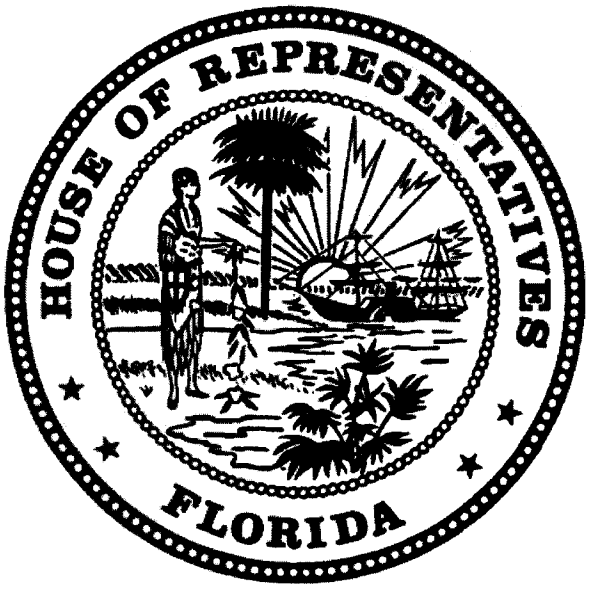


Health Quality Subcommittee

Wednesday, January 24, 2018
8:00 AM - 11:00 AM
Mashburn Hall (306 HOB)

Richard Corcoran
Speaker

James Grant
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time:	Wednesday, January 24, 2018 08:00 am
End Date and Time:	Wednesday, January 24, 2018 11:00 am
Location:	Mashburn Hall (306 HOB)
Duration:	3.00 hrs

Consideration of the following bill(s):

HB 369 Dental Student Loan Repayment Program by Burton
HB 579 Infectious Disease Elimination Pilot Programs by Jones
HB 1045 Immunization Registry by Pigman
HB 1047 Department of Health by Gonzalez
HB 1155 Anatomical Gifts by La Rosa
HB 1429 Dismemberment Abortion by Grall, Gruters

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Tuesday, January 23, 2018.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Tuesday, January 23, 2018.

NOTICE FINALIZED on 01/22/2018 4:04PM by Krause.Jessica

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 369 Dental Student Loan Repayment Program
SPONSOR(S): Burton and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Langston	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The U.S. Department of Health and Human Services' Health Resources and Services Administration (HRSA) designates Health Professional Shortage Areas (HPSAs) to identify areas and population groups within the United States that are experiencing a shortage of health care providers. HPSAs identify shortages in primary care, dental health, or mental health. The threshold for a dental HPSA is a population-to-provider ratio of at least 5,000:1. HRSA also designates Medically Underserved Areas (MUAs) and Medically Underserved Populations (MUPs); MUAs and MUPs identify geographic areas and populations with a lack of access to primary care services.

A typical dentist's debt post-graduation is between $250,000 and $500,000. Florida is one of nine states that does not have an operational state-funded dental student loan repayment program.

HB 369 creates the Dental Student Loan Repayment Program (Program) for licensed dentists who practice in specific public health programs located in in dental HPSAs or MUAs. Subject to the availability of funds, the Department of Health (DOH) may award up to $50,000 per year per eligible dentist in the Program for a minimum of one year and a maximum of five years.

The bill requires DOH to adopt rules to administer the Program.

The bill has a significant, negative fiscal impact on DOH and no fiscal impact on local governments. *See Fiscal Comments & Economic Impact Statement.*

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

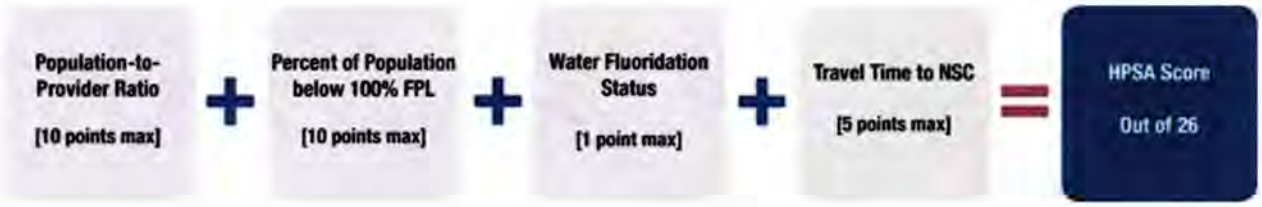
Current Situation

Health Professional Shortage Areas

The U.S. Department of Health and Human Services' Health Resources and Services Administration (HRSA) designates Health Professional Shortage Areas (HPSAs) according to criteria developed in accordance with section 332 of the Public Health Services Act. HPSA designations are used to identify areas and population groups within the United States that are experiencing a shortage of health care provider shortages in primary care, dental health, or mental health.[1] The threshold for a dental HPSA is a population-to-provider ratio of at least 5,000:1.[2] For each discipline category, there are three types of HPSA designations based on the area or population group that is experiencing the shortage:[3]

- **Geographic Area:** A shortage of providers for the entire population within a defined geographic area.
- **Population Groups:** A shortage of providers for a specific population group(s) within a defined geographic area (e.g., low income, migrant farmworkers, and other groups)
- **Facilities:** A facility that primarily cares for an underserved population; examples of these include state mental hospitals, federally qualified health centers, and CMS-certified rural health clinics.

