

The DOH may realize costs savings resulting from the elimination of the Council on Certified Nursing Assistants and the Advisory Council of Medical Physicists. The annual cost of face-to-face meetings of the Council on Certified Nursing Assistants is approximately $40,000. The per-meeting cost of the Advisory Council of Medical Physicists is $3,535.[85]

DOH Record Retention

The bill will have an insignificant, negative fiscal impact on the DOH, to pay for annual storage costs for medical records the DOH would have to retain in the event of a practitioner's death, incapacitation, or abandonment. The annual contractual cost is estimated to be $4,020 which current resources are adequate to absorb.[86]

The bill may have an insignificant, negative fiscal impact on the DOH, associated with the promulgation of rules to implement its electronic continuing education tracking system.

The DOH may incur a negative fiscal impact associated with providing administrative support to the BRAC to comply with the bill's new reporting requirements pertaining to biomedical research grants.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

[83] E-mail Correspondence with the Department of Health, (January 29, 2016), on file with the Health Care Appropriations Subcommittee.
[84] *Supra* note 34.
[85] *Id.*
[86] *Id.*

HIV and AIDS Course Requirement

With the elimination of the requirement to complete an HIV/AIDS course and medical errors course prior to licensure, affected licensees may incur less expense when applying for licensure. The course for these professions costs approximately $135 and the total cost savings to applicants in Fiscal Year 2014-2015 was $145,800 for Clinical Laboratory Personnel, $3,375 for Midwives, and $295,065 for Radiologic Technologists and Radiologist Assistants.[87]

Military Health Care Practitioners

The bill expands fee waivers for military spouses and military health care practitioners who will incur less expense when applying for permanent medical professional licensure.

Active duty military health care professionals may incur an additional cost if the DOH implements a $50 application fee and renewal fee for temporary health care licensure.

Dispensing Practitioner

A medical practitioner will experience a cost savings due to the bill eliminating the $100 fee assessed at the time of registration and again upon the renewal of the dispensing practitioner license.

Medical Research Grants

The bill allows the Ed and Ethel Moore Alzheimer's Disease Research Program to carry forward unspent general revenue appropriations up to five years allowing research projects to span multiple years. This will enable the department to offer longer grant periods, thus enabling researchers to benefit from having access to allocated grant funds over the course of a five-year period.

D. FISCAL COMMENTS:

Costs of Licensure Regulation

The bill allows the DOH to waive allocated administration and operational indirect costs for professions which operate in a chronic deficit and reallocate those costs to other solvent professions. The total amount of the deficit is $3,682,993 with deficit professions being dentistry, electrolysis, and midwifery. Current law allows each board or the department to assess and collect a one-time fee from each active status licensee and each inactive status licensee in an amount necessary to eliminate a cash deficit. The boards have imposed 4 one-time assessments in the past 10 years ranging from $1,306 to $200.[88]

The department's analysis of the fiscal impact of the reallocation of administrative costs included in the bill implements both a one-time assessment combined with a administrative reallocation as a strategy for achieving fiscal solvency. These two solutions implemented simultaneously would result in the following fees and waivers to be assessed:

- Dentistry would assess a fee of $450 and would waive administrative costs of approximately $600,000 for one fiscal year to reach solvency by June 30, 2016 and based on a six year projection remain solvent.

- Electrolysis would assess a fee of $450 and would waive administrative costs of approximately $40,000 for three fiscal years to reach solvency by June 30, 2016 and based on a six year projection, remain solvent.

[87] *Supra* note 34.
[88] *Id.*

- Midwifery would assess a fee of $4,700 to the program's total 206 licensees and would waive administrative costs of approximately $15,000 for all six years to show an increasing trend to solvency.[89]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill grants the DOH authority to promulgate rules to implement the electronic tracking of continuing education requirements.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 19, 2016, the Health Quality Subcommittee adopted a strike all amendment and an amendment to the strike all amendment. Together, the amendments made the following changes:

- Requires the state-funded biomedical research grant programs to report to the Governor and Legislature about the research being performed, the use of state funds, and the return on the state's investment.
- Allows the balance of any appropriation from the General Revenue fund for the Ed and Ethel Moore Alzheimer's Disease Research Program which has not been disbursed, but which is obligated by contract or otherwise, to be carried forward for up to 5 years after the initial appropriation.
- Revises the eligibility criteria for military health care practitioners to receive a license in this state by allowing those who meet equivalent training and education requirements and who have taken a national or regional examination to be qualified.
- Authorizes spouses of active duty military members who are health care practitioners to become eligible for licensure in this state if they meet certain criteria and repeals temporary licensure provisions for military spouses.
- Allows military health care practitioners who are practicing under a military platform (training agreement with a nonmilitary health care provider) to be issued a temporary certificate to practice in this state.
- Removes the section pertaining to the impaired practitioner treatment program.
- Permits the certificates for emergency medical technicians (EMTs) and paramedics to remain in an inactive status for up to two renewal periods rather than expiring after 180 days.
- Exempts out of out-of-state or military-trained EMTs or paramedics from the certification examination required by the DOH, if the EMT or paramedic is nationally certified or registered.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

[89] *Supra* note 34.

A bill to be entitled

An act relating to the Department of Health; amending s. 215.5602, F.S.; revising the reporting requirements for the Biomedical Research Advisory Council under the James and Esther King Biomedical Research program; revising the reporting requirements for certain entities that perform or are associated with cancer research or care; amending s. 381.0034, F.S.; deleting the requirement that applicants making initial application for certain licensure complete certain courses; amending s. 381.82, F.S.; revising the reporting requirements for the Alzheimer's Disease Research Grant Advisory Board under the Ed and Ethel Moore Alzheimer's Disease Research Program; providing for the carryforward for a limited period of any unexpended balance of an appropriation for the program; amending s. 381.922, F.S.; providing reporting requirements for the Biomedical Research Advisory Council under the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; amending s. 401.27, F.S.; increasing the length of time that an emergency medical technician or paramedic certificate may remain in an inactive status; revising the requirements for reactivating and renewing such a certificate; revising eligibility for certification; deleting a requirement that applicants successfully

complete a certification examination within a specified timeframe; amending s. 456.013, F.S.; revising course requirements for renewing a certain license; amending s. 456.024, F.S.; revising the eligibility criteria for a member of the United States Armed Forces, the United States Reserve Forces, or the National Guard and the spouse of an active duty military member to be issued a license to practice as a health care practitioner in this state; deleting provisions relating to temporary professional licensure for spouses of active duty members of the United States Armed Forces; creating s. 456.0241, F.S.; providing definitions; providing for issuance of a temporary certificate under certain conditions for certain military health care practitioners; providing for the automatic expiration of the temporary certificate unless renewed; providing for application and renewal fees; requiring the department to adopt rules; amending s. 456.025, F.S.; deleting the requirement for an annual meeting of chairpersons of Division of Medical Quality Assurance boards and professions; deleting a requirement that certain recommendations be included in a report to the Legislature; deleting a requirement that the department set license fees and recommend fee cap increases in certain circumstances; authorizing a

profession to operate at a deficit for a certain time period; deleting a provision authorizing the department to advance funds under certain circumstances; deleting a requirement that the department implement an electronic continuing education tracking system; authorizing the department to waive specified costs under certain circumstances; deleting legislative intent; deleting a prohibition against the expenditure of funds by the department from the account of a profession to pay for the expenses of another profession; deleting a requirement that the department include certain information in an annual report to the Legislature; creating s. 456.0361, F.S.; requiring the department to establish an electronic continuing education tracking system; prohibiting the department from renewing a license unless the licensee has complied with all continuing education requirements; authorizing the department to adopt rules; amending s. 456.057, F.S.; requiring a person or entity appointed by the board as a custodian of medical records to be approved by the department; authorizing the department to contract with a third party to provide custodial services; amending s. 456.0635, F.S.; deleting a provision on applicability relating to the issuance of licenses; amending s. 457.107, F.S.; deleting a provision authorizing the

Board of Acupuncture to request certain documentation from applicants; amending s. 458.347, F.S.; deleting a requirement that a physician assistant file a signed affidavit with the department; amending s. 463.007, F.S.; making technical changes; amending s. 464.203, F.S.; revising inservice training requirements for certified nursing assistants; repealing s. 464.2085, F.S., relating to the Council on Certified Nursing Assistants; amending s. 465.0276, F.S.; deleting a requirement that the department inspect certain facilities; amending s. 466.0135, F.S.; deleting a requirement that a dentist file a signed affidavit with the department; deleting a provision authorizing the Board of Dentistry to request certain documentation from applicants; amending s. 466.014, F.S.; deleting a requirement that a dental hygienist file a signed affidavit with the department; deleting a provision authorizing the board to request certain documentation from applicants; amending s. 466.032, F.S.; deleting a requirement that a dental laboratory file a signed affidavit with the department; deleting a provision authorizing the department to request certain documentation from applicants; repealing s. 468.1201, F.S., relating to a requirement for instruction on human immunodeficiency virus and acquired immune deficiency syndrome; amending s.

483.901, F.S.; deleting provisions relating to the Advisory Council of Medical Physicists; authorizing the department to issue temporary licenses in certain circumstances; authorizing the department to adopt rules; amending s. 484.047, F.S.; deleting a requirement for a written statement from an applicant in certain circumstances; amending s. 486.109, F.S.; deleting a provision authorizing the department to conduct a random audit of certain information; amending ss. 499.028 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. Subsections (10) and (12) of section 215.5602, Florida Statutes, are amended to read:

215.5602 James and Esther King Biomedical Research Program.—

(10) The council shall submit a fiscal-year progress report on the programs under its purview to the Governor, the State Surgeon General, the President of the Senate, and the Speaker of the House of Representatives by December 15. The report must include:

(a) For each ~~A list of~~ research project ~~projects~~ supported by grants or fellowships awarded under the program:~~.~~

1.~~(b)~~ A summary ~~list~~ of the research project and results

or expected results of the research ~~recipients of program grants or fellowships~~.

2. The status of the research project, including whether it has concluded or the estimated date of completion.

3. The amount of the grant or fellowship awarded and the estimated or actual cost of the research project.

4.~~(c)~~ A list of principal investigators under the research project.

5. The title, citation, and summary of findings of a publication ~~publications~~ in a peer-reviewed journal resulting from the ~~peer reviewed journals involving~~ research ~~supported by grants or fellowships awarded under the program~~.

6.~~(d)~~ The source and amount of any federal, state, or local government grants or donations or private grants or donations generated as a result of the research project.

7. The status of a patent, if any, generated from the research project and an economic analysis of the impact of the resulting patent.

8. A list of postsecondary educational institutions involved in the research project, a description of each postsecondary educational institution's involvement in the research project, and the number of students receiving training or performing research under the research project.

(b) The state ranking and total amount of biomedical research funding currently flowing into the state from the National Institutes of Health.

~~(e) New grants for biomedical research which were funded based on research supported by grants or fellowships awarded under the program.~~

(c) ~~(f)~~ Progress towards programmatic goals, particularly in the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

(d) ~~(g)~~ Recommendations to further the mission of the programs.

(12)(a) Each ~~Beginning in the 2011-2012~~ fiscal year ~~and thereafter~~, $25 million from the revenue deposited into the Health Care Trust Fund pursuant to ss. 210.011(9) and 210.276(7) shall be reserved for research of tobacco-related or cancer-related illnesses. Of the revenue deposited in the Health Care Trust Fund pursuant to this section, $25 million shall be transferred to the Biomedical Research Trust Fund within the Department of Health. Subject to annual appropriations in the General Appropriations Act, $5 million shall be appropriated to the James and Esther King Biomedical Research Program, and $5 million shall be appropriated to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created under s. 381.922.

(b) ~~Beginning July 1, 2014,~~ An entity that ~~which~~ performs or is associated with cancer research or care that receives a specific appropriation for biomedical research, research-related functions, operations or other supportive functions, or

expansion of operations in the General Appropriations Act without statutory reporting requirements for the receipt of those funds~~,~~ must submit an annual fiscal-year progress report to the President of the Senate and the Speaker of the House of Representatives by December 15. The report must:

1. Describe the general use of the funds.

2. Summarize ~~Specify~~ the research, if any, funded by the appropriation and provide the:

a. Status of the research, including whether the research has concluded.

b. Results or expected results of the research.

c. Names of principal investigators performing the research.

d. Title, citation, and summary of findings of a publication in a peer-reviewed journal resulting from the research.

e. Status of a patent, if any, generated from the research and an economic analysis of the impact of the resulting patent.

f. List of postsecondary educational institutions involved in the research, a description of each postsecondary educational institution's involvement in the research, and the number of students receiving training or performing research.

3. Describe any fixed capital outlay project funded by the appropriation, the need for the project, how the project will be utilized, and the timeline for and status of the project, if applicable.

4. Identify any federal, state, or local government grants or donations or private grants or donations generated as a result of the appropriation or activities funded by the appropriation, if applicable and traceable.

Section 2. Subsection (3) of section 381.0034, Florida Statutes, is amended to read:

381.0034 Requirement for instruction on HIV and AIDS.—

(3) The department shall require, as a condition of granting a license under chapter 467 or part III of chapter 483 ~~the chapters specified in subsection (1)~~, that an applicant making initial application for licensure complete an educational course acceptable to the department on human immunodeficiency virus and acquired immune deficiency syndrome. Upon submission of an affidavit showing good cause, an applicant who has not taken a course at the time of licensure shall~~, upon an affidavit showing good cause,~~ be allowed 6 months to complete this requirement.

Section 3. Subsection (4) of section 381.82, Florida Statutes, is amended, and subsection (8) is added to that section, to read:

381.82 Ed and Ethel Moore Alzheimer's Disease Research Program.—

(4) The board shall submit a fiscal-year progress report on the programs under its purview annually to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General by February 15.

The report must include:

(a) For each ~~A list of~~ research project ~~projects~~ supported by grants or fellowships awarded under the program:~~.~~

1.~~(b)~~ A summary ~~list~~ of the research project and results or expected results of the research ~~recipients of program grants or fellowships~~.

2. The status of the research project, including whether it has concluded or the estimated date of completion.

3. The amount of the grant or fellowship awarded and the estimated or actual cost of the research project.

4.~~(c)~~ A list of principal investigators under the research project.

5. The title, citation, and summary of findings of a publication ~~publications~~ in a peer-reviewed journal resulting from the ~~journals involving~~ research ~~supported by grants or fellowships awarded under the program~~.

6.~~(d)~~ The source and amount of any federal, state, or local government grants or donations or private grants or donations generated as a result of the research project.

7. The status of a patent, if any, generated from the research project and an economic analysis of the impact of the resulting patent.

8. A list of postsecondary educational institutions involved in the research project, a description of each postsecondary educational institution's involvement in the research project, and the number of students receiving training

or performing research under the research project.

(b) The state ranking and total amount of Alzheimer's disease research funding currently flowing into the state from the National Institutes of Health.

~~(e) New grants for Alzheimer's disease research which were funded based on research supported by grants or fellowships awarded under the program.~~

(c)~~(f)~~ Progress toward programmatic goals, particularly in the prevention, diagnosis, treatment, and cure of Alzheimer's disease.

(d)~~(g)~~ Recommendations to further the mission of the program.

(8) Notwithstanding s. 216.301 and pursuant to s. 216.351, the balance of any appropriation from the General Revenue Fund for the Ed and Ethel Moore Alzheimer's Disease Research Program which is not disbursed but which is obligated pursuant to contract or committed to be expended by June 30 of the fiscal year in which the funds are appropriated may be carried forward for up to 5 years after the effective date of the original appropriation.

Section 4. Subsection (6) is added to section 381.922, Florida Statutes, to read:

381.922 William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.—

(6) The Biomedical Research Advisory Council shall submit a report relating to grants awarded under the program to the

Governor, the President of the Senate, and the Speaker of the House of Representatives by December 15 each year. The report must include:

(a) For each research project supported by grants or fellowships awarded under the program:

1. A summary of the research project and results or expected results of the research.

2. The status of the research project, including whether it has concluded or the estimated date of completion.

3. The amount of the grant or fellowship awarded and the estimated or actual cost of the research project.

4. A list of principal investigators under the research project.

5. The title, citation, and summary of findings of a publication in a peer-reviewed journal resulting from the research.

6. The source and amount of any federal, state, or local government grants or donations or private grants or donations generated as a result of the research project.

7. The status of a patent, if any, generated from the research project and an economic analysis of the impact of the resulting patent.

8. A list of postsecondary educational institutions involved in the research project, a description of each postsecondary educational institution's involvement in the research project, and the number of students receiving training

or performing research under the research project.

(b) The state ranking and total amount of cancer research funding currently flowing into the state from the National Institutes of Health.

(c) Progress toward programmatic goals, particularly in the prevention, diagnosis, treatment, and cure of cancer.

(d) Recommendations to further the mission of the program.

Section 5. Subsections (8) and (12) of section 401.27, Florida Statutes, are amended to read:

401.27 Personnel; standards and certification.—

(8) Each emergency medical technician certificate and each paramedic certificate will expire automatically and may be renewed if the holder meets the qualifications for renewal as established by the department. A certificate that is not renewed at the end of the 2-year period will automatically revert to an inactive status for a period not to exceed two renewal periods ~~180 days~~. Such certificate may be reactivated and renewed within the two renewal periods ~~180 days~~ if the certificateholder meets all other qualifications for renewal, including completion of education requirements and passage of the state certification examination, and pays a $25 late fee. Reactivation shall be in a manner and on forms prescribed by department rule.

(12) An applicant for certification as an emergency medical technician or paramedic who is trained outside the state or who is militarily trained must provide proof of current emergency medical technician or paramedic certification or

registration that is nationally recognized and based upon successful completion of a training program approved by the department as equivalent to the most recent EMT-Basic or EMT-Paramedic National Standard Curriculum or the National EMS Education Standards of the United States Department of Transportation and hold a current certificate of successful course completion in cardiopulmonary resuscitation (CPR) or advanced cardiac life support for emergency medical technicians or paramedics, respectively, to be eligible for ~~the~~ certification ~~examination~~. ~~The applicant must successfully complete the certification examination within 2 years after the date of the receipt of his or her application by the department. After 2 years, the applicant must submit a new application, meet all eligibility requirements, and submit all fees to reestablish eligibility to take the certification examination.~~

Section 6. Subsection (7) of section 456.013, Florida Statutes, is amended to read:

456.013 Department; general licensing provisions.—

(7) The boards, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the biennial ~~licensure and~~ renewal process. The 2-hour course counts toward ~~shall count towards~~ the total number of continuing education hours required for the profession. The course must ~~shall~~ be approved by the board or department, as appropriate, and must ~~shall~~ include a study of root-cause analysis, error reduction and prevention,

and patient safety. In addition, the course approved by the Board of Medicine and the Board of Osteopathic Medicine must ~~shall~~ include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed pursuant to chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

Section 7. Subsections (3) and (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) A person is eligible for licensure as a health care practitioner in this state if he or she:

1. ~~who~~ Serves or has served as a health care practitioner in the United States Armed Forces, the United States Reserve Forces, or the National Guard;

2. ~~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; or

3. Is a health care practitioner in another state, the District of Columbia, or a possession or territory of the United States and is the spouse of a person who serves on active duty with the United States Armed Forces ~~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.

(b) ~~(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. If a member of the military, submits proof that he or she has received ~~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.a. 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;

b. Is a military health care practitioner in a profession for which licensure in a state or jurisdiction is not required to practice in the United States Armed Forces, if the applicant submits to the department evidence of military training or experience substantially equivalent to the requirements for licensure in this state in that profession and evidence that the applicant has obtained a passing score on the appropriate

examination of a national or regional standards organization if required for licensure in this state; or

c. Is the spouse of a person serving on active duty in the United States Armed Forces and is a health care practitioner in a profession for which licensure in another state or jurisdiction may not be required, if the applicant submits to the department evidence of training or experience substantially equivalent to the requirements for licensure in this state in that profession and evidence that the applicant has obtained a passing score on the appropriate examination of a national or regional standards organization if 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.

(c) ~~(b)~~ Each applicant who meets the requirements of this subsection shall be licensed with all rights and responsibilities as defined by law. The applicable board, or department if there is no board, may deny an application if the applicant has been convicted of or pled guilty or nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession regulated by this state.

(d) ~~(c)~~ An applicant for initial licensure under this subsection must submit the information required by ss. 456.039(1) and 456.0391(1) no later than 1 year after the license is issued.

~~(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;~~

~~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.~~

~~(b) The applicant must also submit to the Department of Law Enforcement a complete set of fingerprints. The Department of Law Enforcement shall conduct a statewide criminal history check and forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check.~~

~~(c) Each board, or the department if there is no board, shall review the results of the state and federal criminal history checks according to the level 2 screening standards in s. 435.04 when granting an exemption and when granting or denying the temporary license.~~

~~(d) The applicant shall pay the cost of fingerprint processing. If the fingerprints are submitted through an authorized agency or vendor, the agency or vendor shall collect the required processing fees and remit the fees to the Department of Law Enforcement.~~

~~(e) The department shall set an application fee, which may~~

~~not exceed the cost of issuing the license.~~

~~(f) A temporary license expires 12 months after the date of issuance and is not renewable.~~

~~(g) An applicant for a temporary license under this subsection is subject to the requirements under s. 456.013(3)(a) and (c).~~

~~(h) An applicant shall be deemed ineligible for a temporary license pursuant to this section if the applicant:~~

~~1. Has been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;~~

~~2. Has had a health care provider license revoked or suspended from another of the United States, the District of Columbia, or a United States territory;~~

~~3. Has been reported to the National Practitioner Data Bank, unless the applicant has successfully appealed to have his or her name removed from the data bank; or~~

~~4. Has previously failed the Florida examination required to receive a license to practice the profession for which the applicant is seeking a license.~~

~~(i) The board, or department if there is no board, may revoke a temporary license upon finding that the individual violated the profession's governing practice act.~~

~~(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 8. Section 456.0241, Florida Statutes, is created to read:

456.0241 Temporary certificate for active duty military health care practitioners.—

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

(a) "Military health care practitioner" means:

1. A person practicing as a health care practitioner as defined in s. 456.001, as a person licensed under part III of chapter 401, or as a person licensed under part IV of chapter 468, who is serving on active duty in the United States Armed Forces, United States Reserve Forces, or National Guard; or

2. A person who is serving on active duty in the United States Armed Forces and serving in the United States Public Health Service.

(b) "Military platform" means a military training agreement with a nonmilitary health care provider which is designed to develop and support medical, surgical, or other health care treatment opportunities in the nonmilitary health care provider setting to allow a military health care practitioner to develop and maintain the technical proficiency necessary to meet the present and future health care needs of the United States Armed Forces. Such agreements may include Training Affiliation Agreements and External Resourcing Sharing Agreements.

(2) The department may issue a temporary certificate to an

active duty military health care practitioner to practice in a regulated profession if the applicant:

(a) Submits proof that he or she will be practicing pursuant to a military platform.

(b) Submits a complete application and a nonrefundable application fee.

(c) Holds a valid and unencumbered license to practice as a health care professional in another state, the District of Columbia, or a possession or territory of the United States or is a military health care practitioner in a profession for which licensure in a state or jurisdiction is not required for practice in the United States Armed Forces and who provides evidence of military training and experience substantially equivalent to the requirements for licensure in this state in that profession.

(d) 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.

(e) Has been determined to be competent in the profession for which he or she is applying.

(f) 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.

(3) A temporary certificate issued under this section expires 6 months after issuance but may be renewed upon proof of continuing orders in this state and evidence that the military health care practitioner continues to be a military platform participant.

(4) A military health care practitioner applying under this section is exempt from ss. 456.039-456.046. All other provisions of this chapter apply.

(5) An applicant for a temporary certificate under this section is deemed ineligible if the applicant:

(a) Has been convicted of, or pled guilty or nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;

(b) Has had a health care provider license revoked or suspended in another state, the District of Columbia, or a possession or territory of the United States;

(c) Has failed the Florida examination required to receive a license to practice the profession for which he or she is applying; or

(d) Is under investigation in another jurisdiction for an act that would constitute a violation of the applicable licensing chapter or this chapter until the investigation is complete and all charges against the applicant are disposed of

by dismissal, nolle prosequi, or acquittal.

(6) The department shall, by rule, set an application fee not to exceed $50 and a renewal fee not to exceed $50.

(7) Application shall be made on a form prescribed and furnished by the department.

(8) The department shall adopt rules to implement this section.

Section 9. Subsections (3) through (11) of section 456.025, Florida Statutes, are renumbered as subsections (2) through (10), respectively, and present subsections (2), (3), (7), and (8) of that section are amended to read:

456.025 Fees; receipts; disposition.—

~~(2) The chairpersons of the boards and councils listed in s. 20.43(3)(g) shall meet annually at division headquarters to review the long-range policy plan required by s. 456.005 and current and proposed fee schedules. The chairpersons shall make recommendations for any necessary statutory changes relating to fees and fee caps. Such recommendations shall be compiled by the Department of Health and be included in the annual report to the Legislature required by s. 456.026 as well as be included in the long-range policy plan required by s. 456.005.~~

(2)~~(3)~~ Each board within the jurisdiction of the department, or the department when there is no board, shall determine by rule the amount of license fees for the profession it regulates, based upon long-range estimates prepared by the department of the revenue required to implement laws relating to

the regulation of professions by the department and the board. Each board, or the department if there is no board, shall ensure that license fees are adequate to cover all anticipated costs and to maintain a reasonable cash balance, as determined by rule of the agency, with advice of the applicable board. ~~If sufficient action is not taken by a board within 1 year after notification by the department that license fees are projected to be inadequate, the department shall set license fees on behalf of the applicable board to cover anticipated costs and to maintain the required cash balance. The department shall include recommended fee cap increases in its annual report to the Legislature.~~ Further, it is the ~~legislative~~ intent of the Legislature that a ~~no~~ regulated profession not operate with a negative cash balance. If, however, a profession's fees are at their statutory fee cap and the requirements of subsections (1) and (4) are met, a profession may operate at a deficit until the deficit is eliminated ~~The department may provide by rule for advancing sufficient funds to any profession operating with a negative cash balance. The advancement may be for a period not to exceed 2 consecutive years, and the regulated profession must pay interest. Interest shall be calculated at the current rate earned on investments of a trust fund used by the department to implement this chapter. Interest earned shall be allocated to the various funds in accordance with the allocation of investment earnings during the period of the advance~~.

(6) ~~(7)~~ Each board, or the department if there is no board,

shall establish~~,~~ by rule~~,~~ a fee of up to ~~not to exceed~~ $250 for anyone seeking ~~approval~~ to provide continuing education courses or programs and ~~shall establish by rule~~ a biennial renewal fee of up to ~~not to exceed~~ $250 for the renewal of an approval to provide ~~providership of~~ such courses. The fees collected ~~from continuing education providers~~ shall be used for the purposes of reviewing course provider applications, monitoring the integrity of the courses provided, covering legal expenses incurred as a result of not granting or renewing an approval ~~a providership~~, and developing and maintaining an electronic continuing education tracking system pursuant to s. 456.0361. ~~The department shall implement an electronic continuing education tracking system for each new biennial renewal cycle for which electronic renewals are implemented after the effective date of this act and shall integrate such system into the licensure and renewal system.~~ All approved continuing education providers shall provide information on course attendance to the department necessary to implement the electronic tracking system. The department shall, by rule, specify the form and procedures by which the information is to be submitted.

(7)~~(8)~~ All moneys collected by the department from fees or fines or from costs awarded to the agency by a court shall be paid into a trust fund used by the department to implement this chapter. The Legislature shall appropriate funds from this trust fund sufficient to administer ~~carry out~~ this chapter and the provisions of law with respect to professions regulated by the

Division of Medical Quality Assurance within the department and the boards. The department may contract with public and private entities to receive and deposit revenue pursuant to this section. The department shall maintain separate accounts in the trust fund used by the department to implement this chapter for every profession within the department. To the maximum extent possible, the department shall directly charge all expenses to the account of each regulated profession. For the purpose of this subsection, direct charge expenses include, but are not limited to, costs for investigations, examinations, and legal services. For expenses that cannot be charged directly, the department shall provide for the proportionate allocation among the accounts of expenses incurred by the department in the performance of its duties with respect to each regulated profession. If a profession has established renewal fees that meet the requirements of subsection (1), has fees that are at the statutory fee cap, and has been operating in a deficit for 2 or more fiscal years, the department may waive allocated administrative and operational indirect costs until such time as the profession has a positive cash balance. The costs related to administration and operations include, but are not limited to, the costs of the director's office and the costs of system support, communications, central records, and other such administrative functions. Such waived costs shall be allocated to the other professions that must meet the requirements of this section, and cash in the unlicensed activity account under s.

456.065 of the profession whose costs have been waived shall be transferred to the operating account in an amount not to exceed the amount of the deficit. The regulation by the department of professions, as defined in this chapter, must ~~shall~~ be financed solely from revenue collected by the department ~~it~~ from fees and other charges and deposited in the Medical Quality Assurance Trust Fund, and all such revenue is hereby appropriated to the department, which~~. However, it is legislative intent that each profession shall operate within its anticipated fees. The department may not expend funds from the account of a profession to pay for the expenses incurred on behalf of another profession, except that the Board of Nursing must pay for any costs incurred in the regulation of certified nursing assistants. The department~~ shall maintain adequate records to support its allocation of agency expenses. The department shall provide any board with reasonable access to these records upon request. On or before October 1 of each year, the department shall provide each board an annual report of revenue and direct and allocated expenses related to the operation of that profession. The board shall use these reports and the department's adopted long-range plan to determine the amount of license fees. ~~A condensed version of this information, with the department's recommendations, shall be included in the annual report to the Legislature prepared under s. 456.026.~~

Section 10. Section 456.0361, Florida Statutes, is created to read:

456.0361 Compliance with continuing education requirements.—

(1) The department shall establish an electronic continuing education tracking system to monitor licensee compliance with applicable continuing education requirements and to determine whether a licensee is in full compliance with the requirements at the time of his or her application for license renewal. The tracking system shall be integrated into the department's licensure and renewal process.

(2) The department may not renew a license until the licensee complies with all applicable continuing education requirements. This subsection does not prohibit the department or the boards from imposing additional penalties under the applicable professional practice act or applicable rules for failure to comply with continuing education requirements.

(3) The department may adopt rules to implement this section.

Section 11. Subsection (20) of section 456.057, Florida Statutes, is amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(20) The board with department approval, or the department when there is no board, may temporarily or permanently appoint a person or entity as a custodian of medical records in the event of the death of a practitioner, the mental or physical

incapacitation of a ~~the~~ practitioner, or the abandonment of medical records by a practitioner. Such ~~The~~ custodian ~~appointed~~ shall comply with ~~all provisions of~~ this section. The department may contract with a third party to provide these services under the confidentiality and disclosure requirements of this section~~, including the release of patient records~~.

Section 12. Subsection (2) of section 456.0635, Florida Statutes, is amended to read:

456.0635 Health care fraud; disqualification for license, certificate, or registration.—

(2) Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed. Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such

conviction or plea ended:

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application;

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application;

(c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent 5 years;

(d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the candidate or applicant has been in good standing with a state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application; or

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of

Excluded Individuals and Entities.

~~This subsection does not apply to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.~~

Section 13. Subsection (3) of section 457.107, Florida Statutes, is amended to read:

457.107 Renewal of licenses; continuing education.—

(3) The board shall ~~by rule~~ prescribe by rule continuing education requirements of up to~~, not to exceed~~ 30 hours biennially~~,~~ as a condition for renewal of a license. All education programs that contribute to the advancement, extension, or enhancement of professional skills and knowledge related to the practice of acupuncture, whether conducted by a nonprofit or profitmaking entity, are eligible for approval. The continuing professional education requirements must be in acupuncture or oriental medicine subjects, including, but not limited to, anatomy, biological sciences, adjunctive therapies, sanitation and sterilization, emergency protocols, and diseases. The board may ~~shall have the authority to~~ set a fee of up to~~, not to exceed~~ $100~~,~~ for each continuing education provider. The licensee shall retain in his or her records the certificates of completion of continuing professional education requirements ~~to~~

~~prove compliance with this subsection. The board may request such documentation without cause from applicants who are selected at random~~. All national and state acupuncture and oriental medicine organizations and acupuncture and oriental medicine schools are approved to provide continuing professional education in accordance with this subsection.

Section 14. Paragraph (e) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant and~~.~~ ~~Furthermore, the physician assistant must~~ inform the patient that the patient has the right to see the physician before a ~~prior to any~~ prescription is ~~being~~ prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and ~~notify the department~~ of

any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must complete ~~file with the department a signed affidavit that he or she has completed~~ a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal ~~application~~.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the ~~foregoing~~ requirements of this paragraph. The physician assistant is ~~shall~~ not ~~be~~ required to independently register pursuant to s. 465.0276.

5. The prescription must be written in a form that complies with chapter 499 and, in addition to the supervisory physician's name, address, and telephone number, must contain~~,~~ ~~in addition to the supervisory physician's name, address, and telephone number,~~ the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The inclusion ~~appearance~~ of the prescriber number creates a presumption that the physician assistant is authorized to

prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

Section 15. Subsection (3) of section 463.007, Florida Statutes, is amended to read:

463.007 Renewal of license; continuing education.—

(3) As a condition of license renewal, a licensee must ~~Unless otherwise provided by law, the board shall require licensees to periodically~~ demonstrate his or her ~~their~~ professional competence~~, as a condition of renewal of a license,~~ by completing up to 30 hours of continuing education during the 2-year period preceding license renewal. For certified optometrists, the 30-hour continuing education requirement includes ~~shall include~~ 6 or more hours of approved transcript-quality coursework in ocular and systemic pharmacology and the diagnosis, treatment, and management of ocular and systemic conditions and diseases during the 2-year period preceding application for license renewal.

Section 16. Subsection (7) of section 464.203, Florida Statutes, is amended to read:

464.203 Certified nursing assistants; certification requirement.—

(7) A certified nursing assistant shall complete 24 ~~12~~ hours of inservice training during each biennium ~~calendar year~~. The certified nursing assistant shall maintain ~~be responsible for maintaining~~ documentation demonstrating compliance with

~~these provisions. The Council on Certified Nursing Assistants, in accordance with s. 464.2085(2)(b), shall propose rules to implement~~ this subsection.

Section 17. Section 464.2085, Florida Statutes, is repealed.

Section 18. Paragraph (b) of subsection (1) and subsection (3) of section 465.0276, Florida Statutes, are amended to read:

465.0276 Dispensing practitioner.—

(1)

(b) A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. This paragraph does not apply to:

1. The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (4) ~~(5)~~.

2. The dispensing of controlled substances in the health care system of the Department of Corrections.

3. The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception does not allow for the dispensing of a controlled substance listed in

Schedule II or Schedule III more than 14 days after the performance of the surgical procedure. For purposes of this subparagraph, the term "surgical procedure" means any procedure in any setting which involves, or reasonably should involve:

a. Perioperative medication and sedation that allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal or tactile stimulation and makes intra- and postoperative monitoring necessary; or

b. The use of general anesthesia or major conduction anesthesia and preoperative sedation.

4. The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.

5. The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.

6. The dispensing of a controlled substance listed in Schedule II or Schedule III to a patient of a facility licensed under part IV of chapter 400.

~~(3) The department shall inspect any facility where a~~

~~practitioner dispenses medicinal drugs pursuant to subsection (2) in the same manner and with the same frequency as it inspects pharmacies for the purpose of determining whether the practitioner is in compliance with all statutes and rules applicable to her or his dispensing practice.~~

Section 19. Subsection (3) of section 466.0135, Florida Statutes, is amended to read:

466.0135 Continuing education; dentists.—

(3) A ~~In applying for license renewal, the~~ dentist shall complete ~~submit a sworn affidavit, on a form acceptable to the department, attesting that she or he has completed~~ the required continuing education as provided ~~required~~ in this section and ~~in accordance with the guidelines and provisions of this section and listing the date, location, sponsor, subject matter, and hours of completed continuing education courses. The applicant~~ shall retain in her or his records any ~~such~~ receipts, vouchers, or certificates ~~as may be~~ necessary to document completion of such ~~the~~ continuing education ~~courses listed in accordance with this subsection~~. ~~With cause, the board may request such documentation by the applicant, and the board may request such documentation from applicants selected at random without cause.~~

Section 20. Section 466.014, Florida Statutes, is amended to read:

466.014 Continuing education; dental hygienists.—In addition to the other requirements for relicensure for dental hygienists set out in this chapter ~~act~~, the board shall require

each licensed dental hygienist to complete at least ~~not less than~~ 24 hours but not ~~or~~ more than 36 hours of continuing professional education in dental subjects, biennially, in programs prescribed or approved by the board or in equivalent programs of continuing education. Programs of continuing education approved by the board shall be programs of learning which, in the opinion of the board, contribute directly to the dental education of the dental hygienist. The board shall adopt rules and guidelines to administer and enforce ~~the provisions of~~ this section. ~~In applying for license renewal,~~ The dental hygienist shall ~~submit a sworn affidavit, on a form acceptable to the department, attesting that she or he has completed the continuing education required in this section in accordance with the guidelines and provisions of this section and listing the date, location, sponsor, subject matter, and hours of completed continuing education courses. The applicant shall~~ retain in her or his records any ~~such~~ receipts, vouchers, or certificates ~~as may be~~ necessary to document completion of such ~~the~~ continuing education ~~courses listed in accordance with this section~~. ~~With cause, the board may request such documentation by the applicant, and the board may request such documentation from applicants selected at random without cause.~~ Compliance with the continuing education requirements is ~~shall be~~ mandatory for issuance of the renewal certificate. The board may ~~shall have the authority to~~ excuse licensees, as a group or as individuals, from all or part of the continuing education ~~educational~~

requirements if~~, or any part thereof, in the event~~ an unusual circumstance, emergency, or hardship has prevented compliance with this section.

Section 21. Subsection (5) of section 466.032, Florida Statutes, is amended to read:

466.032 Registration.—

(5) A ~~The~~ dental laboratory owner or at least one employee of any dental laboratory renewing registration on or after July 1, 2010, shall complete 18 hours of continuing education biennially. Programs of continuing education must ~~shall~~ be programs of learning that contribute directly to the education of the dental technician and may include, but are not limited to, attendance at lectures, study clubs, college courses, or scientific sessions of conventions and research.

(a) The aim of continuing education for dental technicians is to improve dental health care delivery to the public as such is impacted through the design, manufacture, and use of artificial human oral prosthetics and related restorative appliances.

(b) Continuing education courses shall address one or more of the following areas of professional development, including, but not limited to:

1. Laboratory and technological subjects, including, but not limited to, laboratory techniques and procedures, materials, and equipment; and

2. Subjects pertinent to oral health, infection control,

and safety.

(c) Programs that meet ~~meeting~~ the general requirements of continuing education may be developed and offered to dental technicians by the Florida Dental Laboratory Association and the Florida Dental Association. Other organizations, schools, or agencies may also be approved to develop and offer continuing education in accordance with specific criteria established by the department.

~~(d) Any dental laboratory renewing a registration on or after July 1, 2010, shall submit a sworn affidavit, on a form approved by the department, attesting that either the dental laboratory owner or one dental technician employed by the registered dental laboratory has completed the continuing education required in this subsection in accordance with the guidelines and provisions of this subsection and listing the date, location, sponsor, subject matter, and hours of completed continuing education courses. The dental laboratory shall retain in its records such receipts, vouchers, or certificates as may be necessary to document completion of the continuing education courses listed in accordance with this subsection. With cause, the department may request that the documentation be provided by the applicant. The department may also request the documentation from applicants selected at random without cause.~~

(d) ~~(e)~~ 1. This subsection does not apply to a dental laboratory that is physically located within a dental practice operated by a dentist licensed under this chapter.

2. A dental laboratory in another state or country which provides service to a dentist licensed under this chapter is not required to register with the state and may continue to provide services to such dentist with a proper prescription. However, a dental laboratory in another state or country~~, however,~~ may voluntarily comply with this subsection.

Section 22. Section 468.1201, Florida Statutes, is repealed.

Section 23. Paragraph (a) of subsection (3), subsections (4) and (5), paragraphs (a) and (e) of present subsection (6), and present subsection (7) of section 483.901, Florida Statutes, are amended, and paragraph (k) is added to present subsection (6) of that section, to read:

483.901 Medical physicists; definitions; licensure.—

(3) DEFINITIONS.—As used in this section, the term:

~~(a) "Council" means the Advisory Council of Medical Physicists in the Department of Health.~~

~~(4) COUNCIL.—The Advisory Council of Medical Physicists is created in the Department of Health to advise the department in regulating the practice of medical physics in this state.~~

~~(a) The council shall be composed of nine members appointed by the State Surgeon General as follows:~~

~~1. A licensed medical physicist who specializes in diagnostic radiological physics.~~

~~2. A licensed medical physicist who specializes in therapeutic radiological physics.~~

~~3. A licensed medical physicist who specializes in medical nuclear radiological physics.~~

~~4. A physician who is board certified by the American Board of Radiology or its equivalent.~~

~~5. A physician who is board certified by the American Osteopathic Board of Radiology or its equivalent.~~

~~6. A chiropractic physician who practices radiology.~~

~~7. Three consumer members who are not, and have never been, licensed as a medical physicist or licensed in any closely related profession.~~

~~(b) The State Surgeon General shall appoint the medical physicist members of the council from a list of candidates who are licensed to practice medical physics.~~

~~(c) The State Surgeon General shall appoint the physician members of the council from a list of candidates who are licensed to practice medicine in this state and are board certified in diagnostic radiology, therapeutic radiology, or radiation oncology.~~

~~(d) The State Surgeon General shall appoint the public members of the council.~~

~~(e) As the term of each member expires, the State Surgeon General shall appoint the successor for a term of 4 years. A member shall serve until the member's successor is appointed, unless physically unable to do so.~~

~~(f) An individual is ineligible to serve more than two full consecutive 4-year terms.~~

~~(g) If a vacancy on the council occurs, the State Surgeon General shall appoint a member to serve for a 4-year term.~~

~~(h) A council member must be a United States citizen and must have been a resident of this state for 2 consecutive years immediately before being appointed.~~

~~1. A member of the council who is a medical physicist must have practiced for at least 6 years before being appointed or be board certified for the specialty in which the member practices.~~

~~2. A member of the council who is a physician must be licensed to practice medicine in this state and must have practiced diagnostic radiology or radiation oncology in this state for at least 2 years before being appointed.~~

~~3. The public members of the council must not have a financial interest in any endeavor related to the practice of medical physics.~~

~~(i) A council member may be removed from the council if the member:~~

~~1. Did not have the required qualifications at the time of appointment;~~

~~2. Does not maintain the required qualifications while serving on the council; or~~

~~3. Fails to attend the regularly scheduled council meetings in a calendar year as required by s. 456.011.~~

~~(j) Members of the council may not receive compensation for their services; however, they are entitled to reimbursement, from funds deposited in the Medical Quality Assurance Trust~~

~~Fund, for necessary travel expenses as specified in s. 112.061 for each day they engage in the business of the council.~~

~~(k) At the first regularly scheduled meeting of each calendar year, the council shall elect a presiding officer and an assistant presiding officer from among its members. The council shall meet at least once each year and at other times in accordance with department requirements.~~

~~(l) The department shall provide administrative support to the council for all licensing activities.~~

~~(m) The council may conduct its meetings electronically.~~

~~(5) POWERS OF COUNCIL.—The council shall:~~

~~(a) Recommend rules to administer this section.~~

~~(b) Recommend practice standards for the practice of medical physics which are consistent with the Guidelines for Ethical Practice for Medical Physicists prepared by the American Association of Physicists in Medicine and disciplinary guidelines adopted under s. 456.079.~~

~~(c) Develop and recommend continuing education requirements for licensed medical physicists.~~

(4) ~~(6)~~ LICENSE REQUIRED.—An individual may not engage in the practice of medical physics, including the specialties of diagnostic radiological physics, therapeutic radiological physics, medical nuclear radiological physics, or medical health physics, without a license issued by the department for the appropriate specialty.

(a) The department shall adopt rules to administer this

section which specify license application and renewal fees, continuing education requirements, and standards for practicing medical physics. ~~The council shall recommend to the department continuing education requirements that shall be a condition of license renewal.~~ The department shall require a minimum of 24 hours per biennium of continuing education offered by an organization ~~recommended by the council and~~ approved by the department. The department~~, upon recommendation of the council,~~ may adopt rules to specify continuing education requirements for persons who hold a license in more than one specialty.

(e) Upon ~~On~~ receipt of an application and fee as specified in this section, the department may issue a license to practice medical physics in this state ~~on or after October 1, 1997,~~ to a person who is board certified in the medical physics specialty in which the applicant applies to practice by the American Board of Radiology for diagnostic radiological physics, therapeutic radiological physics, or medical nuclear radiological physics; by the American Board of Medical Physics for diagnostic radiological physics, therapeutic radiological physics, or medical nuclear radiological physics; or by the American Board of Health Physics or an equivalent certifying body approved by the department.

(k) Upon proof of a completed residency program and receipt of the fee set forth by rule, the department may issue a temporary license for no more than 1 year. The department may adopt by rule requirements for temporary licensure and renewal

of temporary licenses.

(5) ~~(7)~~ FEES.—The fee for the initial license application shall be $500 and is nonrefundable. The fee for license renewal may not be more than $500. These fees may cover only the costs incurred by the department ~~and the council~~ to administer this section. By July 1 of each year, the department shall determine whether ~~advise the council if~~ the fees are insufficient to administer this section.

Section 24. Subsection (2) of section 484.047, Florida Statutes, is amended to read:

484.047 Renewal of license.—

(2) In addition to the other requirements for renewal provided in this section and by the board, the department shall renew a license upon receipt of the renewal application and~~,~~ the renewal fee~~, and a written statement affirming compliance with all other requirements set forth in this section and by the board~~. A licensee must maintain, if applicable, a certificate from a manufacturer or independent testing agent certifying that the testing room meets the requirements of s. 484.0501(6) and, if applicable, a certificate from a manufacturer or independent testing agent stating that all audiometric testing equipment used by the licensee has been calibrated acoustically to American National Standards Institute standards on an annual basis ~~acoustically to American National Standards Institute standard specifications~~. Possession of an applicable certificate is ~~the certificates shall be~~ a prerequisite to renewal.

Section 25. Subsections (1) and (4) of section 486.109, Florida Statutes, are amended to read:

486.109 Continuing education.—

(1) The board shall require licensees to ~~periodically~~ demonstrate their professional competence as a condition of renewal of a license by completing 24 hours of continuing education biennially.

(4) Each licensee shall maintain ~~be responsible for maintaining~~ sufficient records ~~in a format as determined by rule which shall be subject to a random audit by the department~~ to demonstrate ~~assure~~ compliance with this section.

Section 26. Paragraph (a) of subsection (15) of section 499.028, Florida Statutes, is amended to read:

499.028 Drug samples or complimentary drugs; starter packs; permits to distribute.—

(15) A person may not possess a prescription drug sample unless:

(a) The drug sample was prescribed to her or him as evidenced by the label required in s. 465.0276(4) ~~465.0276(5)~~.

Section 27. Paragraph (g) of subsection (3) of section 921.0022, Florida Statutes, is amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(g) LEVEL 7

Florida Statute	Felony Degree	Description
316.027(2)(c)	1st	Accident involving death, failure to stop; leaving scene.
316.193(3)(c)2.	3rd	DUI resulting in serious bodily injury.
316.1935(3)(b)	1st	Causing serious bodily injury or death to another person; 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.
327.35(3)(c)2.	3rd	Vessel BUI resulting in serious bodily injury.

402.319(2)	2nd	Misrepresentation and negligence or intentional act resulting in great bodily harm, permanent disfiguration, permanent disability, or death.	
409.920 (2)(b)1.a.	3rd	Medicaid provider fraud; $10,000 or less.	
409.920 (2)(b)1.b.	2nd	Medicaid provider fraud; more than $10,000, but less than $50,000.	
456.065(2)	3rd	Practicing a health care profession without a license.	
456.065(2)	2nd	Practicing a health care profession without a license which results in serious bodily injury.	
458.327(1)	3rd	Practicing medicine without a license.	

459.013(1)	3rd	Practicing osteopathic medicine without a license.
460.411(1)	3rd	Practicing chiropractic medicine without a license.
461.012(1)	3rd	Practicing podiatric medicine without a license.
462.17	3rd	Practicing naturopathy without a license.
463.015(1)	3rd	Practicing optometry without a license.
464.016(1)	3rd	Practicing nursing without a license.
465.015(2)	3rd	Practicing pharmacy without a license.
466.026(1)	3rd	Practicing dentistry or dental hygiene without a license.

467.201	3rd	Practicing midwifery without a license.
468.366	3rd	Delivering respiratory care services without a license.
483.828(1)	3rd	Practicing as clinical laboratory personnel without a license.
483.901(7) ~~483.901(9)~~	3rd	Practicing medical physics without a license.
484.013(1)(c)	3rd	Preparing or dispensing optical devices without a prescription.
484.053	3rd	Dispensing hearing aids without a license.
494.0018(2)	1st	Conviction of any violation of chapter 494 in which the total money and property unlawfully obtained exceeded $50,000

			and there were five or more victims.
560.123(8)(b)1.		3rd	Failure to report currency or payment instruments exceeding $300 but less than $20,000 by a money services business.
560.125(5)(a)		3rd	Money services business by unauthorized person, currency or payment instruments exceeding $300 but less than $20,000.
655.50(10)(b)1.		3rd	Failure to report financial transactions exceeding $300 but less than $20,000 by financial institution.
775.21(10)(a)		3rd	Sexual predator; failure to register; failure to renew driver license or identification card; other

			registration violations.
775.21(10)(b)		3rd	Sexual predator working where children regularly congregate.
775.21(10)(g)		3rd	Failure to report or providing false information about a sexual predator; harbor or conceal a sexual predator.
782.051(3)		2nd	Attempted felony murder of a person by a person other than the perpetrator or the perpetrator of an attempted felony.
782.07(1)		2nd	Killing of a human being by the act, procurement, or culpable negligence of another (manslaughter).
782.071		2nd	Killing of a human being or unborn child by the operation

			of a motor vehicle in a reckless manner (vehicular homicide).
782.072	2nd	Killing of a human being by the operation of a vessel in a reckless manner (vessel homicide).	
784.045(1)(a)1.	2nd	Aggravated battery; intentionally causing great bodily harm or disfigurement.	
784.045(1)(a)2.	2nd	Aggravated battery; using deadly weapon.	
784.045(1)(b)	2nd	Aggravated battery; perpetrator aware victim pregnant.	
784.048(4)	3rd	Aggravated stalking; violation of injunction or court order.	
784.048(7)	3rd	Aggravated stalking;	

			violation of court order.
784.07(2)(d)		1st	Aggravated battery on law enforcement officer.
784.074(1)(a)		1st	Aggravated battery on sexually violent predators facility staff.
784.08(2)(a)		1st	Aggravated battery on a person 65 years of age or older.
784.081(1)		1st	Aggravated battery on specified official or employee.
784.082(1)		1st	Aggravated battery by detained person on visitor or other detainee.
784.083(1)		1st	Aggravated battery on code inspector.
787.06(3)(a)2.		1st	Human trafficking using

			coercion for labor and services of an adult.
787.06(3)(e)2.		1st	Human trafficking using coercion for labor and services by the transfer or transport of an adult from outside Florida to within the state.
790.07(4)		1st	Specified weapons violation subsequent to previous conviction of s. 790.07(1) or (2).
790.16(1)		1st	Discharge of a machine gun under specified circumstances.
790.165(2)		2nd	Manufacture, sell, possess, or deliver hoax bomb.
790.165(3)		2nd	Possessing, displaying, or threatening to use any hoax bomb while committing or attempting to commit a felony.

790.166(3)	2nd	Possessing, selling, using, or attempting to use a hoax weapon of mass destruction.
790.166(4)	2nd	Possessing, displaying, or threatening to use a hoax weapon of mass destruction while committing or attempting to commit a felony.
790.23	1st,PBL	Possession of a firearm by a person who qualifies for the penalty enhancements provided for in s. 874.04.
794.08(4)	3rd	Female genital mutilation; consent by a parent, guardian, or a person in custodial authority to a victim younger than 18 years of age.
796.05(1)	1st	Live on earnings of a prostitute; 2nd offense.

796.05(1)	1st	Live on earnings of a prostitute; 3rd and subsequent offense.
800.04(5)(c)1.	2nd	Lewd or lascivious molestation; victim younger than 12 years of age; offender younger than 18 years of age.
800.04(5)(c)2.	2nd	Lewd or lascivious molestation; victim 12 years of age or older but younger than 16 years of age; offender 18 years of age or older.
800.04(5)(e)	1st	Lewd or lascivious molestation; victim 12 years of age or older but younger than 16 years; offender 18 years or older; prior conviction for specified sex offense.

806.01(2)	2nd	Maliciously damage structure by fire or explosive.
810.02(3)(a)	2nd	Burglary of occupied dwelling; unarmed; no assault or battery.
810.02(3)(b)	2nd	Burglary of unoccupied dwelling; unarmed; no assault or battery.
810.02(3)(d)	2nd	Burglary of occupied conveyance; unarmed; no assault or battery.
810.02(3)(e)	2nd	Burglary of authorized emergency vehicle.
812.014(2)(a)1.	1st	Property stolen, valued at $100,000 or more or a semitrailer deployed by a law enforcement officer; property stolen while causing other property damage; 1st degree grand theft.

812.014(2)(b)2.	2nd	Property stolen, cargo valued at less than $50,000, grand theft in 2nd degree.
812.014(2)(b)3.	2nd	Property stolen, emergency medical equipment; 2nd degree grand theft.
812.014(2)(b)4.	2nd	Property stolen, law enforcement equipment from authorized emergency vehicle.
812.0145(2)(a)	1st	Theft from person 65 years of age or older; $50,000 or more.
812.019(2)	1st	Stolen property; initiates, organizes, plans, etc., the theft of property and traffics in

			stolen property.
812.131(2)(a)	2nd		Robbery by sudden snatching.
812.133(2)(b)	1st		Carjacking; no firearm, deadly weapon, or other weapon.
817.034(4)(a)1.	1st		Communications fraud, value greater than $50,000.
817.234(8)(a)	2nd		Solicitation of motor vehicle accident victims with intent to defraud.
817.234(9)	2nd		Organizing, planning, or participating in an intentional motor vehicle collision.
817.234(11)(c)	1st		Insurance fraud; property value $100,000 or more.

817.2341 (2)(b) & (3)(b)	1st	Making false entries of material fact or false statements regarding property values relating to the solvency of an insuring entity which are a significant cause of the insolvency of that entity.
817.535(2)(a)	3rd	Filing false lien or other unauthorized document.
825.102(3)(b)	2nd	Neglecting an elderly person or disabled adult causing great bodily harm, disability, or disfigurement.
825.103(3)(b)	2nd	Exploiting an elderly person or disabled adult and property is valued at $10,000 or more, but less than $50,000.
827.03(2)(b)	2nd	Neglect of a child causing

			great bodily harm, disability, or disfigurement.
827.04(3)	3rd		Impregnation of a child under 16 years of age by person 21 years of age or older.
837.05(2)	3rd		Giving false information about alleged capital felony to a law enforcement officer.
838.015	2nd		Bribery.
838.016	2nd		Unlawful compensation or reward for official behavior.
838.021(3)(a)	2nd		Unlawful harm to a public servant.
838.22	2nd		Bid tampering.
843.0855(2)	3rd		Impersonation of a public officer or employee.
843.0855(3)	3rd		Unlawful simulation of

			legal process.
843.0855(4)		3rd	Intimidation of a public officer or employee.
847.0135(3)		3rd	Solicitation of a child, via a computer service, to commit an unlawful sex act.
847.0135(4)		2nd	Traveling to meet a minor to commit an unlawful sex act.
872.06		2nd	Abuse of a dead human body.
874.05(2)(b)		1st	Encouraging or recruiting person under 13 to join a criminal gang; second or subsequent offense.
874.10		1st,PBL	Knowingly initiates, organizes, plans, finances, directs, manages, or supervises criminal gang-related

			activity.
893.13(1)(c)1.		1st	Sell, manufacture, or deliver cocaine (or other drug prohibited under s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4.) within 1,000 feet of a child care facility, school, or state, county, or municipal park or publicly owned recreational facility or community center.
893.13(1)(e)1.		1st	Sell, manufacture, or deliver cocaine or other drug prohibited under s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., within 1,000 feet of property used for religious services or a specified business site.

893.13(4)(a)	1st	Deliver to minor cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4. drugs).
893.135(1)(a)1.	1st	Trafficking in cannabis, more than 25 lbs., less than 2,000 lbs.
893.135 (1)(b)1.a.	1st	Trafficking in cocaine, more than 28 grams, less than 200 grams.
893.135 (1)(c)1.a.	1st	Trafficking in illegal drugs, more than 4 grams, less than 14 grams.
893.135 (1)(c)2.a.	1st	Trafficking in hydrocodone, 14 grams or more, less than 28 grams.
893.135 (1)(c)2.b.	1st	Trafficking in hydrocodone, 28 grams or more, less than 50 grams.

893.135 (1)(c)3.a.	1st	Trafficking in oxycodone, 7 grams or more, less than 14 grams.
893.135 (1)(c)3.b.	1st	Trafficking in oxycodone, 14 grams or more, less than 25 grams.
893.135(1)(d)1.	1st	Trafficking in phencyclidine, more than 28 grams, less than 200 grams.
893.135(1)(e)1.	1st	Trafficking in methaqualone, more than 200 grams, less than 5 kilograms.
893.135(1)(f)1.	1st	Trafficking in amphetamine, more than 14 grams, less than 28 grams.
893.135 (1)(g)1.a.	1st	Trafficking in flunitrazepam, 4 grams or more, less than 14 grams.

893.135 (1)(h)1.a.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 1 kilogram or more, less than 5 kilograms.
893.135 (1)(j)1.a.	1st	Trafficking in 1,4-Butanediol, 1 kilogram or more, less than 5 kilograms.
893.135 (1)(k)2.a.	1st	Trafficking in Phenethylamines, 10 grams or more, less than 200 grams.
893.1351(2)	2nd	Possession of place for trafficking in or manufacturing of controlled substance.
896.101(5)(a)	3rd	Money laundering, financial transactions exceeding $300 but less than $20,000.
896.104(4)(a)1.	3rd	Structuring transactions

			to evade reporting or registration requirements, financial transactions exceeding $300 but less than $20,000.
943.0435(4)(c)		2nd	Sexual offender vacating permanent residence; failure to comply with reporting requirements.
943.0435(8)		2nd	Sexual offender; remains in state after indicating intent to leave; failure to comply with reporting requirements.
943.0435(9)(a)		3rd	Sexual offender; failure to comply with reporting requirements.
943.0435(13)		3rd	Failure to report or providing false information about a sexual offender; harbor or conceal a sexual

			offender.
943.0435(14)	3rd	Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.	
944.607(9)	3rd	Sexual offender; failure to comply with reporting requirements.	
944.607(10)(a)	3rd	Sexual offender; failure to submit to the taking of a digitized photograph.	
944.607(12)	3rd	Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.	
944.607(13)	3rd	Sexual offender; failure to report and reregister;	

			failure to respond to address verification; providing false registration information.
985.4815(10)		3rd	Sexual offender; failure to submit to the taking of a digitized photograph.
985.4815(12)		3rd	Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.
985.4815(13)		3rd	Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.

Section 28. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1245 Medicaid Provider Overpayments
SPONSOR(S): Peters
TIED BILLS: **IDEN./SIM. BILLS:** SB 1370

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	13 Y, 0 N	McElroy	Poche
2) Health Care Appropriations Subcommittee		Clark	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In the Florida Medicaid program, the state has one year from the date that the Agency for Health Care Administration (AHCA) or federal Centers for Medicare & Medicaid Services (CMS) discover an overpayment to a Medicaid provider to recover or seek to recover the overpayment. After the one-year period, Florida must refund the federal share of the overpayment, regardless of whether AHCA has actually recovered payment from the Medicaid provider. Federal law provides an exemption from repayment if the Medicaid provider has gone out of business. To use this exemption, AHCA must certify that a Medicaid provider is out of business and that any overpayment cannot be collected. AHCA does not currently have statutory authority to make this certification and, as a result, Florida repays the federal share of the overpayments to out-of-business Medicaid providers. The annual repayment amount has ranged from $1.5 million to $7.3 million.

HB 1245 authorizes AHCA to certify that a Medicaid provider is out of business and that any overpayments made to the provider cannot be collected. This allows Florida to use the exemption from any mandatory repayment of the federal share for Medicaid provider overpayments.

The bill appears to have an indeterminate, positive fiscal impact on state government. There is no fiscal impact to local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Medicaid

Medicaid is a jointly funded partnership of the federal and state governments that provides access to health care for low-income families and individuals. The structure of each state's Medicaid program varies and what states must pay for is largely determined by the federal government[1], as a condition of receiving federal funds. Federal law sets the amount, scope, and duration of services offered in the program, among other requirements. These federal requirements create an entitlement that comes with constitutional due process protections. The entitlement means that two parts of the Medicaid cost equation – people and utilization – are largely predetermined for the states.

The Centers for Medicare & Medicaid Services (CMS), within the U.S. Department of Health and Human Services, is responsible for the administration of the Medicaid program. CMS, through its Center for Program Integrity, is tasked with identifying, prosecuting and preventing fraud, waste and abuse within the Medicaid program.[2] To accomplish this task, CMS has authority to:

- Hire contractors to review provider activities, audit claims, identify overpayments, and educate providers and others on program integrity issues;
- Provide support and assistance to states in their efforts to combat provider fraud and abuse; and
- Eliminate and recover improper payments.

Medicaid Program in Florida

The Medicaid program in Florida is administered by AHCA. Reimbursement for services provided to Medicaid recipients is established through various methodologies which may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding and other mechanisms that are efficient and effective for purchasing services or goods on behalf of recipients.[3] Reimbursement is limited to claims for services provided for covered injuries or illnesses[4] by a provider who has a valid Medicaid provider agreement.[5] Since its inception in 1970, the program has paid nearly $300 billion to Medicaid providers of goods and services.[6]

AHCA's Office of Medicaid Program Integrity (MPI) and the Medicaid Fraud Control Unit (MFCU) in the Office of the Attorney General are responsible for ensuring that fraudulent and abusive behavior and

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[1] The Federal Medical Assistance Percentages (FMAPs) are used to determine the amount of matching funds for state expenditures for assistance payments for certain social services, and state medical and medical insurance expenditures. The regular average state FMAP is 57%, but ranges from 50% in wealthier states up to 75% in states with lower per capita incomes (the maximum regular FMAP is 82%). *Financing & Reimbursement*, Medicaid.gov https://www.medicaid.gov/medicaid-chip-program-information/by-topics/eligibility/eligibility.html; https://aspe.hhs.gov/federal-medical-assistance-percentages-or-federal-financial-participation-state-assistance-expenditures (last viewed on January 20, 2016).

[2] *Program Integrity*, Medicaid.gov https://www.medicaid.gov/medicaid-chip-program-information/by-topics/eligibility/eligibility.html (last viewed on January 20, 2016).

[3] Section 409.908, F.S.

[4] "Covered injury or illness" means any sickness, injury, disease, disability, deformity, abnormality disease, necessary medical care, pregnancy, or death for which a third party is, may be, could be, should be, or has been liable, and for which Medicaid is, or may be, obligated to provide, or has provided, medical assistance. S. 409.901(9), F.S.

[5] Section 409.907, F.S. Medicaid provider agreements are voluntary agreements between AHCA and a provider for the provision of services to Medicaid recipients and include background screening requirements, notification requirements for change of ownership, authority for AHCA site visits of provider service locations, and surety bond requirements.

[6] Id.

neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate.[7]

MPI is statutorily required to develop statistical methodologies to identify providers who exhibit aberrant billing patterns.[8] MPI utilizes these methodologies to perform comprehensive audits and generalized analyses of Medicaid providers.[9] Overpayments identified through these audits are referred to AHCA's Division of Operations, Bureau of Financial Services (Financial Services) for collection.[10] Financial Services collects the overpayments through either direct payment or through withholding payment to the provider.[11]

Any suspected criminal violation identified by AHCA is referred to the MFCU. MFCU is responsible for investigating and prosecuting provider fraud within the Medicaid program which commonly involves fraud related to providers' billing practices, including billing for services that were not provided, overcharging for services that were provided and billing for services that were not medically necessary.[12] AHCA and MFCU are required to submit an annual joint report to the Legislature documenting the effectiveness of the state's efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year.[13]

Reimbursement of Medicaid Overpayment

Federal law requires the state to refund the federal share of any overpayment made to a Medicaid provider. An overpayment occurs when a Medicaid provider is paid in an amount in excess of the Medicaid established allowable amount for the service.[14] Overpayments can be discovered in a variety of ways, including audits performed by AHCA or CMS under their program integrity offices.[15] The state has one year from the date that AHCA or CMS discover an overpayment to recover or seek to recover the overpayment.[16] After one year, the state must refund the federal share of the overpayment, regardless of whether AHCA has actually recovered payment from the provider.[17]

Federal law also provides an exception to the mandatory federal share repayment provision. Audits are not always performed contemporaneously with payment and may occur several years after the overpayment to the Medicaid provider. Sometimes, the provider has gone out of business prior to the discovery of the overpayment. A state is not required to refund the federal portion of the overpayment if the provider is out of business on the date of discovery of the overpayment or if the provider goes out of business before the end of the one year period following discovery.[18] To prove the provider is out of business, a state must:[19]

- Document its efforts to locate the party and its assets;[20] and
- Provide an affidavit or certification from the appropriate state legal authority establishing that the provider is out of business and that the overpayment cannot be collected under state law and procedures, and citing the effective date of that determination.

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[7] Section 409.913, F.S.
[8] Id.
[9] Agency for Health Care Administration and the Department of Legal Affairs, *The State's Efforts to Control Medicaid Fraud and Abuse, FY 2014-15*, December 15, 2015, available at https://ahca.myflorida.com/Executive/Inspector_General/docs/Medicaid_Fraud_Abuse_Annual_Reports/2014-15_MedicaidFraudandAbuseAnnualReport.pdf (last viewed January 23, 2016).
[10] Id.
[11] Id.
[12] Id.
[13] Id.
[14] 42 C.F.R. 433.304
[15] Section 409.913, F.S.; Section 1936 of the Social Security Act.
[16] 42 C.F.R. 433.312(a)(1).
[17] 42 C.F.R. 433.312(a)(2).
[18] 42 C.F.R. 433.318(d)(1).
[19] 42 C.F.R. 433.318(d)(2)(i) and (ii).
[20] These efforts must be consistent with applicable state policies and procedures.

Florida is currently required to repay the federal share of an overpayment when a provider is out business. There are no state law provisions that authorize AHCA to certify that a provider is out of business and that the overpayment cannot be collected, so the exemption from mandatory repayment is not available. As a result, Florida refunded the federal government $7.3 million in FY 2011-12, $1.5 million in FY 2012-13 and $2.8 million in FY 2013-14 for the federal share of Medicaid provider overpayments that it could have otherwise retained.[21]

Effect of Proposed Changes

HB 1245 authorizes AHCA to certify that a Medicaid provider is out of business and that any overpayments made to the provider cannot be collected under state law and procedures. This allows Florida to qualify for the exemption from mandatory federal share repayment for Medicaid provider overpayments, and retain those funds.

B. SECTION DIRECTORY:

Section 1: Amends s. 409.908, F.S., relating to reimbursement of Medicaid providers.
Section 2: Reenacts s. 409.8132, F.S., relating to Medikids program component.
Section 3: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Florida refunded to the federal government $7.3 million in FY 2011-12, $1.5 million in FY 2012-13 and $2.8 million in FY 2013-14 for the federal share of Medicaid provider overpayments. The bill permits AHCA to certify that a provider is out-of-business and that overpayments cannot be collected. As a result, Florida will retain the federal share of future Medicaid overpayments to providers who are certified as out-of-business, which AHCA estimates will total between $1 and $3 million per fiscal year.[22]

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

[21] Agency for Health Care Administration, *2016 Agency Legislative Bill Analysis for HB 1245*, January 23, 2016 (on file with the Health Care Appropriations Subcommittee staff).
[22] Id.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

AHCA has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to Medicaid provider overpayments; amending s. 409.908, F.S.; authorizing the Agency for Health Care Administration to certify that a Medicaid provider is out of business and that overpayments made to a provider cannot be collected under state law; reenacting s. 409.8132(4), F.S., relating to the applicability of certain laws to the Medikids program, to incorporate the amendment made by the act to s. 409.908, F.S., in a reference thereto; providing an effective date.

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

Section 1. Subsection (25) is added to section 409.908, Florida Statutes, to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. If a provider is reimbursed based

on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the adjustment is consistent with legislative intent.

(25) In accordance with 42 C.F.R. s. 433.318(d), the agency may certify that a Medicaid provider is out of business and that any overpayments made to the provider cannot be collected under state law and procedures.

Section 2. For the purpose of incorporating the amendment made by this act to section 409.908, Florida Statutes, in a reference thereto, subsection (4) of section 409.8132, Florida Statutes, is reenacted to read:

409.8132 Medikids program component.—

(4) APPLICABILITY OF LAWS RELATING TO MEDICAID.—The provisions of ss. 409.902, 409.905, 409.906, 409.907, 409.908, 409.912, 409.9121, 409.9122, 409.9123, 409.9124, 409.9127, 409.9128, 409.913, 409.916, 409.919, 409.920, and 409.9205 apply to the administration of the Medikids program component of the Florida Kidcare program, except that s. 409.9122 applies to Medikids as modified by the provisions of subsection (7).

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1277 Licensure of Foreign-Trained Physicians
SPONSOR(S): Campbell
TIED BILLS: **IDEN./SIM. BILLS:** SB 1626

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N	Siples	O'Callaghan
2) Health Care Appropriations Subcommittee		Garner	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Department of Health (DOH), in conjunction with the Board of Medicine (board), oversees the licensure and regulation of allopathic physicians in this state, pursuant to ch. 458, F.S. Florida law prescribes the minimum standards an applicant for licensure must meet to be licensed as a physician.

For licensure by examination, an applicant must meet minimum medical education and postgraduate training standards, as well as achieve an acceptable score on a board-approved national licensing examination. Licensure by endorsement is available to an individual who is licensed in another state or U.S. territory for a specified period of time, and who can demonstrate compliance with the minimum medical education and postgraduate training standards, as well as a passing score on a board-approved national licensing examination.

The bill provides an alternative option for graduates of foreign medical schools to meet the education and training requirements for licensure as a physician. The bill allows a graduate of an allopathic foreign medical school listed in the World Directory of Medical Schools that has not been certified by the state, pursuant to s. 458.314, F.S., to apply for licensure. The World Directory of Medical Schools is a world-wide directory of medical schools that was jointly developed by the World Federation for Medical Education and the Foundation for Advancement of International Medical Education and Research, in collaboration with the World Health Organization and the University of Copenhagen. The applicant must also demonstrate that he or she is proficient in English, has completed a board-approved residency or fellowship of at least one year, and has held an active physician license and practiced medicine in a foreign jurisdiction for at least the 10 years immediately preceding the date of application for licensure.

The bill also provides that a foreign medical school graduate, who applies for licensure pursuant to its provisions, may meet the licensure examination requirement by achieving a passing score on an examination that the board determines is substantially equivalent to, or more stringent than, the United States Medical Licensing Examination (USMLE).

The bill provides that the board may certify an applicant for licensure who meets the education and training requirements, as well as any other licensure requirements, with a condition, limitation, or restriction, including a probationary period, a scope of practice limitation, or a supervision requirement, to be imposed by the DOH, for a duration specified by the board.

The bill may have an insignificant fiscal impact on the DOH and no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Licensure and Regulation of Physicians

Chapter 458, F.S., provides for the licensure and regulation of the practice of medicine by the Florida Board of Medicine (board) in conjunction the Department of Health (DOH). The chapter provides, among other things, licensure requirements by examination for medical school graduates and licensure by endorsement requirements.

Licensure by Examination

An individual seeking to be licensed by examination as a medical doctor, must meet the following requirements:[1]

- Pay an application fee;[2]
- Be at least 21 years of age;
- Be of good moral character;
- Has not committed an act or offense that would constitute the basis for disciplining a physician, pursuant to s. 458.331, F.S.;
- Complete 2 years of post-secondary education which includes, at a minimum, courses in fields such as anatomy, biology, and chemistry prior to entering medical school;
- Meets one of the following medical education and postgraduate training requirements:
    - Is a graduate of an allopathic medical school recognized and approved by an accrediting agency recognized by the U.S. Office of Education or recognized by an appropriate governmental body of a U.S. territorial jurisdiction, and has completed at least one year of approved residency training;
    - Is a graduate of an allopathic foreign medical school registered with the World Health Organization and certified pursuant to statute as meeting the standards required to accredit U.S. medical schools, and has completed at least one year of approved residency training; or
    - Is a graduate of an allopathic foreign medical school that has not been certified pursuant to statute; has an active, valid certificate issued by the Educational Commission for Foreign Medical Graduates (ECFMG),[3] has passed that commission's examination; and has completed an approved residency or fellowship of at least 2 years in one specialty area;
- Has submitted to a background screening by the DOH; and
- Has obtained a passing score on:
    - The United States Medical Licensing Examination (USMLE);
    - A combination of the USMLE, the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or

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[1] Section 458.311(1), F.S.

[2] Pursuant to r. 64B8-3.002(5), F.A.C., the application fee for a person desiring to be licensed as a physician by examination is $500. The applicant must pay an initial license fee of $429. Section 766.314(4), F.S., assesses a fee to be paid with at time of an initial license to finance the Florida Birth-Related Neurological Injury Compensation Plan. The current assessment amount is $250.

[3] A graduate of a foreign medical school does not need to present an ECFMG certification or pass its exam if the graduate received his or bachelor's degree from an accredited U.S. college or university, studied at a medical school recognized by the World Health Organization, and has completed all but the internship or social service requirements, has passed parts I and II of the National Board Medical Examiners licensing examination or the ECFMG equivalent examination. (Section 458.311, F.S.)

- The Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX), if the applicant was licensed on the basis of a state board examination, is currently licensed in at least one other jurisdiction of the United States or Canada, and has practiced for a period of at least 10 years.

Licensure by Endorsement

An individual who holds an active license to practice medicine in another jurisdiction may seek licensure by endorsement to practice medicine in Florida.[4] The applicant must meet the same requirements for licensure by examination. To qualify for licensure by endorsement, the applicant must also submit evidence of the licensed active practice of medicine in another jurisdiction for at least 2 of the preceding 4 years, or evidence of successful completion of either a board-approved postgraduate training program within 2 years preceding filing of an application or a board-approved clinical competency examination within the year preceding the filing of an application for licensure.

When the board determines that any applicant for licensure by endorsement has failed to meet, to the board's satisfaction, each of the appropriate requirements for licensure by endorsement, it may enter an order requiring one or more of the following terms:

- Refusal to certify to the DOH an application for licensure, certification, or registration;
- Certification to the DOH of an application for licensure, certification, or registration with restrictions on the scope of practice of the licensee; or
- Certification to the DOH of an application for licensure, certification, or registration with placement of the physician on probation for a period of time and subject to such conditions as the board may specify, including, but not limited to, requiring the physician to submit to treatment, attend continuing education courses, submit to reexamination, or work under the supervision of another physician.

Certification of Foreign Educational Institutions

Section 458.314, F.S., authorizes the DOH to develop standards and a process by which a foreign medical school may be certified as meeting standards comparable to those required for the accreditation of a U.S. medical school. A graduate of a foreign medical school certified as meeting the DOH's standards is eligible for licensure as a medical doctor after obtaining a passing score on a medical licensure examination, demonstrating proficiency in English, and successfully completing one year of graduate training in an approved program.[5] In determining whether a foreign medical school is to be certified, the DOH will evaluate several areas, including governance, administration, curriculum, admissions, class size, and the availability of resources, such as faculty and budget.[6]

World Directory of Medical Schools

The World Directory of Medical Schools (world directory) is a world-wide database of medical schools jointly developed by the World Federation for Medical Education and the Foundation for Advancement of International Medical Education and Research (FAIMER), in collaboration with the World Health Organization and the University of Copenhagen.[7] The data contained in the world directory was derived from the University of Copenhagen's Avicenna Directory, which was the successor of the World Health Organization's World Directory of Medical Schools, and the International Medical Education Directory compiled by FAIMER. [8] The information provided in the International Medical Education Directory was

[4] Section 458.313, F.S.
[5] Rule 64B8-15, F.A.C. Prior to being admitted to an approved residency program, the Accreditation Council for Graduate Medical Education must verify that the foreign medical graduate has been certified by the ECFMG.
[6] *See generally* Rule 64B8-15, F.A.C.
[7] World Directory of Medical Schools, *About the World Directory*, *available at* http://www.wdoms.org/about/ (last visited Jan. 13, 2016).
[8] World Directory of Medical Schools, *History of the World Directory of Medical Schools*, *available at* http://www.wdoms.org/history/ (last visited Jan. 13, 2016). The Avicenna Directory is managed by the World Federation for Medical Education.

derived from data collected by the ECFMG throughout its history of evaluating the medical credentials of graduates of foreign medical schools.

The world directory defines a "medical school" as an educational institution that provides a complete or full program leading to a basic medical qualification that permits the holder to obtain a license to practice as a medical doctor or physician.[9]

The database provides basic details about each medical school, such as contact information, operational status, the year instruction began, the percentage of clinical training and access to clinical facilities, curriculum duration, prerequisite education, and language of instruction, if available. However, being listed in the directory does not denote any recognition, accreditation, or endorsement by the world directory or the organizations producing the world directory.[10]

Effective June 30, 2015, the ECFMG uses the world directory to determine eligibility for certification of foreign medical graduates by its organization.[11] If a foreign medical school meets the ECFMG requirements, the school's profile contains a notation of such and its graduates are eligible to apply for ECFMG certification and the USMLE. However, if the medical school is not listed in the world directory or it is listed but its profile does not have the ECFMG notation, its students are ineligible to apply for ECFMG certification and the USMLE.

Effect of the Proposed Changes

All applicants for licensure as a physician must meet minimum medical educational standards by graduating from an accredited or government approved medical school and successfully completing postgraduate training requirements. The bill provides an additional option that graduates of foreign medical schools may use to meet the education requirements for licensure by examination. To qualify for licensure as a physician by examination, the bill allows a graduate of an allopathic foreign medical school listed in the World Directory of Medical Schools that has not been certified by the state, pursuant to s. 458.314, F.S., to qualify for licensure, if the applicant meets the following:

- Demonstrates competency in English by obtaining a satisfactory score on an approved test, if the foreign medical school provides instruction in a language other than English;
- Has completed a board-approved residency or fellowship of at least 1 year in one specialty area, which counts towards the regular or subspecialty certification by a board recognized and certified by the American Board of Medical Specialties; and
- Has held an active physician license and has practiced medicine in a foreign jurisdiction for at least 10 years immediately preceding the date of application.

All licensure applicants must achieve a passing score on a board-approved licensure examination. The bill allows applicants who apply pursuant to this provision to meet the examination requirement by obtaining a passing score on an examination determined by the board to be substantially equivalent to, or more stringent than, the USMLE.

The bill permits the DOH to impose a condition, limitation, or restriction, including but not limited to, a probationary period of practice, a scope of practice limitation, or a supervision requirement for any applicant certified by the board to be licensed pursuant to the provisions of the bill, for a duration specified by the board.

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[9] *Supra* note 1.
[10] World Directory of Medical Schools, *Search the World Directory*, *available at* https://search.wdoms.org/ (last visited on Jan. 13, 2016).
[11] Educational Commission for Foreign Medical Graduates, *Update: World Directory of Medical Schools Replaces International Medical Education Directory for Purposes of Determining Eligibility for ECFMG Certification and USMLE*, (June 30, 2015), *available at* http://www.ecfmg.org/news/2015/06/30/update-world-directory-of-medical-schools-replaces-international-medical-education-directory-for-purposes-of-determining-eligibility-for-ecfmg-certification-and-usmle/ (last visited Jan. 13, 2016).

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

B. SECTION DIRECTORY:

Section 1. Amends s. 458.311, F.S., relating to licensure by examination; requirements; fees.
Section 2. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill may have an indeterminate, positive fiscal impact on the DOH. The DOH may collect application, licensure, and renewal fees from additional individuals that may be eligible to apply for licensure. Section 458.311(1)(a), F.S., allows DOH to assess a nonrefundable application fee not to exceed $500 for licensure.

2. Expenditures:

   The bill may have an indeterminate, insignificant fiscal impact on the DOH. The DOH may experience a recurring workload increase as additional individuals may be eligible to apply for licensure. The DOH will incur an insignificant nonrecurring cost associated with rulemaking which current resources are adequate to absorb.[12]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

For foreign trained physicians intending to become licensed in Florida, this bill may result in cost savings associated with no longer having to take the USMLE or FLEX to become licensed if the foreign trained physician meets the new licensure criteria provided in the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

[12] Department of Health, *2016 Agency Legislative Bill Analysis for House Bill 1277* (January 11, 2015), on file with the Health Care Appropriations Subcommittee.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to licensure of foreign-trained physicians; amending s. 458.311, F.S.; establishing licensure requirements for certain foreign-trained physicians; authorizing the Board of Medicine to impose licensure restrictions, limitations, or conditions on certain foreign-trained physicians; providing an effective date.

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

Section 1. Paragraphs (f) and (h) of subsection (1) and subsection (7) of section 458.311, Florida Statutes, are amended to read:

458.311 Licensure by examination; requirements; fees.—

(1) Any person desiring to be licensed as a physician, who does not hold a valid license in any state, shall apply to the department on forms furnished by the department. The department shall license each applicant who the board certifies:

(f) Meets one of the following medical education and postgraduate training requirements:

1.a. Is a graduate of an allopathic medical school or allopathic college recognized and approved by an accrediting agency recognized by the United States Office of Education or is a graduate of an allopathic medical school or allopathic college within a territorial jurisdiction of the United States

recognized by the accrediting agency of the governmental body of that jurisdiction;

b. If the language of instruction of the medical school is other than English, has demonstrated competency in English through presentation of a satisfactory grade on the Test of Spoken English of the Educational Testing Service or a similar test approved by rule of the board; and

c. Has completed an approved residency of at least 1 year.

2.a. Is a graduate of an allopathic foreign medical school registered with the World Health Organization and certified pursuant to s. 458.314 as having met the standards required to accredit medical schools in the United States or reasonably comparable standards;

b. If the language of instruction of the foreign medical school is other than English, has demonstrated competency in English through presentation of the Educational Commission for Foreign Medical Graduates English proficiency certificate or by a satisfactory grade on the Test of Spoken English of the Educational Testing Service or a similar test approved by rule of the board; and

c. Has completed an approved residency of at least 1 year.

3.a. Is a graduate of an allopathic foreign medical school which has not been certified pursuant to s. 458.314;

b. Has had his or her medical credentials evaluated by the Educational Commission for Foreign Medical Graduates, holds an active, valid certificate issued by that commission, and has

passed the examination utilized by that commission; and

c. Has completed an approved residency of at least 1 year; however, after October 1, 1992, the applicant shall have completed an approved residency or fellowship of at least 2 years in one specialty area. However, to be acceptable, the fellowship experience and training must be counted toward regular or subspecialty certification by a board recognized and certified by the American Board of Medical Specialties.

4.a. Is a graduate of an allopathic foreign medical school listed in the World Directory of Medical Schools produced as a joint venture of the World Federation for Medical Education and the Foundation for Advancement of International Medical Education and Research, in collaboration with the World Health Organization, and accredited by an accrediting agency recognized by the governmental body of the foreign jurisdiction, but which is not certified pursuant to s. 458.314;

b. If the language of instruction of the foreign medical school is other than English, has demonstrated competency in English through presentation of a satisfactory grade on the Test of Spoken English of the Educational Testing Service or a similar test approved by rule of the board;

c. Has completed a board-approved residency or fellowship of at least 1 year in one specialty area, which must be counted toward regular or subspecialty certification by a board recognized and certified by the American Board of Medical Specialties; and

d. Has held an active physician license and practiced medicine in a foreign jurisdiction for at least the 10 years immediately preceding the application for licensure under this section.

(h) Has obtained a passing score, as established by rule of the board, on the licensure examination of the United States Medical Licensing Examination (USMLE); or a combination of the United States Medical Licensing Examination (USMLE), the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or for the purpose of examination of any applicant who was licensed on the basis of a state board examination and who is currently licensed in at least one other jurisdiction of the United States or Canada, and who has practiced pursuant to such licensure for a period of at least 10 years, use of the Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX) upon receipt of a passing score as established by rule of the board. An applicant meeting the medical education and postgraduate training requirements in subparagraph (f)4. may meet the examination requirement of this paragraph by obtaining a passing score on an examination determined by the board to be substantially equivalent to, or more stringent than, the United States Medical Licensing Examination (USMLE). However, for the purpose of examination of any applicant who was licensed on the basis of a state board

examination prior to 1974, who is currently licensed in at least three other jurisdictions of the United States or Canada, and who has practiced pursuant to such licensure for a period of at least 20 years, this paragraph does not apply.

(7) Upon certification by the board, the department shall impose conditions, limitations, or restrictions on a license if the applicant is on probation in another jurisdiction for an act which would constitute a violation of this chapter. The board may certify an applicant for licensure who has met the medical education and postgraduate training requirements under subparagraph (1)(f)4. and all other licensure requirements with a condition, limitation, or restriction, including, but not limited to, a probationary period of practice, a scope of practice limitation, or a supervision requirement, which shall be imposed by the department for a duration specified by the board.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1313 Low-THC Cannabis
SPONSOR(S): Brodeur
TIED BILLS: None **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N	O'Callaghan	O'Callaghan
2) Health Care Appropriations Subcommittee		Pridgeon	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In 2014, the Legislature enacted the Compassionate Medical Cannabis Act (CMCA) to authorize dispensing organizations approved by the Department of Health (DOH) to manufacture, possess, sell, and dispense low-THC cannabis for medical use by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. A physician may only order low-THC cannabis for medical use if the patient is a permanent resident of Florida, no other satisfactory alternative treatment option exists, the physician has determined that the risks of ordering the low-THC cannabis are reasonable in light of the potential benefit for the patient, and the physician has obtained voluntary informed consent to such treatment.

Under the CMCA, an applicant for approval as a dispensing organization has to meet certain criteria to be selected by DOH and DOH may select only five dispensing organizations in the state to grow, process, and dispense low-THC cannabis. Although there is specific criteria that must be met before DOH may approve an applicant as a dispensing organization, the CMCA does not include regulatory standards for the operation, security, and safety of dispensing organizations or the growing, processing, testing, packaging, labeling, dispensing, or transportation of low-THC cannabis.

The bill creates new regulatory standards for dispensing organizations, including standards for the growing, processing, testing, packaging, labeling, dispensing, and transportation of low-THC cannabis. The bill also provides DOH with greater regulatory oversight by authorizing DOH to perform inspections, create a patient and caregiver registration card system, assess fees and take disciplinary action, and create standards for laboratories testing low-THC cannabis.

The bill also increases the criteria a physician must meet to be eligible to order low-THC cannabis for a patient by requiring the physician to specialize in certain practice areas and specifying the length of time the physician must have treated the patient. The bill also limits a physician's order to a 30-day supply of low-THC cannabis. The bill prohibits a physician ordering low-THC cannabis from being employed by a dispensing organization and authorizes the appropriate regulatory board to take disciplinary action against a physician who orders low-THC cannabis and receives compensation from a dispensing organization related to the order.

The bill has an indeterminate negative fiscal impact on DOH; however DOH has authority to impose fees sufficient to cover the cost of the regulation of the program. There is no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Marijuana, also called cannabis, has been used for a variety of health conditions for at least 3,000 years.[1] Currently, the U.S. Food and Drug Administration (FDA) hasn't approved the use of cannabis to treat any health condition due to the lack of research to show that the benefits of using cannabis outweigh the risks.[2] However, based on the scientific study of cannabinoids, which are chemicals contained in cannabis, the FDA has approved two synthetic prescription drugs that contain certain cannabinoids.[3]

Although there are more than 100 cannabinoids in a marijuana plant, the two main cannabinoids of medical interest are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is a mind-altering chemical that increases appetite and reduces nausea and may also decrease pain, inflammation, and muscle control problems. CBD is a chemical that does not affect the mind or behavior, but may be useful in reducing pain and inflammation, controlling epileptic seizures, and possibly treating mental illness and addictions.[4]

Research on the Medical Use of Cannabis

During the course of drug development, a typical compound is found to have some medical benefit and then extensive tests are undertaken to determine its safety and proper dosage for medical use.[5] In contrast, marijuana has been widely used in the United States for decades. In 2014, just over 49% of the U.S. population over 12 years old had tried marijuana or hashish at least once and just over 10% were current users.[6] The data on the adverse effects of marijuana are more extensive than the data on its effectiveness.[7] Clinical studies of marijuana are difficult to conduct as researchers interested in clinical studies of marijuana face a series of barriers, research funds are limited, and there is a daunting thicket of federal and state regulations to be negotiated.[8] In fact, recently, there has been an exponential rise in the use of marijuana compared to the rise in scientific knowledge of its benefits or adverse effects because some states have allowed the public or patients to access marijuana while the federal government continues to limit scientific and clinical investigators' access to marijuana for research.[9]

In 1999, the Institute of Medicine published a study based on a comprehensive review of existing scientific data and clinical studies pertaining to the medical value of marijuana.[10] The study concluded that there is potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of

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[1] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *Medical Marijuana, available at* https://nccih.nih.gov/health/marijuana (last visited on December 27, 2015).
[2] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *What is medical marijuana?, available at* http://www.drugabuse.gov/publications/drugfacts/marijuana-medicine (last visited on December 27, 2015).
[3] *Id.*
[4] *Id.*
[5] Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base*, The National Academies Press, 1999, available at http://www.nap.edu/catalog/6376/marijuana-and-medicine-assessing-the-science-base (last visited on December 27, 2015).
[6] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, *Results from the 2014 National Survey on Drug Use and Health: Detailed Tables, available at* http://www.samhsa.gov/data/population-data-nsduh/reports (last visited on December 27, 2015).
[7] *Supra* note 5 at 137.
[8] *Id.*
[9] Friedman, Daniel, M.D., Devinsky, Orrin, M.D., *Cannabinoids in the Treatment of Epilepsy*, NEW ENG. J. MED., September 10, 2015, on file with the Health Quality Subcommittee.
[10] *Supra* note 5 at 179.

nausea and vomiting, and appetite stimulation.[11] The study reports that smoked marijuana, however, is a crude THC delivery system that also delivers harmful substances.[12]

The Institute of Medicine's study, which warned that smoking marijuana is harmful, was corroborated by a study published in the New England Journal of Medicine in 2014.[13] The 2014 study further warned that long-term marijuana use can lead to addiction and that adolescents have an increased vulnerability to adverse long-term outcomes from marijuana use.[14] Specifically, the study found that, as compared with persons who begin to use marijuana in adulthood, those who begin in adolescence are approximately 2 to 4 times as likely to have symptoms of cannabis dependence within 2 years after first use.[15] The study also found that cannabis-based treatment with THC may have irreversible effects on brain development in adolescents as the brain's endocannabinoid system undergoes development in childhood and adolescence.[16]

More recently, a study published in 2015 in the Journal of the American Medical Association found that there is moderate-quality evidence to support the use of cannabinoids for the treatment of chronic pain and spasticity and that there is low-quality evidence suggesting that cannabinoids are associated with improvements in nausea and vomiting due to chemotherapy, weight gain in HIV infection, sleep disorders, and Tourette syndrome.[17]

Despite the uncertainty of the efficacy of marijuana on various medical conditions, there has recently been much interest in the use of marijuana, especially the compound CBD, to treat epilepsy.[18] A few factors contributing to the interest of the public, media, and researchers in such treatment are that new anti-seizure drugs have not substantially reduced the proportion of patients with medically refractory seizures, the side effects of such drugs continue to have negative side effects to the central nervous system and affect quality of life, and there appears to be some evidence-based efficacy of such treatment based on case stories and limited preclinical and clinical studies.[19]

Federal Regulation of Cannabis

The Federal Controlled Substances Act[20] lists cannabis as a Schedule 1 drug, meaning it has a high potential for abuse, has no currently accepted medical use, and has a lack of accepted safety for use under medical supervision.[21] The Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, dispense, and use cannabis.[22] A first misdemeanor offense for possession of cannabis in any amount can result in a $1,000 fine and up to a year in prison, climbing for subsequent offenses to as much as $5,000 and three years.[23] Selling and cultivating cannabis are subject to even greater penalties.[24]

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[11] *Id.*
[12] *Id.*
[13] Volkow, N.D., Baler, R.D., Compton, W.M. and Weiss, S.R., *Adverse Health Effects of Marijuana Use*, NEW ENG. J. MED., June 5, 2014, *available at* dfaf.org/assets/docs/Adverse%20health%20effects.pdf (last visited on December 27, 2015).
[14] *Id.* at 2219.
[15] *Id.* at 2220.
[16] *Id.* at 2219.
[17] American Medical Association, *Cannabinoids for Medical Use: A Systematic Review and Meta-analysis*, JAMA, June 2015, on file with the Health Quality Subcommittee.
[18] *Supra* note 9 at 1048.
[19] *Supra* note 9 at 1048, 1052-1053, and 1056.
[20] 21 U.S.C. ss. 801-971.
[21] 21 U.S.C. s. 812.
[22] 21 U.S.C. ss. 841-65.
[23] 21 U.S.C. s. 844.
[24] 21 U.S.C. ss. 841-65.

In August of 2013, the United States Department of Justice (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century."[25] This document details the federal government's changing stance on low-level drug crimes announcing a "change in Department of Justice charging policies so that certain people who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels will no longer be charged with offenses that impose draconian mandatory minimum sentences. Under the revised policy, these people would instead receive sentences better suited to their individual conduct rather than excessive prison terms more appropriate for violent criminals or drug kingpins."[26]

On August 29, 2013, United States Deputy Attorney General James Cole issued a memorandum to federal attorneys that appeared to relax the federal government's cannabis-related offense enforcement policies.[27] The memo stated that the USDOJ was committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational ways, and outlined eight areas of enforcement priorities.[28] These enforcement priorities focused on offenses that would result in cannabis being distributed to minors, cannabis sale revenues going to criminal gangs or other similar organizations, and cannabis being grown on public lands.[29] The memo indicated that outside of the listed enforcement priorities, the federal government would not enforce federal cannabis-related laws in states that have legalized the drug and that have a robust regulatory scheme in place.[30]

In 2014, Congress enacted the Consolidated and Further Continuing Appropriations Act of 2015 (Appropriations Act of 2015). Section 538 of the Appropriations Act of 2015 prohibits the USDOJ from expending any funds in connection with the enforcement of any law that interferes with a state's ability to implement its own state law that authorizes the use, distribution, possession, or cultivation of medical marijuana.[31] Despite this prohibition in the Appropriations Act of 2015, the USDOJ has continued to take some enforcement measures against medical cannabis dispensaries. However, in October 2015, the United States District Court for the Northern District of California held that section 538 plainly on its face prohibits the Department of Justice from taking such action.[32] Congress recently re-enacted the prohibition in section 542 of the Consolidated Appropriations Act of 2016.[33]

Regulation of Cannabis in Other States

Currently, 23 states[34] and the District of Columbia have comprehensive laws that permit and regulate the use of cannabis for medicinal purposes.[35] While these laws vary widely, most specify the medical conditions a patient must be diagnosed with to be eligible to use cannabis for treatment, allow a caregiver to assist with such treatment, require the registration of the patient and caregiver and a

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[25] U.S. Department of Justice, *Smart on Crime: Reforming the Criminal Justice System for the 21st Century, available at* http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on December 27, 2015).
[26] *Id.*
[27] U.S. Department of Justice, *Guidance Regarding Marijuana Enforcement*, August 29, 2014, *available at* http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (last visited on December 27, 2015).
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] Pub. L. 113-235 (2014).
[32] *U.S. v. Marin Alliance for Medical Marijuana*, 2015 WL 6123062 (N.D. Cal. Oct. 19, 2015).
[33] Pub. L. 114-113 (2015).
[34] These states include: Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and New York was the most recent state to pass medical marijuana legislation which took effect in July 2014. National Conference of State Legislatures, *State Medical Marijuana Laws*, *available at* http://www.ncsl.org/issues-research/health/state-medical-marijuana-laws.aspx (last visited on December 27, 2015).
[35] According to the National Conference of State Legislatures, 17 other states allow the use of low-THC cannabis for medical use or allow a legal defense for such use, including Florida. National Conference of State Legislatures, *State Medical Marijuana Laws*, *available at* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited on December 27, 2015).

registration ID card to be issued to the patient and caregiver, restrict where cannabis can be used, and provide standards pertaining to the growing, processing, packaging, transport, and dispensing of medical cannabis.

Patients' Use of Medical Cannabis

While nearly every state has a list of medical conditions for which the patient may be treated with medical cannabis, the particular conditions vary from state to state. Most states also provide a mechanism for the list of qualifying medical conditions to be expanded, usually by allowing a state agency or a board to add qualifying medical conditions to the list or by providing a physician with some discretion in determining whether such treatment would benefit the patient.[36] The most common qualifying conditions named[37] in the statutes of the states with comprehensive medical cannabis laws are:[38]

- Cancer- 22 states
- HIV/AIDS- 22 states
- Multiple sclerosis- 20 states
- Epilepsy- 20 states
- Glaucoma- 19 states
- Crohn's disease- 12 states
- Amyotrophic lateral sclerosis- 10 states
- Hepatitis C- 8 states
- Alzheimer's disease- 8 states

Most states require that at least one, but sometimes states require two, physicians to certify that the patient has a qualifying condition. Some states require physicians to have certain qualifications to be able to order medical cannabis for qualifying patients.[39] Qualifying patients are usually required to be registered in an electronic registry and must be issued a registration ID card, usually from a state agency.[40]

Most states place general restrictions on where medical cannabis may be used. Typically, medical cannabis may not be used in public places, such as parks and on buses, or in areas where there are more stringent restrictions placed on the use of drugs, such as in or around schools or in prisons.[41]

There are two general methods by which patients can obtain medical cannabis. They must either self-cultivate the cannabis in their homes, or buy cannabis from specified points of sale or dispensaries. Regulations governing the amount of medical cannabis that may be grown or dispensed varies widely. For example, the amount of medical cannabis patients are allowed to have ranges from 1 ounce of

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[36] For example, see the following state laws allowing an agency to approve other conditions: AS § 17.37.070 (Alaska), A.R.S. § 36-2801 (Arizona), C.R.S.A. Const. Art. 18, § 14 (Colorado), C.G.S.A. § 21a-408 (Connecticut), 16 Del.C. § 4902A (Delaware), HRS § 329-121 (Hawaii), 410 ILCS 130/10 (Illinois), M.C.L.A. 333.26423 (Michigan), M.S.A. §152.22 (Minnesota), N.R.S. 453A.050 (Nevada), N.H. Rev. Stat. §126-X:1 (New Hampshire), N.J.S.A. 24:6I-3 (New Jersey), N.M.S.A. 1978, § 26-2B-3 (New Mexico), O.R.S. § 475.302 (Oregon), and Gen. Laws 1956, § 21-28.6-3 (Rhode Island). For examples of states allowing for physician discretion in treating other conditions with medical cannabis, see M.G.L.A. 94C App. §1-2.

[37] These are diseases specified in states' statutes. The state statutes also included symptoms or conditions of diseases that could apply to several other diseases, such as cachexia or wasting syndrome, severe pain, severe nausea, seizures, or muscle spasms.

[38] Information based on research performed by Health Quality Subcommittee staff. The laws of each state are on file with the subcommittee.

[39] For example, the following states require the ordering physician to be a neurologist: Iowa (I.C.A. § 124D.3), Missouri (V.A.M.S. 192.945), Utah (U.C.A. 1953 § 26-56-103), and Wyoming (W.S.1977 § 35-7-1902). Additionally, Vermont requires a physician to establish a bona fide relationship with the patient for not less than 6 months before ordering such treatment. *See* 18 V.S.A. § 4472.

[40] *Supra* note 38.

[41] For example, see N.R.S. 453A.322 (Nevada), N.J.S.A. 18A:40-12.22 (New Jersey), 5 CCR 1006-2:12 (Colorado), and West's Ann.Cal.Health & Safety Code § 11362.768 (California).

usable[42] cannabis to 24 ounces of usable cannabis, depending on the state. Furthermore, the number of cannabis plants that patients are allowed to grow ranges from 2 mature marijuana plants to 18 seedling marijuana plants. At least 10 states limit the amount of medical cannabis that may be ordered by specifying the number of days or months of a supply a physician may order.[43]

Caregivers

Caregivers are generally allowed to purchase or grow cannabis for the patient, be in possession of a specified quantity of cannabis, and aid the patient in using cannabis, but are strictly prohibited from using cannabis themselves. Some states may also require the caregiver to be at least 21[44] and may prohibit the caregiver from being the patient's physician.[45] Like the patient receiving treatment, the caregiver is usually required to be registered and have a registration ID card, typically issued by a state agency.[46]

Quality and Safety Standards

States vary in their regulations of entities that grow, process, transport, and dispense medical cannabis. However, most states with comprehensive medical cannabis laws require such entities to meet certain standards to ensure the quality and safety of the medical cannabis and standards to ensure the security of the facilities possessing the medical cannabis. For example, some states require a state agency to establish and enforce standards for laboratory testing of medical cannabis.[47] States may also require certain packaging and labeling standards for medical cannabis, including the requirement for packaging to meet the standards under the United States Poison Prevention Packaging Act.[48] States' security measures may require facilities that grow, process, transport, and dispense medical cannabis to implement an inventory tracking system that tracks the cannabis from "seed-to-sale."[49]

Florida's Cannabis Laws

Criminal Law

Florida's drug control laws are set forth in ch. 893, F.S., entitled the Florida Comprehensive Drug Abuse Prevention and Control Act (Drug Control Act).[50] The Drug Control Act classifies controlled substances into five categories, ranging from Schedule I to Schedule V.[51] Cannabis is currently a Schedule I controlled substance,[52] which means it has a high potential for abuse, it has no currently accepted medical use in treatment in the United States, and its use under medical supervision does not meet accepted safety standards.[53] Cannabis is defined as:

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[42] "Usable cannabis" generally means the seeds, leaves, buds, and flowers of the cannabis plant and any mixture or preparation thereof, but does not include the stalks and roots of the plant or the weight of any non-cannabis ingredients combined with cannabis. For example, see 410 ILCS 130/10 (Illinois) and OAR 333-008-0010 (Oregon).

[43] *See* C.G.S.A. §21a-4089 (Connecticut), 410 ILCS 130/10 (Illinois), MD Code, Health-General, § 13-3301 (Maryland), M.G.L.A. 94C App. §1-2 (Massachusetts), M.S.A. § 152.29 (Minnesota), N.R.S. 453A.200 (Nevada), N.H. Rev. Stat. § 126-X:8 (New Hampshire), N.J.S.A. 24:6I-10 (New Jersey), N.M.S.A. 1978, § 26-2B-3 (New Mexico), and McKinney's Public Health Law § 3362 (New York).

[44] See, for example, 22 M.R.S.A. § 2423-A (Maine), 105 CMR 725.020 (Massachusetts), and Gen.Laws 1956, § 44-67-2 (Rhode Island).

[45] For an example of a law prohibiting a physician from being a caregiver, see the definition of "primary caregiver" in C.R.S.A. § 25-1.5-106 (Colorado).

[46] *Supra* note 38.

[47] *See* HRS § 329D-8 (Hawaii), N.R.S. 453A.368 (Nevada), and West's RCWA 69.50.348 (Washington).

[48] *See* C.R.S.A. § 12-43.3-104(Colorado) and Haw. Admin. Rules (HAR) § 11-850-92 (Hawaii).

[49] *See* C.R.S.A. § 35-61-105.5 (Colorado), OAR 333-064-0100 (Oregon), and West's RCWA 69.51A.250 (Washington- effective July 1, 2016).

[50] s. 893.01, F.S.

[51] s. 893.03, F.S.

[52] s. 893.03(1)(c)7., F.S.

[53] s. 893.03(1), F.S.

> All parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. The term does not include "low-THC cannabis," as defined in s. 381.986, if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with s. 381.986.[54]

The Drug Control Act contains a variety of provisions criminalizing behavior related to cannabis:

- Section 893.13, F.S., makes it a crime to sell, manufacture, deliver, purchase, or possess cannabis. The penalties for these offenses range from first degree misdemeanors to second degree felonies.[55]
- Section 893.135(1)(a), F.S., makes it a first degree felony[56] to traffic in cannabis, i.e., to possess, sell, purchase, manufacture, deliver, or import more than 25 pounds of cannabis or 300 or more cannabis plants. Depending on the amount of cannabis or cannabis plants trafficked, mandatory minimum sentences of three to 15 years and fines of $25,000 to $200,000 apply to a conviction.[57]
- Section 893.147, F.S., makes it a crime to possess, use, deliver, manufacture, transport, or sell drug paraphernalia.[58] The penalties for these offenses range from first degree misdemeanors to second degree felonies.[59]

Medical Necessity Defense

Florida courts have held that persons charged with offenses based on the possession, use, or manufacture of marijuana may use the medical necessity defense, which requires a defendant to prove that:

- He or she did not intentionally bring about the circumstance which precipitated the unlawful act;
- He or she could not accomplish the same objective using a less offensive alternative; and
- The evil sought to be avoided was more heinous than the unlawful act.[60]

In *Jenks v. State,*[61] the defendants, a married couple, suffered from uncontrollable nausea due to AIDS treatment and had testimony from their physician that they could find no effective alternative treatment. The defendants tried cannabis, and after finding that it successfully treated their symptoms, decided to grow two cannabis plants.[62] They were subsequently charged with manufacturing and possession of drug paraphernalia. Under these facts, the First District Court of Appeal found that "section 893.03 does not preclude the defense of medical necessity" and that the defendants met the criteria for the medical necessity defense.[63] The court ordered the defendants to be acquitted.[64]

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[54] s. 893.02(3), F.S.

[55] A first degree misdemeanor is punishable by up to one year in county jail and a $1,000 fine; a third degree felony is punishable by up to five years imprisonment and a $5,000 fine; and a second degree felony is punishable by up to 15 years imprisonment and a $10,000 fine. ss. 775.082 and 775.083, F.S.

[56] A first degree felony is punishable by up to 30 years imprisonment and a $10,000 fine. ss. 775.082 and 775.083, F.S.

[57] s. 893.13(1)(a), F.S.

[58] Drug paraphernalia is defined in s. 893.145, F.S., as:

> All equipment, products, and materials of any kind which are used, intended for use, or designed for use in the planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of ch. 893, F.S., or s. 877.111, F.S.

[59] s. 893.147, F.S.

[60] *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *rev. denied,* 589 So.2d 292 (Fla. 1991).

[61] 582 So.2d 676 (Fla. 1st DCA 1991).

[62] *Id.*

[63] *Id.*

[64] *Id.*

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State*.[65] More recently, the State Attorney's Office in the Twelfth Judicial Circuit cited the medical necessity defense as the rationale for not prosecuting a person arrested for cultivating a small amount of cannabis in his home for his wife's medical use.[66]

Compassionate Medical Cannabis Act of 2014

The Compassionate Medical Cannabis Act of 2014[67] (CMCA) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)[68] for the medical use[69] by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms.

The CMCA provides that a Florida licensed allopathic or osteopathic physician who has completed certain training[70] and has examined and is treating such a patient may order low-THC cannabis for that patient to treat the disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for the patient. To meet the requirements of the CMCA, each of the following conditions must be satisfied:

- The patient must be a permanent resident of Florida.
- The physician must determine that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient.[71]
- The physician must register as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the Department of Health (DOH) and must update the registry to reflect the contents of the order.
- The physician must maintain a patient treatment plan and must submit the plan quarterly to the University of Florida College of Pharmacy.
- The physician must obtain the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis.[72]

Under the CMCA, DOH was required to approve five dispensing organizations by January 1, 2015, with one dispensing organization in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. DOH was also authorized to impose an initial application and biennial renewal fee that is sufficient to cover the costs of regulating the program.[73] To be approved as a dispensing organization, an applicant must establish that it:

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[65] 739 So.2d 333 (Fla. 1st DCA 1998).

[66] *Interdepartmental Memorandum*, State Attorney's Office for the Twelfth Judicial Circuit of Florida, SAO Case # 13CF007016AM, April 2, 2013, on file with the Health Quality Subcommittee.

[67] *See* ch. 2014-157, L.O.F., and s. 381.986, F.S.

[68] The act defines "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. *See* s. 381.986(1)(b), F.S.

[69] Section 381.986(1)(c), F.S., defines "medical use" as "administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also does not include the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative on behalf of the qualified patient." Section 381.986(1)(e), F.S., defines "smoking" as "burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer."

[70] Section 381.986(4), F.S., requires such physicians to successfully complete an 8-hour course and examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompasses the clinical indications for the appropriate use of low-THC cannabis, appropriate delivery mechanisms, contraindications for such use, and the state and federal laws governing its ordering, dispensing, and processing

[71] If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record. s. 381.986(2)(b), F.S.

[72] s. 381.986(2), F.S.

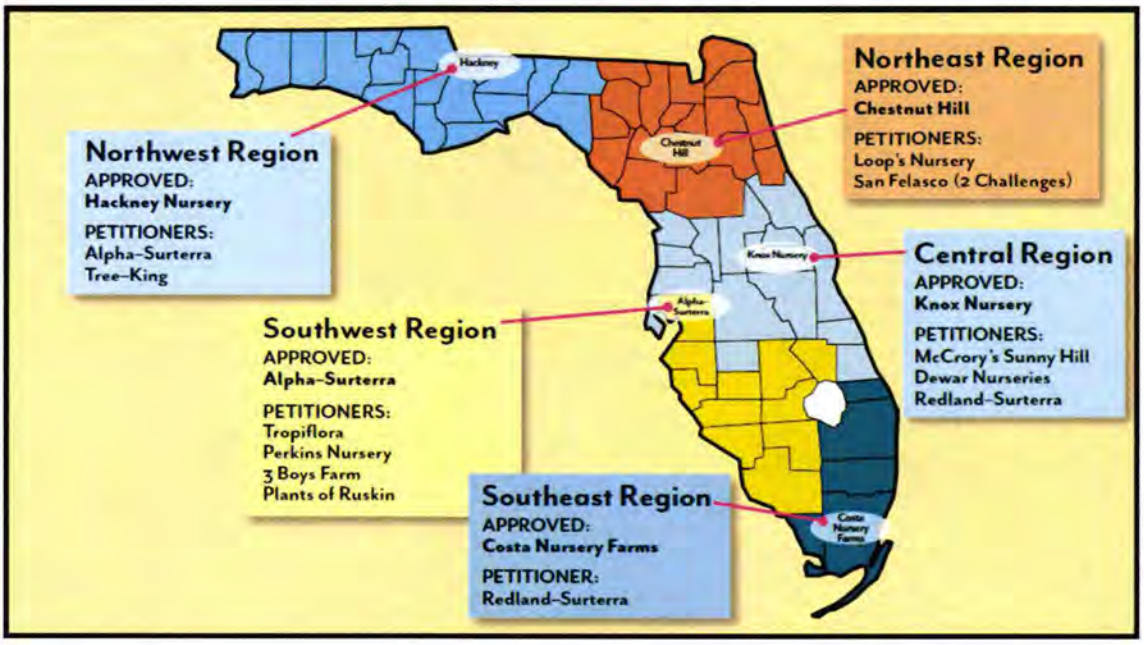
[73] s. 381.986(5)(b), F.S.

- Possesses a certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants;
- Is operated by a nurseryman;
- Has been operating as a registered nursery in this state for at least 30 continuous years;
- Has the technical and technological ability to cultivate and produce low-THC cannabis;
- Employs a medical director, who must be a physician and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis; and
- Other specified requirements.[74]

Implementation by DOH of the dispensing organization approval process was delayed due to litigation challenging proposed rules that addressed the initial application requirements for dispensing organizations, revocation of dispensing organization approval, and inspection and cultivation authorization procedures for dispensing organizations. Such litigation was resolved on May 27, 2015, with an order entered by the Division of Administrative Hearings holding that the challenged rules do not constitute an invalid exercise of delegated legislative authority.[75] Thereafter, the rules took effect on June 17, 2015.[76]

The application process to become a dispensing organization closed on July 8, 2015, with 28 applications received by DOH. On November 23, 2015, DOH announced the five approved dispensing organizations: Hackney Nursery in the northwest region, Chestnut Hill Tree Farm in the northeast region, Knox Nursery in the central region, Costa Nursery Farms in the southeast region, and Alpha Foliage in the southwest region. To date, 13 petitions[77] have been filed contesting DOH's approval of these five dispensing organizations.[78]

APPROVED DISPENSING ORGANIZATIONS AND PENDING CHALLENGES



[74] *Id.*
[75] *Baywood v.Nurseries Co., Inc. v. Dep't of Health,* Case No. 15-1694RP (Fla. DOAH May 27, 2015).
[76] Rule Chapter 64-4, F.A.C.
[77] A copy of each petition is available at http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/ (last visited on December 28, 2015).
[78] Chestnut Hill Tree Farm also filed a counter-petition to San Felasco Nurseries' challenge to the Chestnut Hill Tree Farm being approved as the northeast region dispensing organization. *Chestnut Hill Tree Farm, LLC v. San Felasco Nurseries, Inc.*, Case. No. 15-007276, (Fla. DOAH, Dec. 18, 2015).

SOURCE: Department of Health, Office of Compassionate Use.

The CMCA provides that it is a first degree misdemeanor for:

- A physician to order low-THC cannabis for a patient without a reasonable belief that the patient is suffering from a required condition; or
- Any person to fraudulently represent that he or she has a required condition to a physician for the purpose of being ordered low-THC cannabis.[79]

The CMCA specifies that notwithstanding ss. 893.13, 893.135, or 893.147, F.S., or any other law that:

- Qualified patients[80] and their legal representatives may purchase and possess low-THC cannabis up to the amount ordered for the patient's medical use.
- Approved dispensing organizations and their owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by DOH rule, of low-THC cannabis. Such dispensing organizations and their owners, managers, and employees are not subject to licensure or regulation under ch. 465, F.S., relating to pharmacies.[81]

The CMCA requires DOH to create a secure, electronic, and online registry for the registration of physicians and patients.[82] Physicians must register as the orderer of low-THC cannabis for a named patient on the registry and must update the registry to reflect the contents of the order.[83] The registry must prevent an active registration of a patient by multiple physicians and must be accessible to law enforcement agencies and to a dispensing organization to verify patient authorization for low-THC cannabis and to record the low-THC cannabis dispensed.[84]

Effect of Proposed Changes

This bill creates additional regulatory standards under the Compassionate Medical Cannabis Act (CMCA) for dispensing organizations approved by DOH to grow, process, transport, and dispense low-THC cannabis. Additionally, the bill strengthens the criteria for physicians to be able to order low-THC cannabis, the criteria for physicians to become medical directors of dispensing organizations, and DOH's responsibilities under the CMCA. The bill includes other measures to increase the accountability of those who have access to low-THC cannabis, to increase the safety and quality of the low-THC cannabis being dispensed, and to increase the security of premises and personnel in possession of low-THC cannabis.

Dispensing Organizations

Current law requires approved dispensing organizations to maintain compliance with certain criteria required to be met prior to their selection, but it does not provide standards specifically relating to the quality or safety of low-THC cannabis or the security of entities possessing or transporting low-THC cannabis. The bill establishes new quality and safety standards for growing, processing, transporting and dispensing low-THC cannabis and security standards for those entities performing such acts.

[79] s. 381.986(3), F.S.
[80] Section 381.986(1)(d), F.S., provides that a "qualified patient" is a Florida resident who has been added by a physician licensed under ch. 458, F.S. or ch. 459, F.S., to the compassionate use registry to receive low-THC cannabis from a dispensing organization.
[81] s. 381.986(7), F.S.
[82] s. 381.985(5)(a), F.S.
[83] s. 381.986(2)(c), F.S.
[84] s. 381.985(5)(a), F.S.

Growing Low-THC Cannabis

When growing low-THC cannabis, the bill provides that a dispensing organization may use pesticides determined by DOH to be safely applied to plants intended for human consumption and requires the dispensing organization to:

- Grow and process low-THC cannabis within an enclosed structure and in a room separate from any other plant;
- Inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and Consumer Services within 10 calendar days of a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures; and
- Perform fumigation or treatment of plants or the removal and destruction of infested or infected plants in accordance with ch. 581, F.S., or any rules adopted thereunder.

Processing Low-THC Cannabis

When processing low-THC cannabis, a dispensing organization must:

- Process the low-THC cannabis in an enclosure separate from other plants or products;
- Package the low-THC cannabis in compliance with the United States Poison Prevention Packaging Act (15 U.S.C. §§1471-1477);[85]
- Package the low-THC cannabis in a receptacle that has a firmly affixed and legible label stating the following information:
    - The name of the dispensing organization.
    - The quantity of low-THC cannabis contained within.
    - The cannabinoid profile of the low-THC cannabis, including the THC level.
    - Any ingredient other than low-THC cannabis contained within.
    - The date the low-THC is dispensed.
    - The patient's name and registration identification number.
    - A statement that the product is for medical use and not for resale or transfer to another person.
    - A unique serial number that will match the product with the original batch of low-THC cannabis from which the product was made to facilitate necessary warnings or recalls by DOH.
    - A recommended "use by" date or expiration date; and
- Reserve two processed samples per each batch, retain such samples for at least one year, and make those samples available for testing.

Dispensing Low-THC Cannabis

The bill prohibits a dispensing organization from dispensing more than a 30-day supply of low-THC cannabis to a patient or the patient's caregiver or selling any other type of retail product other than the physician ordered low-THC cannabis or paraphernalia. The bill also requires the dispensing organization to:

- Have the dispensing organization employee dispensing the low-THC cannabis enter into the compassionate use registry his or her name or unique employee identifier;

[85] The Poison Prevention Packaging Act requires packaging to be designed or constructed in a manner to make it significantly difficult for children under five years of age to open within a reasonable time, and not difficult for normal adults to use properly. *See* U.S. Consumer Product Safety Commission, *Poison Prevention Packaging Act*, *available at* http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/Poison-Prevention-Packaging-Act/ (last visited on December 29, 2015).

- Verify in the compassionate use registry that a physician has ordered low-THC cannabis or a specific type of paraphernalia for the patient;
- Verify the patient or patient's caregiver holds a valid and active registration card; and
- Record in the compassionate use registry the paraphernalia dispensed, if any, in addition to the other information required under current law to be recorded in the registry.

Safety and Security Measures

The bill also requires the dispensing organization to implement and maintain certain safety and security measures relating to its facilities and certain safety and quality measures for low-THC cannabis dispensed or transported by the dispensing organization. Specifically, the bill requires the dispensing organization to:

- Maintain a fully operational security alarm system;
- Maintain a video surveillance system that records continuously 24 hours per day and meets specific minimum criteria;
- Retain video surveillance recordings for a minimum of 45 days, or longer upon the request of law enforcement;
- Enclose the perimeter of any buildings used in the cultivation, processing, or dispensing of low-THC cannabis with at least a six-foot high fence;
- Ensure that the outdoor premises of the dispensing organization has sufficient lighting from dusk until dawn;
- Dispense low-THC cannabis or paraphernalia only between the hours of 9 p.m. and 7 a.m., but allows the dispensing organization to perform all other operations 24 hours per day;
- Establish and maintain a tracking system approved by DOH that traces the low-THC cannabis from seed to sale, including key notification of events as determined by DOH;
- Store low-THC cannabis in secured, locked rooms or a vault;
- Have at least 2 employees of the dispensing organization or of a contracted security agency be on the dispensing organization premises at all times;
- Have all employees wear a photo identification badge at all times while on the premises;
- Have visitors wear a visitor's pass at all times while on the premises;
- Implement an alcohol and drug free workplace policy; and
- Report to local law enforcement within 24 hours of the dispensing organization being notified or becoming aware of the theft, diversion, or loss of low-THC cannabis.

To ensure the safe transport of low-THC cannabis to dispensing organization facilities, laboratories, or patients, the bill requires dispensing organizations to:

- Maintain a transportation manifest, which must be retained for at least one year;
- Ensure only vehicles in good-working order are used to transport low-THC cannabis;
- Lock low-THC cannabis in a separate compartment or container within the vehicle;
- Have at least two persons in a vehicle transporting low-THC cannabis and at least one person remain in the vehicle while the low-THC cannabis is being delivered; and
- Provide specific safety and security training to those employees transporting low-THC cannabis.

Physicians

Current law requires a physician to meet certain criteria, including additional training and education, to be qualified to order low-THC cannabis. The bill increases the qualification criteria and allows the physician to order paraphernalia for the administration of low-THC cannabis. "Paraphernalia" is defined by the bill as objects used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis into the human body. The additional criteria in the bill require the physician to:

- Be board-certified as an oncologist, neurologist, or epileptologist or specialize in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms. When treating a patient who is a minor and a second physician's concurrence for treatment using low-THC cannabis is required, the second physician must also meet this criterion.
- Have treated the patient for cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms for at least six months.
- Include in the registry the ordered amount of low-THC cannabis that will provide the patient with not more than a 30-day supply and any paraphernalia needed by the patient for the medical use of low-THC cannabis.

The bill prohibits a physician ordering low-THC cannabis from being employed as a medical director of a dispensing organization and provides that a physician who orders low-THC cannabis and receives compensation from a dispensing organization related to the ordering of low-THC cannabis may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(n), F.S.

The bill also increases the qualification criteria for medical directors of dispensing organizations by requiring the medical director to be board-certified as an oncologist, neurologist, or epileptologist or provide proof that he or she specializes in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms.

Testing Laboratories

Current law does not require the testing of low-THC cannabis by laboratories to ensure the composition of the low-THC cannabis to be dispensed complies with law or to ensure that it is safe. The bill requires a dispensing organization to contract with a laboratory approved by DOH for purposes of testing low-THC cannabis for compliance with the law and to detect any mold, bacteria, or other contaminant which may result in adverse effects to human health or the environment. The contract must require the laboratory to report to the dispensing organization, within 48 hours of a test, the cannabinoid composition of the product and whether the laboratory has detected any mold, bacteria, or other contaminant in the product which may result in adverse effects to human health or the environment.

The bill also creates an exemption from criminal law for DOH approved laboratories and their employees, allowing the laboratories and laboratory employees to possess, test, transport, and lawfully dispose of low-THC cannabis.

Department of Health

The bill grants DOH greater regulatory oversight of dispensing organizations by authorizing DOH to conduct inspections, set certain standards for laboratory testing of low-THC cannabis, establish a registration card system for patients and caregivers, and assess fines or take disciplinary action for certain violations. The bill also grants DOH authority to conduct additional acts to administer the CMCA. Specifically, the bill provides that DOH:

- May conduct announced or unannounced inspections of dispensing organizations to determine compliance with the law.
- Must inspect a dispensing organization upon complaint or notice provided to DOH that the dispensing organization has dispensed low-THC cannabis containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.
- Must conduct at least an annual inspection to evaluate dispensing organization records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.
- May inspect laboratories to ensure laboratories are using standardized procedures to test low-THC cannabis.

- May adopt standards for the approval of laboratories contracting with dispensing organizations, including standardized procedures, required equipment, and conflict of interest provisions.
- May enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency agreement with DOH, to conduct inspections or perform other responsibilities assigned to DOH under the CMCA.
- Make a list of all approved dispensing organizations and qualified ordering physicians and medical directors publicly available on its website.
- May establish a system for issuing and renewing patient and caregiver registration cards, establish the circumstances under which the cards may be revoked by or must be returned to DOH, and establish fees to implement such system. DOH must require, at a minimum, the registration cards to:
    - State the name, address, and date of birth of the patient or caregiver.
    - Have a full-face, passport-style photograph of the patient or caregiver that has been taken within 90 days prior to registration.
    - Identify whether the cardholder is a patient or caregiver.
    - List a unique numerical identifier for the patient or caregiver that is matched to the identifier used for such person in DOH's compassionate use registry.
    - Provide the expiration date, which shall be from one year from the physician's initial order of low-THC cannabis.
    - For the caregiver, provide the name and unique numerical identifier of the patient the caregiver is assisting.
    - Be resistant to counterfeiting or tampering.
- Must create a schedule of violations in rule to impose reasonable fines not to exceed $10,000 on a licensee, and before assessing a fine must consider the severity of the violation, any actions taken by the licensee to correct the violation or to remedy complaints, and any previous violations.
- May suspend, revoke, or refuse to renew the license of a licensee for having a license, or the authority to practice any regulated profession or the authority to conduct any business, revoked, suspended, or otherwise acted against, including the denial of licensure by the licensing authority, for a violation that would constitute a violation under Florida law.
- May adopt rules necessary to implement the CMCA.

DOH is also responsible for overseeing a dispensing organization's advertising as the bill only allows a dispensing organization to use an insignia or logo approved by DOH.

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

B. SECTION DIRECTORY:

Section 1. Amends s. 381.986, F.S., relating to compassionate use of low-THC cannabis.
Section 2. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Section 381.986, F.S. authorizes DOH to impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering the CMCA. This bill also authorizes DOH to establish fees to implement the registration card system should DOH create such a system. This will have an indeterminate positive fiscal impact on DOH associated with the collection of fees.

DOH may also generate revenue from any fines assessed against dispensing organizations in violation of the CMCA which would also positively affect revenues.

2. Expenditures:

The DOH will incur costs associated with the regulatory standards for the operation, security, and safety of dispensing organizations or the growing, processing, testing, packaging, labeling, dispensing, or transportation of low-THC cannabis. These costs will be offset by the initial application and biennial renewal fees collected under s. 381.986, F.S.

DOH will also incur expenditures associated with implementation of the registration card system, however implementation of this system is permissive and the bill authorizes DOH to establish fees to implement the system. The impact is indeterminate, however, the costs would be covered by fee revenue collected. DOH may also incur minimal costs associated with rulemaking.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill does not appear to have any impact on local government revenues.

2. Expenditures:

The bill does not appear to have any impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Dispensing organizations may incur costs associated with meeting the bill's new quality, safety, and security standards unless they already meet such standards. Dispensing organizations will also incur costs associated with contracting with testing laboratories. The contract cost is indeterminate and may vary within each dispensing organization.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH appears to have sufficient rulemaking authority to carry out its responsibilities under the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to low-THC cannabis for medical use; amending s. 381.986, F.S.; providing and revising definitions; revising requirements for physicians ordering low-THC cannabis; providing that a physician who orders low-THC cannabis and receives related compensation from a dispensing organization is subject to disciplinary action; revising requirements relating to physician education; requiring the Department of Health to include caregiver information in the online compassionate use registry; revising requirements for dispensing organizations; specifying duties and responsibilities of the department; authorizing an approved laboratory and its employees to possess, test, transport, and lawfully dispose of low-THC cannabis or paraphernalia in certain circumstances; exempting an approved dispensing organization and related persons from the Florida Drug and Cosmetic Act; providing an effective date.

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

Section 1. Section 381.986, Florida Statutes, is amended to read:

381.986 Compassionate use of low-THC cannabis.—

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

(a) "Caregiver" means an individual who is 21 years of age or older, a permanent resident of the state, and registered with the department to assist a patient with the medical use of low-THC cannabis.

(b) ~~(a)~~ "Dispensing organization" means an organization approved by the department to cultivate, process, and dispense low-THC cannabis pursuant to this section.

(c) ~~(b)~~ "Low-THC cannabis" means a plant of the genus Cannabis, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only from a dispensing organization.

(d) ~~(c)~~ "Medical use" means administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also does not include the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered, ~~or~~ the qualified patient's legal guardian if the guardian is a registered caregiver, or other registered caregiver ~~representative~~ on behalf of the qualified patient.

(e) "Paraphernalia" means objects used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis into the human body.

(f) ~~(d)~~ "Qualified patient" means a permanent resident of

this state who has been added to the compassionate use registry by a physician licensed under chapter 458 or chapter 459 to receive low-THC cannabis from a dispensing organization.

(g) ~~(e)~~ "Smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.

(2) PHYSICIAN ORDERING. ~~Effective January 1, 2015,~~ A physician is authorized to ~~licensed under chapter 458 or chapter 459 who has examined and is treating a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms may~~ order ~~for the patient's medical use~~ low-THC cannabis to treat a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms; ~~such disease, disorder, or condition or to~~ order low-THC cannabis to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the ~~that~~ patient; or order paraphernalia for the medical use of low-THC cannabis, only if the physician ~~and all of the following conditions apply~~:

(a) Holds an active, unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459;

(b) Is board-certified as an oncologist, neurologist, or epileptologist or specializes in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle

spasms;

(c) Has treated the patient for cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms for at least 3 months immediately preceding the patient's registration in the compassionate use registry;

(d) Has successfully completed the course and examination required under paragraph (4)(a);

(e) ~~(b)~~ Has determined ~~The physician determines~~ that the risks of treating the patient with ~~ordering~~ low-THC cannabis are reasonable in light of the potential benefit to the ~~for that~~ patient. If a patient is younger than 18 years of age, a second physician having a board certification or specialization described in paragraph (b) must concur with this determination, and such determination must be documented in the patient's medical record; ~~.~~

(f) ~~(c) The physician~~ Registers as the orderer of low-THC cannabis for the named patient on the compassionate use registry maintained by the department and updates the registry to reflect the contents of the order, including the amount of low-THC cannabis that will provide the patient with not more than a 30-day supply and any paraphernalia needed by the patient for the medical use of low-THC cannabis. The physician must also update the registry within 7 days after any change is made to the original order to reflect the change. The physician shall deactivate the patient's and caregiver's registration when

treatment is discontinued;~~.~~

(g) ~~(d) The physician~~ Maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis;~~.~~

(h) ~~(e) The physician~~ Submits the patient treatment plan quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of low-THC cannabis on patients;~~.~~

(i) ~~(f) The physician~~ Obtains the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects; and

(j) Is not a medical director employed by a dispensing organization.

~~(a) The patient is a permanent resident of this state.~~

(3) PENALTIES.—

(a) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders low-THC cannabis or paraphernalia for a patient without a reasonable belief that the patient is suffering from:

1. Cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle

spasms that can be treated with low-THC cannabis; or

2. Symptoms of cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be alleviated with low-THC cannabis.

(b) Any person who fraudulently represents that he or she has cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms to a physician for the purpose of being ordered low-THC cannabis or paraphernalia by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c) A physician who orders low-THC cannabis or paraphernalia and receives compensation from a dispensing organization related to the ordering of low-THC cannabis is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).

(4) PHYSICIAN EDUCATION.—

(a) Before ordering low-THC cannabis or paraphernalia for medical use by a patient in this state, the appropriate board shall require the ordering physician ~~licensed under chapter 458 or chapter 459~~ to successfully complete an 8-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of low-THC cannabis, the appropriate delivery mechanisms, the

contraindications for such use, as well as the relevant state and federal laws governing the ordering, dispensing, and possessing of this substance. The ~~first~~ course and examination shall ~~be presented by October 1, 2014, and shall~~ be administered at least annually ~~thereafter~~. Successful completion of the course may be used by a physician to satisfy 8 hours of the continuing medical education requirements required by his or her respective board for licensure renewal. This course may be offered in a distance learning format.

(b) The appropriate board shall require the medical director of each dispensing organization to hold an active, unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459 and be board-certified as an oncologist, neurologist, or epileptologist or provide proof that he or she specializes in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms. Additionally, the medical director must ~~approved under subsection (5) to~~ successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses appropriate safety procedures and knowledge of low-THC cannabis.

(c) Successful completion of the course and examination specified in paragraph (a) is required for every physician who orders low-THC cannabis or paraphernalia each time such

physician renews his or her license. In addition, successful completion of the course and examination specified in paragraph (b) is required for the medical director of each dispensing organization each time such physician renews his or her license.

(d) A physician who fails to comply with this subsection and who orders low-THC cannabis or paraphernalia may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).

(5) DUTIES OF THE DEPARTMENT. ~~By January 1, 2015,~~ The department shall:

(a) Create and maintain a secure, electronic, and online compassionate use registry for the registration of physicians, ~~and~~ patients, and caregivers as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization ~~in order~~ to verify patient and caregiver authorization for low-THC cannabis and paraphernalia and record the low-THC cannabis and paraphernalia dispensed. The registry must prevent an active registration of a patient by multiple physicians.

(b) Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis or paraphernalia under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. The

department shall develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. An applicant for approval as a dispensing organization must be able to demonstrate:

1. The technical and technological ability to cultivate and produce low-THC cannabis. The applicant must possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 that is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years.

2. The ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization.

3. The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances.

4. An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department.

5. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a $5 million performance bond.

6. That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04.

7. The employment of a medical director who meets the qualifications of paragraph (4)(b) ~~is a physician licensed under chapter 458 or chapter 459~~ to supervise the activities of the dispensing organization.

(c) Monitor physician registration and ordering of low-THC cannabis or paraphernalia for ordering practices that could facilitate unlawful diversion or misuse of low-THC cannabis and take disciplinary action as indicated.

~~(d) Adopt rules necessary to implement this section.~~

(6) DISPENSING ORGANIZATION.—An approved dispensing organization, at all times, must ~~shall~~ maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization under subsection (5) and the criteria required in this subsection ~~at all times~~.

(a) When growing low-THC cannabis, a dispensing organization:

1. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

2. Must grow and process low-THC cannabis within an enclosed structure and in a room separate from any other plant.

3. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and Consumer Services within 10 calendar days after a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures.

4. Must perform fumigation or treatment of plants, or the removal and destruction of infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

(b) When processing low-THC cannabis, a dispensing organization must:

1. Process the low-THC cannabis in an enclosure separate from other plants or products.

2. Package the low-THC cannabis in compliance with the United States Poison Prevention Packaging Act, 15 U.S.C. ss. 1471-1477.

3. Package the low-THC cannabis in a receptacle that has a firmly affixed and legible label stating the following information:

a. The name of the dispensing organization.

b. The quantity of low-THC cannabis contained in the receptacle.

c. The cannabinoid profile of the low-THC cannabis, including the THC level.

d. Any ingredient other than low-THC cannabis contained in the receptacle.

e. The date that the low-THC is dispensed.

f. The patient's name and registration identification number.

g. A statement that the low-THC cannabis is for medical use and not for resale or transfer to another person.

h. A unique serial number corresponding to the original batch of low-THC cannabis from which the low-THC cannabis contained in the receptacle was made, to facilitate necessary warnings or recalls by the department.

i. A recommended "use by" date or expiration date.

4. Reserve two processed samples from each batch, retain such samples for at least 1 year, and make such samples available for testing.

(c) When dispensing low-THC cannabis or paraphernalia, a dispensing organization:

1. May not dispense more than a 30-day supply of low-THC cannabis to a patient or the patient's caregiver.

2. Must have the dispensing organization's employee who dispenses the low-THC cannabis or paraphernalia enter into the compassionate use registry his or her name or unique employee identifier.

3. Must verify in the compassionate use registry that a physician has ordered the low-THC cannabis or a specific type of paraphernalia for the patient.

4. May not dispense or sell any other type of retail product, other than physician-ordered paraphernalia, while

dispensing low-THC cannabis.

5. Must ~~Before dispensing low-THC cannabis to a qualified patient, the dispensing organization shall~~ verify that the patient has an active registration in the compassionate use registry, the patient or patient's caregiver holds a valid and active registration card, the order presented matches the order contents as recorded in the registry, and the order has not already been filled.

6. Must, upon dispensing the low-THC cannabis, ~~the dispensing organization shall~~ record in the registry the date, time, quantity, and form of low-THC cannabis and any paraphernalia dispensed.

(d) To ensure the safety and security of its premises and any off-site storage facilities, and to maintain adequate controls against the diversion, theft, and loss of low-THC cannabis, a dispensing organization must:

1. Maintain a fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detectors; pressure switches; and duress, panic, and hold-up alarms.

2. Maintain a video surveillance system that records continuously 24 hours each day and meets the following minimum criteria:

a. Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of the premises. Controlled areas include grow rooms, processing

rooms, storage rooms, disposal rooms or areas, and point-of-sale rooms.

b. Cameras are fixed in entrances and exits to the premises, which shall record from both indoor and outdoor, or ingress and egress, vantage points.

c. Recorded images must clearly and accurately display the time and date.

3. Retain video surveillance recordings for a minimum of 45 days or longer upon the request of a law enforcement agency.

4. Enclose the perimeter of any buildings used in cultivating, processing, or dispensing low-THC cannabis with a fence or wall at least 6 feet in height.

5. Ensure that the organization's outdoor premises have sufficient lighting from dusk until dawn.

6. Establish and maintain a tracking system approved by the department that traces the low-THC cannabis from seed to sale. The tracking system shall include notification of key events as determined by the department, including when low-THC cannabis seeds are planted, low-THC cannabis plants are harvested, low-THC cannabis plants are destroyed, low-THC cannabis is transported, low-THC cannabis is sold, or a theft, diversion, or loss of low-THC cannabis occurs.

7. Not dispense low-THC cannabis or paraphernalia between the hours of 9 p.m. and 7 a.m., but may perform all other operations 24 hours each day.

8. Store low-THC cannabis in a secured, locked room or a

vault.

9. Require at least two of its employees, or two employees of a security agency with whom it contracts, to be on the organization's premises at all times.

10. Require each employee to wear a photo identification badge at all times while on the premises.

11. Require each visitor to wear a visitor's pass at all times while on the premises.

12. Implement an alcohol and drug-free workplace policy.

13. Report to local law enforcement within 24 hours after it is notified or becomes aware of the theft, diversion, or loss of low-THC cannabis.

(e) To ensure the safe transport of low-THC cannabis to dispensing organization facilities, laboratories, or patients, the dispensing organization must:

1. Maintain a transportation manifest, which must be retained for at least 1 year.

2. Ensure only vehicles in good working order are used to transport low-THC cannabis.

3. Lock low-THC cannabis in a separate compartment or container within the vehicle.

4. Require at least two persons to be in a vehicle transporting low-THC cannabis, and require at least one person to remain in the vehicle while the low-THC cannabis is being delivered.

5. Provide specific safety and security training to

employees transporting or delivering low-THC cannabis.

(f) A dispensing organization may only use an insignia or logo approved by the department to advertise its product.

(g) A dispensing organization must contract with a laboratory approved by the department for purposes of testing low-THC cannabis for compliance with this section and to detect any mold, bacteria, or other contaminant in the product that may result in adverse effects to human health or the environment. The contract must require the laboratory to report to the dispensing organization, within 48 hours after a test, the cannabinoid composition of the product and whether the laboratory has detected any mold, bacteria, or other contaminant in the product that may result in adverse effects to human health or the environment.

(7) DEPARTMENT AUTHORITY AND RESPONSIBILITIES.—

(a) The department:

1. May conduct announced or unannounced inspections of dispensing organizations to determine compliance with this section or rules adopted pursuant to this section.

2. Must inspect a dispensing organization upon complaint or notice provided to the department that the dispensing organization has dispensed low-THC cannabis containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.

3. Must conduct at least a biennial inspection of each dispensing organization to evaluate the dispensing

organization's records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.

(b) The department may inspect laboratories to ensure they are using standardized procedures to test low-THC cannabis.

(c) The department may adopt standards for the approval of laboratories contracting with dispensing organizations, including standardized procedures, required equipment, and conflict-of-interest provisions.

(d) The department may enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency agreement with the department, to conduct inspections or perform other responsibilities assigned to the department under this section.

(e) The department must make a list of all approved dispensing organizations and qualified ordering physicians and medical directors publicly available on its website.

(f) The department may establish a system for issuing and renewing patient and caregiver registration cards, establish the circumstances under which the cards may be revoked by or must be returned to the department, and establish fees to implement such system. The department must require, at a minimum, the

registration cards to:

1. Provide the name, address, and date of birth of the patient or caregiver.

2. Have a full-face, passport-type, color photograph of the patient or caregiver taken within the 90 days immediately preceding registration.

3. Identify whether the cardholder is a patient or caregiver.

4. List a unique numeric identifier for the patient or caregiver that is matched to the identifier used for such person in the department's compassionate use registry.

5. Provide the expiration date, which shall be 1 year after the date of the physician's initial order of low-THC cannabis.

6. For the caregiver, provide the name and unique numeric identifier of the patient that the caregiver is assisting.

7. Be resistant to counterfeiting or tampering.

(g) The department must create a schedule of violations in rule to impose reasonable fines not to exceed $10,000 on a dispensing organization. In determining the amount of the fine to be levied for a violation, the department shall consider:

1. The severity of the violation.

2. Any actions taken by the dispensing organization to correct the violation or to remedy the complaint.

3. Any previous violations.

(h) The department may suspend, revoke, or refuse to renew

a dispensing organization's approval if the organization has had a license or authority to practice any regulated profession or the authority to conduct any business in any other state or country revoked, suspended, or otherwise acted against, including the denial of licensure by the licensing authority, for a violation that would constitute a violation under Florida law.

(i) The department may adopt rules necessary to implement this section.

(8) ~~(7)~~ EXCEPTIONS TO OTHER LAWS.—

(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a qualified patient and the qualified patient's caregiver ~~legal representative~~ may purchase and possess for the patient's medical use up to the amount of low-THC cannabis ordered for the patient, but not more than a 30-day supply of low-THC cannabis.

(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved dispensing organization and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of low-THC cannabis. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

(c) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved laboratory and its employees may possess, test, transport, and lawfully dispose of low-THC cannabis or paraphernalia as provided by department rule.

(d) An approved dispensing organization and its owners, managers, and employees are not subject to licensure or regulation under chapter 465 or chapter 499 for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of reasonable quantities, as established by department rule, of low-THC cannabis.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1335 Long-term Care Prioritization
SPONSOR(S): Magar
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	11 Y, 2 N	Guzzo	Poche
2) Health Care Appropriations Subcommittee		Clark	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In 2011, the Legislature created the Statewide Medicaid Managed Care Program as an integrated managed care program for all covered services, including long-term care services. The Statewide Medicaid Managed Care Program consists of two programs: the Managed Medical Assistance Program (MMA Program) and the Long-Term Care Managed Care Program (LTC Program). The MMA Program covers primary and acute medical assistance and related services to Medicaid recipients.

The LTC Program provides services to Medicaid recipients in nursing facilities and in community settings, including an individual's home, an assisted living facility, or an adult family care home. To be eligible for the LTC Program, an individual must be:

- Age 65 or older and eligible for Medicaid, or age 18 or older and eligible for Medicaid by reason of a disability; and
- Determined to require nursing home care, or be at imminent risk of requiring nursing home care.

When an individual, or the individual's representative, expresses an interest in receiving LTC services, the Department of Elder Affairs (DOEA) screens and scores the individual based on his or her frailty and need for services. The individual is then placed on the waitlist for services. When funding is available, individuals are released from the waitlist based on their priority score, which indicates their level of frailty. The individual must be determined to be medically eligible for services by DOEA, and financially eligible for Medicaid by the Department of Children and Families (DCF), before they are approved to be enrolled in the LTC Program.

The process for prioritizing individuals to be placed on the waitlist, placing them on the waitlist, and releasing them from the waitlist for enrollment in the LTC Program is not currently provided in statute or administrative rule.

HB 1335 establishes in statute the process DOEA uses to prioritize individuals for enrollment in the LTC Program. The process involves frailty-based screening, which results in a priority score that is used to place individuals on the waitlist. The bill requires DOEA to make the methodology used to calculate an individual's priority score publicly available on its website. The bill requires DOEA to rescreen individuals on the waitlist annually and provides for a rescreening due to a significant change in the individual's condition or circumstances. The bill establishes specific criteria for DOEA to terminate an individual from the waitlist. The bill exempts the following persons from the screening and waitlist process:

- Individuals age 18, 19, or 20, who have a chronic debilitating disease or conditions of one or more physiological or organ systems which make them dependent on 24-hour medical supervision;
- Individuals determined to be at high risk and referred by the adult protective services program within DCF; and
- Nursing facility residents who wish to transition into the community and who have resided in a skilled nursing facility licensed in Florida for at least 60 consecutive days.

The bill does not appear to have a fiscal impact on state or local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Statewide Medicaid Managed Care

In 2010, the Florida House of Representatives contracted with a consultant to analyze Florida's Medicaid program and identify problems and possible solutions; the consultant concluded that Florida Medicaid's fragmented, complex system made it difficult to improve value for patients and taxpayers.[1] As a result, in 2011, the Legislature established the Statewide Medicaid Managed Care (SMMC) program as Part IV of Chapter 409, F.S.

The SMMC program is an integrated managed care program for Medicaid enrollees to provide all mandatory and optional Medicaid benefits. A unified, coordinated system of care is a primary characteristic of the SMMC program, in part because it solves the problem of complexity with which Florida's Medicaid program was plagued for decades. In the SMMC program, each Medicaid recipient has one managed care organization to coordinate all health care services, rather than various entities.[2] Within the SMMC program, the Managed Medical Assistance (MMA) program provides primary and acute medical assistance and related services to enrollees. The Long-term Care Managed Care (LTC) program provides services to Medicaid recipients in nursing facilities and in community settings, including an individual's home, an assisted living facility, or an adult family care home.

Managed Medical Assistance Program

The MMA Program requires AHCA to make payments for primary and acute medical assistance and related services using a managed care model.[3] Managed care plans in the MMA Program are required to cover, at a minimum, the following services:

- Advanced registered nurse practitioner services;
- Ambulatory surgical treatment center services;
- Birthing center services;
- Chiropractic services;
- Dental Services;
- Early periodic screening diagnosis and treatment services for recipients under age 21;
- Emergency services;
- Family planning services and supplies;
- Health start services;
- Hearing services;
- Home health agency services;
- Hospice services;
- Hospital inpatient services;
- Hospital outpatient services;
- Laboratory and imaging services;
- Medical supplies, equipment, prostheses, and orthoses;
- Mental health services;

[1] Medicaid Managed Care Study, Pacific Health Policy Group, p. 73, March 2010
[2] This comprehensive coordinated system of care was first successfully implemented in the 5-county Medicaid reform pilot program from 2006-2014.
[3] S. 409.971, F.S.

- Nursing care;
- Optical services and supplies;
- Optometrist services;
- Physical, occupational, respiratory, and speech therapy services;
- Physician services, including physician assistant services;
- Podiatric services;
- Prescription drugs;
- Renal dialysis services;
- Respiratory equipment and supplies;
- Rural health clinic services;
- Substance abuse treatment services; and
- Transportation to access covered services.[4]

Long Term Care Program

The LTC Program provides long term care services, including nursing facility and home and community based services, to eligible Medicaid recipients. Long-term care plans are required to, at a minimum, cover the following:

- Nursing facility care;
- Services provided in assisted living facilities;
- Hospice;
- Adult day care;
- Medical equipment and supplies, including incontinence supplies;
- Personal care;
- Home accessibility adaptation;
- Behavior management;
- Home-delivered meals;
- Case Management;
- Occupation therapy;
- Speech therapy;
- Respiratory therapy;
- Physical therapy;
- Intermittent and skilled nursing;
- Medication administration;
- Medication Management;
- Nutritional assessment and risk reduction;
- Caregiver training;
- Respite care;
- Transportation; and
- Personal emergency response systems.[5]

To be eligible for the LTC Program, an individual must be:

- Age 65 or older and eligible for Medicaid, or age 18 or older and eligible for Medicaid by reason of a disability; and
- Determined by the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) Program to require nursing facility care as defined in s. 409.985(3), F.S.[6]

[4] S. 409.973(1), F.S.
[5] S. 409.98, F.S.
[6] S. 409.979(1), F.S.

When determining the need for nursing facility care, the nature of the services prescribed, the level of nursing or other health care personnel necessary to provide such services, and the availability of and access to community or alternative resources are all considered.[7] For purposes of the LTC Program, "nursing facility care" means the individual requires, or is at imminent risk of,:

- 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;
    - Also, the services 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.
- 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;
    - Also, the services needed on a daily or intermittent basis are to be performed under the supervision of licensed nursing or other health professionals because the individual is incapacitated mentally or physically.
- 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.
    - Also, the necessary limited services are to be performed under the supervision of licensed nursing or other health professionals because the individual is mildly incapacitated mentally or physically.

The Department of Elder Affairs (DOEA) administers programs and services for elders through 11 Area Agencies on Aging (AAAs), which also operate Aging and Disability Resource Centers (ADRCs). The ADRCs provide information and referral services to individuals seeking long-term care services. The ADRCs also screen individuals for eligibility for long-term care services.

The LTC Program enrollment process is administered by DOEA, the Department of Children and Families (DCF), and AHCA. An individual in need of services or seeking services must contact the appropriate ADRC to request a screening. The screening is intended to provide the ADRC with information describing the individual's level of frailty. During the screening, the ADRC gathers basic information about the individual, including general health information and any assistance the individual needs with activities of daily living. Based on the screening, the individual receives a priority score, which indicates the level of need for services and reflects the level of the individual's frailty. Using the priority score, the individual is then placed on the waitlist.

When funding becomes available, the frailest individuals are taken off the waitlist first, based upon priority score. The individual must then go through a comprehensive face-to-face assessment conducted by the local Comprehensive Assessment and Review for Long-Term Care Services (CARES) staff.[8] After CARES determines the medical eligibility of the individual, DCF determines the financial eligibility of the individual. If approved for both medical and financial eligibility, AHCA must notify the individual and provide information on selecting a long-term care plan.

The process for prioritizing individuals to be placed on the waitlist, placing them on the waitlist, and releasing them from the waitlist for enrollment in the LTC Program is not currently provided in statute or administrative rule.

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[7] S. 409.985(3), F.S.

[8] Florida Department of Elder Affairs, *Comprehensive Assessment and Review for Long-Term Care Services (CARES)*, available at: www.elderaffairs.state.fl.us/does/cares.php (last viewed January 23, 2016). Comprehensive Assessment and Review for Long-Term Care Services (CARES) is Florida's federally mandated pre-admission screening program for nursing home applicants. A registered nurse or assessor performs client assessments. A physician or registered nurse reviews each application to determine the level of care that is most appropriate for the applicant. The assessment identifies long-term care needs, and establishes the appropriate level of care (medical eligibility for nursing facility care), and recommends the least restrictive, most appropriate placement. Federal law also mandates that the CARES Program perform an assessment or review of each individual who requests Medicaid reimbursement for nursing facility placement, or who seeks to receive home and community-based services through Medicaid waivers.

Effect of Proposed Changes

HB 1335 establishes in statute the process DOEA uses to prioritize individuals for enrollment in the LTC Program. The process involves frailty-based screening that provides a priority score that is used to place individuals on the waitlist. The screening must be conducted by a person certified by DOEA. The bill requires DOEA to make the methodology used to calculate an individual's priority score publicly available on its website. The bill requires DOEA to rescreen individuals on the waitlist annually and provides for a rescreening due to a significant change in the individual's condition or circumstances.

The bill authorizes DOEA to terminate an individual from the waitlist if he or she:

- Does not have a current priority score;
- Wishes to be removed from the waitlist;
- Does not keep an appointment to complete the rescreening without rescheduling beforehand;
- Is no longer eligible to receive services because he or she has not completed or met clinical or financial eligibility requirements;
- Begins the eligibility process for the LTC Program; or
- Begins receiving home and community-based services through the long-term care managed care program.

The bill provides that certain individuals have priority for enrollment in the LTC Program and are exempt from participating in the screening or waitlist process, including individuals:

- Age 18, 19, or 20, who have a chronic debilitating disease or conditions of one or more physiological or organ systems which make them dependent on 24-hour medical supervision;
- Determined to be at high risk and referred by the adult protective services program within DCF; and
- Nursing facility residents who wish to transition into the community and who have resided in a skilled nursing facility licensed in Florida for at least 60 consecutive days.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 409.962, F.S., relating to definitions.
Section 2: Amends s. 409.979, F.S., relating to eligibility.
Section 3: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The process DOEA uses to prioritize individuals in the LTC Program has been included within the General Appropriations Act Implementing Bill for the last two fiscal years (Chapter 2014-56 and Chapter 2015-222, Laws of Florida). This bill permanently codifies the process in statute.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

See Drafting Issues, Section III, c., below.

C. DRAFTING ISSUES OR OTHER COMMENTS:

DOEA requires specific rulemaking authority to promulgate rules associated with the LTC Program enrollment process. The bill does not provide authority for DOEA to engage in the required rulemaking process.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to long-term care prioritization; amending s. 409.962, F.S.; defining terms; amending s. 409.979, F.S.; providing a process for waitlist prioritization and enrollment in the long-term care managed care program; requiring the Agency for Health Care Administration and the Department of Elderly Affairs to implement a screening and prioritization process; requiring the department to send written correspondence under certain circumstances; authorizing the department to terminate an individual from the waitlist under certain circumstances; requiring individuals to be financially and clinically eligible before enrollment in the program; providing exemptions from the screening or waitlist process; providing an effective date.

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

Section 1. Section 409.962, Florida Statutes, is amended to read:

409.962 Definitions.—As used in this part, except as otherwise specifically provided, the term:

(1) "Accountable care organization" means an entity qualified as an accountable care organization in accordance with federal regulations, and which meets the requirements of a

provider service network as described in s. 409.912(2).

(2) "Agency" means the Agency for Health Care Administration.

(3) "Aging network service provider" means a provider that participated in a home and community-based waiver administered by the Department of Elderly Affairs or the community care service system pursuant to s. 430.205 as of October 1, 2013.

(4) "APPL" means the assessed priority pipeline list, maintained by the Department of Elderly Affairs, which lists individuals who have been released from the waitlist for potential enrollment in the long-term care managed care program.

(5) "Authorized or designated representative" means an individual who has the legal authority to make decisions on behalf of a Medicaid enrollee or potential Medicaid enrollee in matters related to the screening process, the eligibility process, or the managed care plan.

(6) ~~(4)~~ "Comprehensive long-term care plan" means a managed care plan, including a Medicare Advantage Special Needs Plan organized as a preferred provider organization, provider-sponsored organization, health maintenance organization, or coordinated care plan, which ~~that~~ provides services described in s. 409.973 and also provides the services described in s. 409.98.

(7) ~~(5)~~ "Department" means the Department of Children and Families.

(8) ~~(6)~~ "Eligible plan" means a health insurer authorized

under chapter 624, an exclusive provider organization authorized under chapter 627, a health maintenance organization authorized under chapter 641, or a provider service network authorized under s. 409.912(2) or an accountable care organization authorized under federal law. For purposes of the managed medical assistance program, the term also includes the Children's Medical Services Network authorized under chapter 391 and entities qualified under 42 C.F.R. part 422 as Medicare Advantage Preferred Provider Organizations, Medicare Advantage Provider-sponsored Organizations, Medicare Advantage Health Maintenance Organizations, Medicare Advantage Coordinated Care Plans, and Medicare Advantage Special Needs Plans, and the Program of All-inclusive Care for the Elderly.

(9) ~~(7)~~ "Long-term care plan" means a managed care plan that provides the services described in s. 409.98 for the long-term care managed care program.

(10) ~~(8)~~ "Long-term care provider service network" means a provider service network a controlling interest of which is owned by one or more licensed nursing homes, assisted living facilities with 17 or more beds, home health agencies, community care for the elderly lead agencies, or hospices.

(11) ~~(9)~~ "Managed care plan" means an eligible plan under contract with the agency to provide services in the Medicaid program.

(12) ~~(10)~~ "Medicaid" means the medical assistance program authorized by Title XIX of the Social Security Act, 42 U.S.C.

ss. 1396 et seq., and regulations thereunder, as administered in this state by the agency.

(13)~~(11)~~ "Medicaid recipient" or "recipient" means an individual who the department or, for Supplemental Security Income, the Social Security Administration determines is eligible pursuant to federal and state law to receive medical assistance and related services for which the agency may make payments under the Medicaid program. For the purposes of determining third-party liability, the term includes an individual formerly determined to be eligible for Medicaid, an individual who has received medical assistance under the Medicaid program, or an individual on whose behalf Medicaid has become obligated.

(14)~~(12)~~ "Prepaid plan" means a managed care plan that is licensed or certified as a risk-bearing entity, or qualified pursuant to s. 409.912(2), in the state and is paid a prospective per-member, per-month payment by the agency.

(15) "Priority score" means a number that indicates an individual's need for services and that is used to prioritize an individual's enrollment in the long-term care managed care program.

(16)~~(13)~~ "Provider service network" means an entity qualified pursuant to s. 409.912(2) of which a controlling interest is owned by a health care provider, or group of affiliated providers, or a public agency or entity that delivers health services. Health care providers include Florida-licensed

health care professionals or licensed health care facilities, federally qualified health care centers, and home health care agencies.

(17) "Rescreening" means the use of a screening tool by staff of the Department of Elderly Affairs to conduct a recurring annual screening of an individual or a screening due to a significant change in the individual's condition. The Department of Elderly Affairs shall conduct the annual screening within 13 months after the previous screening.

(18) "Screening" means the use of a screening tool by Department of Elderly Affairs staff for initial screenings, which must occur prior to placement on the waitlist.

(19) "Significant change in the individual's condition" means, in relation to screening or rescreening for long-term care services, a change in the individual's health status after an accident or illness; a change in his or her living situation; a change in his or her caregiver relationship; the loss, damage, or deterioration of his or her home environment; or the loss of his or her spouse or caregiver.

(20)~~(14)~~ "Specialty plan" means a managed care plan that serves Medicaid recipients who meet specified criteria based on age, medical condition, or diagnosis.

(21) "Waitlist" means the statewide assessed priority consumer list, maintained by the Department of Elderly Affairs, which lists in priority order individuals who have completed the scoring and placement process before enrollment in the home and

community-based services portion of the long-term care managed care program.

Section 2. Subsection (3) of section 409.979, Florida Statutes, is amended, and subsections (4) through (10) are added to that section, to read:

409.979 Eligibility.—

(3) The Department of Elderly Affairs shall prioritize individuals for enrollment in the long-term care managed care program using a frailty-based screening that provides a priority score that is used to place individuals on the waitlist. The Department of Elderly Affairs shall make offers for enrollment to eligible individuals based on the assigned priority score ~~a wait-list prioritization~~ and subject to the availability of funds. Before making enrollment offers, the department must ~~shall~~ determine that sufficient funds exist to support additional enrollment into plans.

(4) The Department of Elderly Affairs shall maintain the waitlist, which is the only waitlist for the long-term care managed care program and, with the agency, may limit enrollment in the program so as not to exceed:

(a) The number of Medicaid recipients who may be enrolled, or who are projected to be enrolled, in the long-term care managed care program under the total long-term care managed care program allocation in the General Appropriations Act.

(b) The available funding to serve the total number of individuals on the APPL.

(5) A person certified by the Department of Elderly Affairs shall complete the screening for each individual requesting enrollment in the long-term care managed care program. The individual requesting long-term care services, or the individual's authorized or designated representative, must participate in an initial screening. The screening must be completed in its entirety before an individual may be placed on the waitlist for the program.

(6) The Department of Elderly Affairs shall generate a priority score upon completion of the screening, which shall be used to prioritize an individual's order of enrollment into the program. Upon completion of the scoring and waitlist placement process, the Department of Elderly Affairs shall provide the individual, or his or her authorized or designated representative, with notification of waitlist placement and shall make publicly available on its website the specific methodology used to calculate an individual's priority score. The individual, or his or her authorized or designated representative, may request a rescreening due to a significant change in the individual's condition. The Department of Elderly Affairs shall perform a rescreening annually so that an individual may remain on the waitlist.

(7) If the Department of Elderly Affairs is unable to contact the individual to schedule an initial screening, a significant change rescreening, or an annual rescreening, it shall send written correspondence to the last documented address

of the individual or to the authorized or designated representative listed for that individual. The written correspondence shall request that the individual contact the Department of Elderly Affairs within 10 business days after the date of the notice and notify the individual that he or she may be terminated from the screening process or waitlist due to the Department of Elderly Affairs' inability to successfully make contact and perform the screening or rescreening.

(8) The Department of Elderly Affairs may terminate an individual from the waitlist if he or she meets any of the following criteria:

(a) Does not have a current priority score.

(b) Wishes to be removed from the waitlist.

(c) Does not keep an appointment to complete the rescreening without rescheduling beforehand.

(d) Is no longer eligible to receive services because he or she has not completed or met clinical or financial eligibility requirements.

(e) Begins the eligibility process for the long-term care managed care program.

(f) Begins receiving home and community-based services through the long-term care managed care program.

(9) Before enrollment in the program, individuals must be determined financially and clinically eligible. The Department of Elderly Affairs shall determine clinical eligibility, and the Department of Children and Families shall determine financial

eligibility, for Medicaid pursuant to s. 409.919.

(10) The following individuals have priority for enrollment in the long-term care managed care program and are exempt from participating in the screening or waitlist process if all other program eligibility requirements are met:

(a) Individuals who are at least 18 years, but younger than 21 years, of age who have chronic debilitating diseases or conditions of one or more physiological or organ systems which generally make them dependent on 24-hour-a-day medical, nursing, or health supervision or intervention.

(b) Individuals determined to be at high risk and referred by the adult protective services program within the Department of Children and Families.

(c) Nursing facility residents who wish to transition into the community and who have resided in a skilled nursing facility licensed in this state for at least 60 consecutive days.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1411 Termination of Pregnancies
SPONSOR(S): Burton and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1722

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	7 Y, 6 N	McElroy	O'Callaghan
2) Health Care Appropriations Subcommittee		Pridgeon	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 1411 amends abortion clinic licensure requirements, prohibits the sale or donation of fetal remains, prohibits certain public funding, and creates a registration program for abortion referral and counseling agencies.

Abortion clinics are regulated by the Agency for Health Care Administration (AHCA) under ch. 390, F.S. The bill amends the regulatory requirements for abortion clinics. It establishes the manner for disposal of fetal remains and clarifies the penalty for failing to do so. It requires all abortion clinics to comply with the reporting requirements for the United States Standard Report of Induced Termination of Pregnancy adopted by the Centers for Disease Control and Prevention. It removes an existing license fee cap and requires AHCA to establish fees which may not be more than the costs incurred by AHCA in licensing and regulating abortion clinics.

The bill requires abortion clinics that perform abortions after the first trimester to have a written transfer agreement with a hospital within a reasonable proximity to the clinic, and requires physicians who perform abortions in the clinic to have admitting privileges with a hospital within a reasonable proximity to the clinic. Abortion clinics that perform only first trimester abortions must have such a transfer agreement, or physicians who perform abortions in the clinic must have such admitting privileges. The bill also defines "gestation" and the trimesters of pregnancy, which are not currently defined in the licensure act.

The bill requires the AHCA to perform annual licensure inspections of all abortion clinics, including a review of at least 50 percent of the patient records generated since the last inspection. The bill requires AHCA to submit an annual report to the President of the Senate and the Speaker of the House of Representatives which summarizes all regulatory actions it has taken against abortion clinics during the prior year.

The bill prohibits selling, purchasing, donating or transferring fetal remains obtained through an abortion, as well as advertising or offering to do any of the preceding acts.

The bill prohibits public funding for an organization that owns, operates, or is affiliated with a licensed abortion clinic, and provides exemptions to this prohibition.

The bill requires abortion referral or counseling agencies to register with AHCA, and AHCA must include actions against referral agencies in the annual report of ch. 390, F.S., licensure actions required by the bill.

The bill has a negative fiscal impact on AHCA of $59,951 in recurring and $185,213 in non-recurring costs. The bill will also require 0.5 FTE for additional inspections and records reviews. The bill has no impact on local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Federal Law on Abortion

Right to Abortion

In 1973, the foundation of modern abortion jurisprudence, *Roe v. Wade*[1], was decided by the U.S. Supreme Court. Using strict scrutiny, the Court determined that a woman's right to an abortion is part of a fundamental right to privacy guaranteed under the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution. Further, the Court reasoned that state regulation limiting the exercise of this right must be justified by a compelling state interest, and must be narrowly drawn.[2] In 1992, the fundamental holding of *Roe* was upheld by the U.S. Supreme Court in *Planned Parenthood v. Casey*.[3]

Undue Burden

In *Planned Parenthood v. Casey*, the U.S. Supreme Court established the undue burden standard for determining whether a law places an impermissible obstacle to a woman's right to an abortion. The Court held that health regulations which impose undue burdens on the right to abortion are invalid.[4] State regulation imposes an "undue burden" on a woman's decision to have an abortion if it has the purpose or effect of placing a substantial obstacle in the path of the woman who seeks the abortion of a nonviable fetus.[5] However, the court opined, not every law which makes the right to an abortion more difficult to exercise is an infringement of that right.[6]

Physician Admitting Privileges

An admitting privilege is the right of a physician to admit patients to a particular hospital, and to provide specific services in that facility.[7] Ten states have enacted legislation requiring physicians who perform abortions to have admitting privileges with a local hospital.[8] The required distance between the location where the abortion is performed and the location of the hospital where the physician has admitting privileges varies in these statutes from within the same metropolitan area to within 30 miles.[9]

At least 10 states have enacted laws which require physicians who perform abortions to have hospital admitting privileges. Eight of these laws generated constitutional challenges.[10] In Wisconsin, a federal court ruled that the admitting privilege law was unconstitutional and permanently enjoined it.[11] In Alabama, Louisiana and Mississippi federal courts ruled the laws unconstitutional and enjoined them

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[1] *Roe v. Wade*, 410 U.S. 113 (1973).
[2] Id.
[3] *Casey*, 505 U.S. 833 (1992).
[4] Id. at 878.
[5] Id. at 877
[6] Id. at 873.
[7] *FAQ: The Next Abortion Battle: The Courts And Hospital Admitting-Privilege Laws*, Kaiser Health News, Julie Rovner, August 8, 2014. http://khn.org/news/abortion-admitting-privileges-fight/ (last visited January 25, 2016).In order for a physician to be granted privileges, a hospital generally checks the individual's medical credentials, license and malpractice history. Many hospitals also require physicians to admit a minimum number of patients to the hospital each year before they will grant or renew privileges. Others require the doctor to live within a minimum distance of the hospital.
[8] Alabama (Ala. Code 1975 s. 26-23E-4); Louisiana (LSA-R.S. 40:1061.10); Mississippi (Miss. Code Ann s. 41-75-1); Missouri (V.A.M.S. 188.080); North Dakota (NDCC 14-02.1-04); Oklahoma (Okla. Sess. Laws 370 (2014)); Tennessee (T.C.A. s. 39-15-202); Texas (V.T.C.A. s. 171.0031); and Wisconsin (W.S.A. 253.095).
[9] Alabama (Ala. Code 1975 s. 26-23E-4; and Texas (V.T.C.A. s. 171.0031), respectively.
[10] Admitting privilege laws in Tennessee and North Dakota were not challenged, and are in effect.
[11] *Planned Parenthood of Wisconsin, Inc. v. Schimel*, 806 F.3d 908 (7th Cir. 2015).

temporarily, but final orders have not yet issued and the cases are ongoing.[12] Similarly, in Oklahoma the Oklahoma Supreme Court temporarily enjoined the law without ruling on its constitutionality, and the case is ongoing.[13] Federal courts in Missouri and South Carolina upheld the admitting privilege laws, finding they did not violate the constitution.[14] Finally, in Texas, a federal court of appeal ruled that the admitting privilege law did not violate the constitution, but the U.S. Supreme Court stayed its effect pending appeal. That appeal is ongoing in the U.S. Supreme Court.[15]

In Florida, s. 390.012(3)(c), F.S., requires the medical director of an abortion clinic to have *either* admitting privileges at a licensed hospital in Florida, *or* a transfer agreement with a licensed hospital within "reasonable proximity" of the clinic. AHCA defines "reasonable proximity" in Rule 59A-9.019, F.A.C., as a distance not to exceed thirty minutes transport time by emergency vehicle. This requirement applies only to clinics which perform abortions after the first trimester. Individual physicians who perform abortions are not required to have admitting privileges or transfer agreements. Clinics that only provide abortions during the first trimester are not required to have transfer agreements or physicians with admitting privileges.

Federal Funding of Abortions

The Hyde Amendment is a rider to the annual appropriations bill for the U.S. Departments of Labor and Education, which prevents Medicaid and any other programs under these departments from funding abortions, except in limited cases. The Hyde Amendment does not prohibit the use of state or local public funds to pay for abortions.

The Hyde Amendment has been enacted into law in various forms since 1976.[16] In 1980, the U.S. Supreme Court affirmed the constitutionality of the Hyde Amendment in *Harris v. McRae*.[17] In *Harris*, the Court determined that funding restrictions created by the Hyde Amendment did not violate the U.S. Constitution's Fifth Amendment and, therefore, did not contravene the liberty or equal protection guarantees of the Due Process Clause of the Fifth Amendment.[18] The Court opined that, although government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those obstacles that are not created by the government (in this case indigence).[19] The Court further opined that, although Congress has opted to subsidize medically necessary services generally, but not certain medically necessary abortions, the Hyde Amendment leaves an indigent woman with at least the same range of choice in deciding whether to obtain a medically necessary abortion as she would have had if Congress had chosen to subsidize no health care costs at all.[20]

Consistent with the Hyde Amendment, the Florida Medicaid program reimburses for abortions for the following reasons:

- The woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused or arising from the pregnancy itself, that would place the woman in danger of death unless an abortion is performed;
- The pregnancy is the result of rape (sexual battery) as defined in s. 794.011, F.S.; or

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[12] *Planned Parenthood Southeast, Inc. v. Strange*, 33 F.Supp.3d 1330 (M.D. Ala. 2014) (non-final order); *June Medical Services, LLC v. Caldwell*, 2014 WL 4296679 (M.D. La. 2014) (non-final order); *Jackson Women's Health Organization v. Currier*, 760 F.3d 448 (5th Cir. 2014) (petition for certiorari currently pending before the United States Supreme Court).

[13] *Burns v. Cline*, District Court of Oklahoma County, State of Oklahoma, case no. 2014-cv-1896; 339 P.3d 887 (OK 2014) (order remanding to trial court for further proceedings). The case is pending with trial currently set for February 2016.

[14] *Women's Health Center of West County, Inc. v. Webster*, 871 F.2d 1377 (8th Cir. 1989); *Greenville Women's Clinic v. Comm'r, S.C. Dept. of Health and Environmental Control*, 317 F.3d 357 (4th Cir.) 2002; cert. den. 538 U.S. 1008 (U.S. 2003).

[15] *Whole Woman's Health v. Cole*, 790 F.3d 563 (5th Cir. 2015); cert. granted 136 S.Ct. 499 (U.S. 2015).

[16] *See, e.g.,* Consolidated Appropriations Act of 2016, Pub. L. No. 114-113 (H.R. 2029, — 114th Congress (2015-2016). https://www.congress.gov/bill/114th-congress/house-bill/2029/text (last visited on January 15, 2016).

[17] 448 U.S. 297 (1980). *See also Rust v. Sullivan*, 500 U.S. 173 (1991), and *Webster v. Reproductive Health Services*, 492 U.S. 490 (1989), upholding *Harris v. McRae*.

[18] *Harris*, 448 U.S. at 326-27.

[19] *Harris*, *Id.* at 316-17.

[20] Id.

- The pregnancy is the result of incest as defined in s. 826.04, F.S.[21]

An Abortion Certification Form must be completed and signed by the physician who performed the abortion for the covered procedures. The form must be submitted with the facility claim, the physician's claim, and the anesthesiologist's claim. The physician must record the reason for the abortion in the physician's medical records for the recipient.[22]

Fetal Tissue Sale, Donation, and Research

Federal law prohibits the sale of fetal tissue: a person may not knowingly transfer fetal tissue for valuable consideration.[23] Federal law also prohibits directed donation for use in transplantation. This applies to a donation which is made pursuant to a promise that the fetal tissue will be transplanted in a specific individual, as well as for a donation in which the recipient has paid for the donor's abortion.[24] Finally, solicitation or acceptance of tissues from fetuses gestated for the purpose of research is prohibited.[25] This includes fetal tissue that was donated related to a pregnancy that was deliberately initiated to provide tissue for research or fetal tissue that was gestated in the uterus of a nonhuman animal.[26] Violation of any of these prohibitions can result in fines and imprisonment of up to 10 years.[27]

Federal law authorizes the Secretary of the U.S. Department of Health and Human Services to conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.[28] The human fetal tissue used in the research may come from a spontaneous abortion, an induced abortion or a stillbirth.[29] However, before the fetal tissue may be used for research, informed consent must be obtained.

The woman electing to donate fetal tissue must sign a written statement declaring the donation is for research, made without restriction as to who may receive the tissue, and that she has not been informed of the identity of any potential recipients. The attending physician must sign a written statement declaring that the tissue has been donated with the woman's consent and that the physician fully disclosed any interest in the research and of any known medical or privacy risks to the woman. If the fetal tissue was obtained through an induced abortion, the physician must also attest that the physician obtained consent to the abortion prior to obtaining consent for the donation; that no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and the abortion was performed in accordance with applicable state law. The researcher must sign a written statement declaring awareness that the tissue is human and that it has been donated as a result of an abortion or stillbirth; and that the researcher had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.[30]

Florida Abortion Law

Right to Abortion

The Florida Constitution, as interpreted by Florida courts, affords greater privacy rights than those provided by the U.S. Constitution. While the federal Constitution traditionally shields enumerated and implied individual liberties from state or federal intrusion, the U.S. Supreme

[21] *See, e.g.,* Agency for Health Care Administration, Florida Medicaid Practitioner Services Coverage and Limitations Handbook, April 2014; and Agency for Health Care Administration, Florida Medicaid Managed Medical Assistance Program Model Contract, Attachment II, Exhibit II-A, Section V.(23), Nov. 11, 2015.
[22] Id.
[23] Valuable consideration does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. 42 U.S. Code § 289g–2(a).
[24] 42 U.S. Code § 289g–2(b).
[25] 42 U.S. Code § 289g–2(c).
[26] Id.
[27] 42 U.S. Code § 289g–2(d).
[28] 42 U.S. Code § 289g–1.
[29] Id.
[30] Id.

Court has noted that state constitutions may provide greater protections.[31] Unlike the U.S. Constitution, Article I, s. 23 of the Florida Constitution contains an express right to privacy:

> Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.

The Florida Supreme Court opined in *In re T.W.* that this section provides greater privacy rights than those implied by the U.S. Constitution. [32]

The Florida Supreme Court has recognized Florida's constitutional right to privacy "is clearly implicated in a woman's decision whether or not to continue her pregnancy."[33] In *In re T.W.,* the Florida Supreme Court ruled that[34]:

> [P]rior 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 procedures.

The court recognized that after viability, the state can regulate abortion in the interest of the unborn child if the mother's health is not in jeopardy.[35]

Abortion Regulation

In Florida, abortion is defined as the termination of a human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.[36] An abortion must be performed by a physician[37] licensed under ch. 458, F.S., or ch. 459, F.S., or a physician practicing allopathic or osteopathic medicine in the employment of the United States.[38]

The Agency for Health Care Administration (AHCA) licenses and regulates abortion clinics in the state, pursuant to ch. 390, F.S., and part II of ch. 408, F.S.[39] Section 408.805, F.S., requires AHCA to establish license fees for all regulated facilities at a rate necessary to cover its administrative costs, unless otherwise limited by facility-specific statutes. That section also requires AHCA to increase the fees annually based on the Consumer Price Index. However, s. 390.014, F.S., limits licensure fees for abortion clinics to not less than $70 or more than $500. AHCA currently charges a biennial licensure fee of $545.00 pursuant to Rule 59A-9.020, F.A.C.

All abortion clinics and physicians performing abortions are subject to the following requirements:

- An abortion may only be performed in a validly licensed hospital, abortion clinic, or in a physician's office;[40]
- An abortion clinic must be operated by a person with a valid and current license;[41]

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[31] *Pruneyard Shopping Center v. Robins*, 100 S.Ct. 2035, 2040 (1980), cited in *In re T.W.*, 551 So.2d 1186, 1191 (Fla. 1989).
[32] Id. at 1191-1192.
[33] Id. at 1192.
[34] Id. at 1193.
[35] Id. at 1194.
[36] Section 390.011(1), F.S.
[37] Section 390.0111(2), F.S.
[38] Section 390.011(8), F.S.
[39] Section 408.802(3) provides for the applicability of the Health Care Licensing Procedures Act to abortion clinics.
[40] Section 797.03 (1), F.S.

- A third trimester abortion may only be performed in a hospital;[42]
- Proper medical care must be given and used for a fetus when an abortion is performed during viability;[43]
- Experimentation on a fetus is prohibited;[44]
- Except when there is a medical emergency, an abortion may only be performed after a patient has given voluntary and written informed consent;[45]
- Consent includes verification of the fetal age via ultrasound imaging;[46]
- Fetal remains are to be disposed of in a sanitary and appropriate manner;[47] and
- Parental notice must be given 48 hours before performing an abortion on a minor,[48] unless waived by a parent or otherwise ordered by a judge.

The level of regulation prescribed by AHCA depends on the trimester in which the abortion is being performed, and the viability of the fetus. However, current law does not define "trimester". Section 390.011(11), F.S., defines "third trimester" as the weeks of pregnancy after the 24th week of pregnancy. AHCA Rule 59A-9.019, F.A.C., defines the trimesters as follows:

> First Trimester. The first 12 weeks of pregnancy (the first 14 completed weeks from the last normal menstrual period).
> Second Trimester. That portion of a pregnancy following the 12th week and extending through the 24th week of gestation.
> Third Trimester. That portion of pregnancy beginning with the 25th week of gestation.

Current law does not define "gestation".[49]

For clinics performing only first trimester abortions, AHCA is required to adopt rules which are 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.[50] AHCA has not adopted a rule specific to first trimester-only facilities; rather, the regulations are those stated in the statute: abortions must be performed by a licensed physician at a licensed facility, and clinics must meet some minimal record-keeping and reporting requirements.[51] Other regulations related to first trimester abortions have been held unconstitutional, including rules which required first trimester abortion clinics and physicians to:[52]

- Maintain specified equipment in the clinic;
- Prepare a written pamphlet outlining post-operative treatment;
- Perform specified tests prior to the abortion procedure;
- Make available certain medications for post-operative treatment;
- Establish procedures to maintain proper sanitation; and
- Dispose of fetal remains in a nuisance-free manner.

AHCA has greater authority to establish rules for abortion clinics which perform abortions after the first trimester. Pursuant to s. 390.012(3), F.S., AHCA established by rule standards for:[53]

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[41] Section 797.03 (2), F.S.
[42] Section 797.03(3), F.S. The violation of any of these provisions results in a second degree misdemeanor.
[43] Section 390.0111(4), F.S.
[44] Section 390.0111(6), F.S.
[45] Section 390.0111(3), F.S. A physician violating this provision is subject to disciplinary action.
[46] Section 390.0111(3)(a)1.b., F.S.
[47] Section 390.0111(8), F.S. A person who improperly disposes of fetal remains commits a second degree misdemeanor.
[48] Section 390.01114(3), F.S. A physician who violates this provision is subject to disciplinary action.
[49] Ten states use gestation to measure trimesters, and measure gestation from fertilization: Georgia (Ga. Code Ann., § 31-9B-1); Idaho (I.C. § 18-604); Illinois (720 ILCS 510/2); Indiana (IC 16-18-2-287.5); Kentucky (KRS § 311.720); Minnesota (M.S.A. § 145.4241); Oklahoma (63 Okl.St.Ann. § 1-730); North Dakota (NDCC, 14-02.1-02); South Carolina (Code 1976 § 44-41-10); and South Dakota (SDCL § 34-23A-1). Other states measure gestation from the woman's last menstrual period, or do not specify.
[50] Section 390.012(2), F.S.
[51] Sections 390.0111(2); 390.0112; 390.014, F.S.
[52] *Florida Women's Medical Clinic, Inc. v. Smith*, 536 F.Supp. 1048 (S.D. Fla. 1982).
[53] Ch. 59A-9, F.A.C.

- Adequate private space for interviewing, counseling, and medical evaluations;
- Dressing rooms for staff and patients;
- Appropriate lavatory areas;
- Areas for pre-procedure hand-washing;
- Private procedure rooms;
- Adequate lighting and ventilation for procedures;
- Surgical or gynecological examination tables and other fixed equipment;
- Post-procedure recovery rooms that are equipped to meet the patients' needs;
- Emergency exits to accommodate a stretcher or gurney;
- Areas for cleaning and sterilizing instruments;
- Adequate areas for the secure storage of medical records and necessary equipment;
- Medical directors, personnel and staff training; and
- Conspicuous display of the clinic's license.

AHCA has broad authority to inspect abortion clinics, which must occur biennially and be unannounced.[54] AHCA has authority to inspect all records of abortion clinics.[55] The law does not specify the number or percent of records AHCA must review during an inspection.

DOH and AHCA have authority to take licensure action against practitioners and clinics, respectively, which violate licensure statutes or rules.[56] Additionally, abortion clinics are subject to criminal penalties for violation of certain statutes and rules.

Fetal Tissue Regulation

Section 873.05, F.S., prohibits anyone from advertising, selling, purchasing or otherwise transferring a human embryo for valuable consideration. "Valuable consideration" does not include the reasonable costs associated with the removal, storage, and transportation of a human embryo, and there is no prohibition against the donation of a human embryo. A violation of this section is a second degree felony. Section 873.01, F.S., prohibits the sale of any human organ or tissue for valuable consideration. In this section, "valuable consideration" does not include the reasonable costs associated with the removal, storage, and transportation of a human organ or tissue. Florida law does not address donation of fetal remains, or advertising for the transfer of fetal remains.[57]

Chapter 390, F.S., contains two standards for the disposal of fetal remains. Pursuant to s. 390.0111, F.S., all fetal remains must be disposed of in a "sanitary and appropriate" manner and in accordance with standard health practices established by DOH. Failure to dispose of fetal remains in accordance with department rules is a second degree misdemeanor.[58] Pursuant to s. 390.012, F.S., abortion clinics are required to dispose of fetal tissue in a "competent professional manner" consistent with the manner in which other human tissue is disposed.[59] Failure to adhere to this requirement is a first degree misdemeanor.[60]

Abortion Data Collection and Reporting Requirements

Section 390.0112 (1), F.S., requires facilities that perform abortions to submit a monthly report to AHCA containing the number of abortions performed, the reason for the procedure, and the gestational age of the fetus.

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[54] Section 408.811, F.S.
[55] Id.
[56] Section 390.018, F.S.
[57] Florida law also prohibits experimentation on any live fetus or infant either prior to or subsequent to an abortion unless it is necessary to preserve the life of such fetus or infant. S. 390.0111(6), F.S.
[58] Section 390.0111(7), F.S.
[59] Section 390.012(7), F.S.
[60] Id.

AHCA must keep this information in a central location from which statistical data can be drawn.[61] If the abortion is performed in a location other than a medical facility, the physician who performed the abortion is responsible for reporting the information to AHCA.[62] The reports are confidential and exempt from public records requirements.[63] AHCA may impose fines for violations of the reporting requirements.[64]

In 2014, DOH reported that there were 220,138 live births in the state of Florida.[65] In the same year, AHCA reported that there were 72,073 abortion procedures performed in the state. Of those: [66]

- 65,902 were performed in the first trimester (12 weeks and under);
- 6,171 were performed in the second trimester (13 to 24 weeks); and
- None were performed in the third trimester (25 weeks and over).

The majority of the procedures (65,210) were elective.[67] The remainder of the abortions were performed due to: [68]

- Emotional or psychological health of the mother (76);
- Physical health of the mother that was not life endangering (158);
- Life endangering physical condition (69);
- Rape (749);
- Serious fetal genetic defect, deformity, or abnormality (560); and
- Social or economic reasons (5,115).

The federal Centers for Disease Control and Prevention (CDC), compiles statistics voluntarily reported by the 50 states, the District of Columbia and New York City, related to termination of pregnancies to produce a national data report.[69] The last national data report was issued in 2012.[70] The CDC requests the following information from states for the U.S. Standard Report of Induced Termination of Pregnancy:

- Facility name (clinic or hospital);
- City, town or location;
- County;
- Hospital or clinic's patient identification number (used for querying for missing information without identifying the patient);
- Age;
- Marital status;
- Date of termination;
- Residence of patient;
- Ethnicity;
- Race;
- Education attainment;
- Date of last menses;
- Clinical estimate of gestation;

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[61] Id.
[62] Section 390.0112(2), F.S.
[63] Section 390.0112(3), F.S.
[64] Section 390.0112(4), F.S.
[65] Correspondence from the Department of Health to the House of Representatives Health Quality Subcommittee dated February 26, 2015, on file with Health Quality Subcommittee Staff.
[66] Reported Induced Terminations of Pregnancy by Reason, By Weeks of Gestation for Calendar Year 2014, AHCA, on file with the Health Quality Subcommittee Staff.
[67] Id.
[68] Id.
[69] *Abortion Surveillance- United States, 2012*, Surveillance Summaries, Centers for Disease Control and Prevention, November 27, 2015 / 64(SS10);1-40 http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6410a1.htm?s_cid=ss6410a1_e (last visited on January 4, 2016).
[70] Id.

- Previous pregnancy history;
- Previous abortion history;
- Type of abortion procedure; and
- Name of attending physician and name of person completing report.[71]

The CDC uses this data to provide an annual Abortion Surveillance Report (ASR). The CDC notes that they receive data from some states, but not all.[72] Florida only reports the annual number of terminations that occur in the state,[73] so Florida data is absent from 19 of the 22 statistical charts in the ASR. For example, Florida does not collect information on the number of teenagers who receive abortions, or on the race or ethnicity of abortion patients.[74]

TABLE 6. Reported abortions among adolescents, by known age and year — selected reporting areas,* United States, 2003–2012

	Year										% change			
Age (yrs)	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2003 to 2007	2008 to 2012	2011 to 2012	2003 to 2012
% of abortions														
<15	3.5	3.3	3.4	3.1	3.1	3.0	3.0	3.0	3.0	3.1	-11.4	3.3	3.3	**-11.4**
15	6.3	6.1	6.4	6.1	5.9	5.8	5.6	5.8	5.5	5.5	-6.3	-5.2	0.0	**-12.7**
16	11.6	11.6	11.4	11.6	11.3	10.8	10.6	10.3	10.0	9.8	-2.6	-9.3	-2.0	**-15.5**
17	17.3	16.9	17.1	17.3	17.4	17.1	16.9	16.3	16.1	15.6	0.6	-8.8	-3.1	**-9.8**
18	28.1	28.3	27.8	28.0	28.1	28.3	28.0	27.7	28.1	27.8	0.0	-1.8	-1.1	**-1.1**
19	33.2	33.8	33.9	34.0	34.1	34.9	35.9	36.8	37.2	38.2	2.7	9.5	2.7	**15.1**
Abortion rate†														
<15	1.4	1.2	1.2	1.2	1.2	1.1	1.0	1.0	0.8	0.7	-14.3	-36.4	-12.5	**-50.0**
15	5.1	4.7	4.6	4.6	4.4	4.3	3.9	3.6	3.1	2.6	-13.7	-39.5	-16.1	**-49.0**
16	9.4	9.0	8.5	8.6	8.3	7.8	7.1	6.3	5.5	4.7	-11.7	-39.7	-14.5	**-50.0**
17	14.0	13.3	13.0	13.2	12.6	12.3	11.2	9.9	8.7	7.3	-10.0	-40.7	-16.1	**-47.9**
18	22.4	22.0	21.0	21.4	20.8	19.6	18.0	16.2	14.9	12.8	-7.1	-34.7	-14.1	**-42.9**
19	26.9	25.9	25.3	26.0	25.4	24.9	22.5	21.1	19.0	17.2	-5.6	-30.9	-9.5	**-36.1**
Abortion ratio§														
<15	833	764	776	747	770	795	810	833	820	781	-7.6	-1.8	-4.8	**-6.2**
15	553	531	545	529	504	520	505	540	514	480	-8.9	-7.7	-6.6	**-13.2**
16	457	440	434	432	414	397	391	393	384	355	-9.4	-10.6	-7.6	**-22.3**
17	372	361	359	354	345	339	332	329	328	301	-7.3	-11.2	-8.2	**-19.1**
18	385	381	367	359	346	345	329	335	334	309	-10.1	-10.4	-7.5	**-19.7**
19	329	324	316	311	299	304	295	300	288	271	-9.1	-10.9	-5.9	**-17.6**
Total (no.)	**117,310**	**114,501**	**112,076**	**115,185**	**111,046**	**111,046**	**101,875**	**92,511**	**81,145**	**69,967**	—	—	—	—

* Data from 40 reporting areas; by year, these areas represent 90%–97% of all abortions reported to CDC for adolescents during 2003–2012. Excludes 12 reporting areas (California, District of Columbia, Florida, Illinois, Louisiana, Maine, Maryland, New Hampshire, Rhode Island, Vermont, West Virginia, and Wyoming) that did not report, did not report age among adolescents by individual year, or did not meet reporting standards for ≥1 year.

Abortion Referral or Counseling Agencies

Chapter 390, F.S., also regulates abortion referral or counseling agencies. An "abortion referral or counseling agency" is any person, group, or organization that provides advice or help to persons in obtaining abortions.[75] These entities may be funded publicly or privately and are prohibited from charging or accepting any referral fees from a physician, hospital, clinic, or other medical facility.[76] Abortion referral or counseling agencies are required to provide an individual with a full explanation of an abortion, including alternatives to this procedure.[77] If the individual is a minor, then this explanation must also be provided to the parent or guardian of the minor.[78]

[71] Centers for Disease Control, Handbook on the Reporting of Induced Termination of Pregnancy, www.cdc.gov/nchs/data/misc/hb_itop.pdf (last visited on January 4, 2016).
[72] *Abortion Surveillance- United States, 2012*, Surveillance Summaries, Centers for Disease Control and Prevention, November 27, 2015 / 64(SS10);1-40 http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6410a1.htm?s_cid=ss6410a1_e (last visited on January 4, 2016).
[73] Id.
[74] Id.
[75] Section 390.025, F.S.
[76] Id.
[77] Id.
[78] Id.

These requirements are not enforced by AHCA; rather, the law makes a violation of this section a first degree misdemeanor.

Public Funding for Abortion Providers and Affiliated Entities

DOH contracts with some providers to perform services under the Title V Maternal and Child Health[79] and Title X Family Planning[80] programs and for other contracted services like disability determinations and screening for sexually transmitted diseases. Some of those contracted providers perform, or are affiliated with entities that perform, abortions. For example, in Fiscal Year 2014-2015, DOH expended $139,128.60 on non-abortion contracted services provided by Planned Parenthood, and expects to spend $162,834.00 in Fiscal Year 2015-2016.[81]

Similarly, the Florida Medicaid program pays for non-abortion services provided by entities that perform, or are affiliated with entities that perform, abortions. For example, from July 2014 to June 2015, the Medicaid fee-for-service program paid $105,962.03 in claims to Planned Parenthood, and 10 plans in the Medicaid Managed Medical Assistance program contract with Planned Parenthood affiliates for non-abortion services.[82]

Effect of Proposed Changes

HB 1411 amends abortion clinic licensure requirements, prohibits sale or donation of fetal remains, prohibits certain public funding, and creates a registration program for abortion referral and counseling agencies.

Abortion Regulations

The bill amends the licensure requirements for abortion clinics in ch. 390, F.S. The bill requires AHCA to perform annual, rather than biennial, licensure inspections of all abortion clinics. In those inspections, AHCA must review at least 50 percent of the patient records generated since the last inspection. AHCA is also required to promptly investigate allegations that unlicensed abortions are being performed at a clinic. The bill requires, AHCA to submit an annual report to the President of the Senate and the Speaker of the House of Representatives which summarizes all regulatory actions taken by it against abortion clinics and referral or counseling agencies during the prior year, beginning February 1, 2017.

The bill requires abortion clinics that perform abortions after the first trimester to have a written transfer agreement with a hospital within a reasonable proximity to the clinic, and requires physicians who

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[79] Title V of the Social Security Act authorizes federal funding for mothers and children through the Maternal and Child Services Program block grant. States apply for funding established by Congress, which is then allocated by a formula which considers the proportion of the number of low-income children in a particular state compared to the total number of low-income children in the United States. States must match every four dollars of federal Maternal and Child Services Block Grant money that they receive with at least three dollars of nonfederal money (state and/or local funds). The Maternal and Child Health program provides services for infants, children and pregnant women, particularly children with special health care needs, including: Comprehensive prenatal and postnatal care for women, especially low-income and at-risk pregnant women; health assessments and follow-up diagnostic and treatment services; preventive and child care services, and rehabilitative services for certain children; family-centered, community-based systems of coordinated care for children with special healthcare needs; and toll-free hotlines and assistance in applying for services to pregnant women with infants and children who are eligible for Medicaid. See, *MCH Block Grant*, Florida Department of Health, http://www.floridahealth.gov/programs-and-services/womens-health/pregnancy/mch-block-grant.html (last visited January 25, 2016); *Title V Maternal and Child Health Services Block Grant Program*, U.S. Department of Health and Human Services, http://mchb.hrsa.gov/programs/titlevgrants/ (last visited January 25, 2016).

[80] The Title X Family Planning program is a federal program that provides low-income or uninsured individuals with comprehensive family planning and related preventive health services. Nearly 4,200 Title X-funded family planning centers serve about 4.5 million clients a year, including state and local health departments, community health centers, Planned Parenthood centers and private, nonprofit programs (hospital-based, school-based and faith-based). Family planning centers offer FDA-approved contraceptive methods and related counseling, breast and cervical cancer screening, pregnancy testing and counseling, and screening and treatment for sexually transmitted infections, including HIV testing. Title X does not fund abortion as a method of family planning. (Title 42 U.S. Code § 300a–6.) See, *Title X: The National Family Planning Program*, U.S. Department of Health and Human Services, http://www.hhs.gov/opa/title-x-family-planning/ (last visited January 25, 2016).

[81] DOH email correspondence dated August 10, 2015, on file with Health Quality Subcommittee staff.

[82] AHCA email correspondence dated September 17, 2015, on file with Health Quality Subcommittee staff.

perform abortions in the clinic to have admitting privileges with a hospital within a reasonable proximity to the clinic. Abortion clinics that perform only first trimester abortions must have such a transfer agreement, or physicians who perform abortions in the clinic must have such admitting privileges.

The bill defines "gestation" and the trimesters of pregnancy to delineate when the first, second and third trimesters begin and end. Under the bill, "gestation" is the development of a human embryo or fetus between fertilization and birth, and the trimesters are defined by 12-week increments counting from gestation.

The bill removes the abortion clinic statutory license fee cap of not less than $70 and not more than $500 and requires AHCA to establish fees which may not be more than required to pay for the costs incurred by AHCA in licensing and regulating abortion clinics.

Abortion Data Collection and Reporting

In addition to current reporting requirements, the bill requires all abortion clinics, by January 1, 2017, to report to AHCA information consistent with the United States Standard Report of Induced Termination of Pregnancy adopted by the CDC. AHCA must submit this data to the CDC upon request.

Fetal Remains

Chapter 390, F.S., currently contains two methods, each with different standards and levels of criminal penalties, for the disposal of fetal remains. The bill eliminates this potential conflict by amending s. 390.0111, F.S., to require disposal of fetal remains in a sanitary manner pursuant to s. 381.0098, F.S., rules adopted thereunder and rules adopted by AHCA under this provision. Violations of this requirement are first degree misdemeanors.

The bill amends s. 873.025, F.S., to prohibit selling, purchasing, donating or transferring fetal remains obtained through an abortion, as well as advertising or offering to do any of those acts. These prohibitions do not apply to transfers that comply with s. 390.0111, F.S. (above).

Public Funding

The bill prohibits state agencies, local governmental entities, and Medicaid managed care plans from expending funds for the benefit of, pay funds to, or initiating or renewing a contract with an organization that owns, operates, or is affiliated with a licensed abortion clinic. The bill provides exceptions to this prohibition for any of the following circumstances:

- All abortions performed by the organization are due to rape or incest or are medically necessary to preserve the life of the pregnant woman;
- The public funds are expended to fulfill the terms of a contract entered into before July 1, 2016; and
- The funds are expended as reimbursement for Medicaid services provided on a fee-for-service basis.

State agencies and local governmental entities, including DOH and Medicaid managed care plans, may contract with other providers and organizations to perform services.

Abortion Referral or Counseling Agencies

The bill requires abortion referral or counseling agencies to register with AHCA. AHCA will set a registration fee which may not exceed the cost to administer the registration program. Facilities licensed pursuant to chapters 390, 395, 400 and 408, F.S., are exempt from registering, as are health care clinics and health care practitioners defined in s. 456.001, F.S., if they refer less than 6 patients each month. The bill allows AHCA to assess the costs of successful investigations and prosecutions of violations of the registration requirement, which costs do not include attorney's fees.

Provides an effective date of July 1, 2016, or as otherwise specified in the bill.

B. SECTION DIRECTORY:

Section 1: Amending s. 390.011, F.S., relating to definitions.
Section 2: Amending s. 390.0111, F.S., relating to termination of pregnancies.
Section 3: Amending s. 390.0112, F.S., relating to termination of pregnancies and reporting.
Section 4: Amending s. 390.012, F.S., relating to powers of agency, rules and disposal of fetal remains.
Section 5: Amending s. 390.014, F.S., relating to licenses fees.
Section 6: Amending s. 390.025, F.S., relating to abortion referral or counseling agencies and penalties.
Section 7: Amending s. 873.05, F.S., relating to advertising or sale of human embryos prohibited.
Section 8: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill amends s. 390.014 (3), F.S. giving the agency authority to establish a fee not more than required to pay for the costs incurred by the agency in administering the program. AHCA currently collects $545 in licensure fees biennially for each clinic. AHCA reports that as of February 1, 2016 there will be 62 licensed abortion clinics. Current revenues received annually are estimated to be $16,895. If the Agency established fees to fully fund costs incurred with program administration, the Agency would increase the licensure fee by $1,933.90 for recurring costs and $5,974.61 to cover the nonrecurring cost. Licensure fees would be $8,453.51 in year one and $2,478.90 in year two and beyond. (See Fiscal Comments)

2. Expenditures:

The bill requires AHCA to perform annual, rather than biennial, licensure inspections of all abortion clinics, including a review of at least 50 percent of the patient records generated since the last inspection. AHCA anticipates this will cause an increase in surveyor workload requiring an additional 0.50 full-time equivalent nurse surveyor position. This position will require $53,651 in recurring funds, $3,569 in nonrecurring funds, and 39,230 in salary rate.

The bill requires AHCA to collect and report information consistent with the United States Standard Report of Induced Termination of Pregnancy (ITOP) adopted by the CDC. Data systems changes will be required to AHCA's ITOP reporting system to be consistent with the bills reporting requirements. AHCA estimates programming and developer costs of $187,944 for the first year and $6,300 in recurring costs thereafter. (See Fiscal Comments)

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Abortion clinics may incur an indeterminate, negative fiscal impact associated with compliance with the bill's data reporting requirements.

The bill prohibits public funding for an organization that owns, operates, or is affiliated with a licensed abortion clinic. This applies to funding provided through local governmental entities, state agencies and managed care plans. This may result in an indeterminate, negative fiscal impact for clinics and associated business organizations.

Abortion referral and counseling agencies will incur a negative fiscal impact related to the bill's registration requirement.

D. FISCAL COMMENTS:

Revenues				
Annual Clinic Licensure Renewals	**License Fee**	**Year 1**	**Year 2**	**Note**
31	$545.00	$ 16,895.00	$ 16,895.00	Current Regulatory Fee
31	$1,730.68	$ 53,651.08	$ 53,651.08	Additional Personnel
31	$115.12	$ 3,568.72		Nonrecurring personnel costs
31	$203.23	$ 6,300.00	$ 6,300.00	Recurring System Maintenance
31	$5,859.48	$ 181,644.00		One time system upgrades and nonrecurring employee costs.
Total		**$ 262,058.80**	**$ 76,846.08**	
Annual Licensure Fee		**$ 8,453.51**	**$ 2,478.91**	
Expenditures				
Annual Licensure Expenditures	**FTE**	**Year One**	**Year Two**	**Note**
Current Licensure Administration Costs		$ 16,895.00	$ 16,895.00	Current Costs
Additional 0.5 FTE-Recurring	0.5	$ 53,651.00	$ 53,651.00	Recurring FTE costs
Additional 0.5 FTE nonrecurring	0.5	$ 3,569.00		Nonrecurring FTE costs
System Enhancements		$ 6,300.00	$ 6,300.00	Recurring System Maintenance
System Enhancements		$ 181,644.00		Nonrecurring System Modifications
Total		**$ 262,059.00**	**$ 76,846.00**	
Annual Licensure Costs		**$ 8,453.52**	**$ 2,478.90**	

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditure of funds; reduce the authority that counties and municipalities have to raise revenue in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

The bill requires clinics which perform only first trimester abortions to have a written patient transfer agreement with a hospital within a reasonable proximity, or the physician who performs the abortion must have admitting privileges at such a hospital. Florida courts have limited regulation of first trimester abortions to certain minimal requirements, and invalidated prior regulations which exceeded these.[83]

Some federal courts have found that physician privilege requirements for abortion providers violate the U.S. Constitution.[84] Other courts have upheld these requirements, finding they do not violate the constitution.[85] The issue is currently before the U.S. Supreme Court.[86]

B. RULE-MAKING AUTHORITY:

AHCA currently has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[83] *Florida Women's Medical Clinic, Inc. v. Smith*, 536 F.Supp. 1048 (S.D. Fla. 1982).
[84] *Planned Parenthood of Wisconsin, Inc. v. Schimel*, 806 F.3d 908 (7th Cir. 2015); *Planned Parenthood Southeast, Inc. v. Strange*, 33 F.Supp.3d 1330 (M.D. Ala. 2014) (non-final order); *June Medical Services, LLC v. Caldwell*, 2014 WL 4296679 (M.D. La. 2014) (non-final order); *Jackson Women's Health Organization v. Currier*, 760 F.3d 448 (5th Cir. 2014) (petition for certiorari currently pending before the United States Supreme Court); *Burns v. Cline*, District Court of Oklahoma County, State of Oklahoma, case number 2014-cv-1896; 339 P.3d 887 (OK 2014)(order remanding to trial court for further proceedings).
[85] *Women's Health Center of West County, Inc. v. Webster*, 871 F.2d 1377 (8th Cir. 1989); *Greenville Women's Clinic v. Comm'r, S.C. Dept. of Health and Environmental Control*, 317 F.3d 357 (4th Cir.) 2002; cert. den. 538 U.S. 1008 (U.S. 2003);
[86] *Whole Woman's Health v. Cole*, 790 F.3d 563 (5th Cir. 2015); cert. granted 136 S.Ct. 499 (U.S. 2015).

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 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 rules.

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 within reasonable proximity to the clinic ~~in this state 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.~~

3.~~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 this chapter, 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 this chapter, 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) commits ~~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 commits ~~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.

Amendment No. 1

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

Committee/Subcommittee hearing bill: Health Care Appropriations Subcommittee

Representative Burton offered the following:

Amendment (with title amendment)

Between lines 331 and 332, insert:

Section 8. For the 2016-2017 fiscal year, 0.5 full-time equivalent positions, with associated salary rate of 39,230, are authorized and the sums of $59,951 in recurring funds and $185,213 in nonrecurring funds from the Health Care Trust Fund are hereby appropriated to the Agency for Health Care Administration for the purpose of implementing the requirements of the act.

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

Remove line 50 and insert:

Amendment No. 1

Transportation of remains; providing an appropriation; providing effective dates.