Once designated, HRSA scores HPSAs on a scale of 0-26 for dental health, with higher scores indicating greater need.[4]



Medically Underserved Area

HRSA also designates Medically Underserved Areas (MUAs) and Medically Underserved Populations (MUPs). MUAs and MUPs identify geographic areas and populations with a lack of access to primary care services.[5] MUAs have a shortage of primary care health services for residents within a geographic area such as a county, a group of neighboring counties, a group of urban census tracts, or a group of county or civil divisions.[6] MUPs are specific sub-groups of people living in a defined geographic area with a shortage of primary care health services who may face economic, cultural, or linguistic barriers to

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[1] Health Resources and Services Administration, *Health Professional Shortage Areas (HPSAs)*, available at https://bhw.hrsa.gov/shortage-designation/hpsas (last visited January 18, 2018).
[2] Id.
[3] Id.
[4] Health Resources and Services Administration, *Health Professional Shortage Area (HPSA) Application and Scoring Process*, https://bhw.hrsa.gov/shortage-designation/hpsa-process (last visited January 18, 2018).
[5] Health Resources and Services Administration, *Medically Underserved Areas and Populations (MUA/Ps)*, https://bhw.hrsa.gov/shortage-designation/muap (last visited January 18, 2018).
[6] Id.

health care.[7] MUPs include, but are not limited to, those who are homeless, low-income, Medicaid-eligible, Native American, or migrant farmworkers.[8]

MUA and MUP designations are based on the Index of Medical Underservice (IMU), which is calculated based on four criteria:[9]

- The population to provider ratio;
- The percent of the population below the federal poverty level;
- The percent of the population over age 65; and
- The infant mortality rate.

IMU can range from 0 to 100, where zero represents the completely underserved; areas or populations with IMUs of 62.0 or less qualify for designation as an MUA or MUP.[10]

Cost of Dental Education

Approximately two-thirds of all undergraduates and 90 percent of dental students rely on student loans to finance their degrees.[11] In the U.S., combined undergraduate and dental school debt jumped from $106,000 in 2000 to more than $220,000 in 2012, an increase of 109 percent in 12 years.[12] Among all U.S. dental schools, total cost of attendance over the same time frame rose by 93 percent for in-state residents (from about $89,000 to $171,000) and by 82 percent for out-of-state residents (from $128,000 to $234,000).[13] Today, the typical dentist's debt post-graduation is between $250,000 and $500,000.[14]

The National Health Service Corps (NHSC) offers tax-free loan repayment assistance of up to $50,000 to support qualified health care providers, including dentists, who work for two years at a NHSC-approved site.[15] Additionally, dental students who commit to serving at least three years at an approved NHSC site in a HPSA of greatest need may earn up to $120,000 in their final year of school through the Students to Service Loan Repayment Program.[16]

Florida is one of nine states[17] that does not have an operational state-funded dental student loan repayment program.[18]

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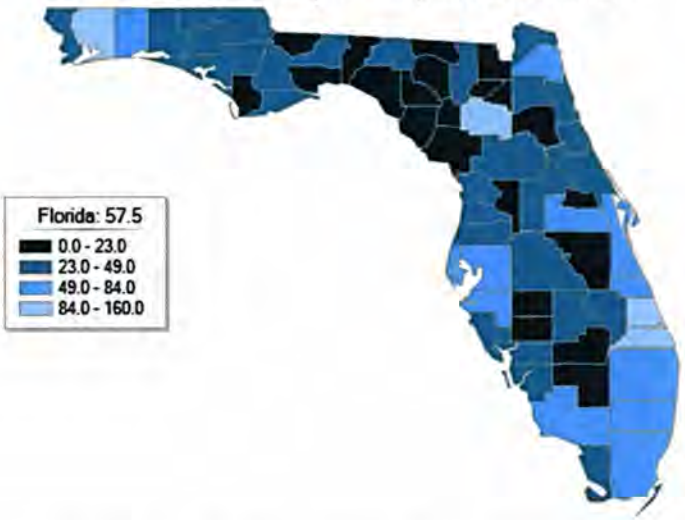
[7] Id.
[8] Id.
[9] Id.
[10] Id.
[11] American Dental Education Association, *A Report of the ADEA Presidential Task Force on the Cost of Higher Education and Student Borrowing*,17 (March 2013), available at: http://www.adea.org/uploadedFiles/ADEA/Content_Conversion_Final/publications/Documents/ADEACostandBorrowingReportMarch2013.pdf (last visited March 13, 2015).
[12] Id.
[13] Id.
[14] Department of Health, Agency Analysis for 2017 House Bill 369, (Nov. 6, 2017) (on file with Health Quality Health Quality Subcommittee staff).
[15] Health Resources and Services Administration, *Loan Repayment*, https://nhsc.hrsa.gov/loanrepayment/ (last visited January 19, 2018).
[16] Id.
[17] Alabama, Connecticut, Florida, Georgia, Indiana, Iowa, Mississippi, Puerto Rico, and Utah do not have operational state-funded dental loan repayment programs. Several of these states had program, but they are no longer operational due to a lack of funding. Connecticut's program is no longer accepting application; Georgia's program ended in 2015; Indiana's program has been suspended since 2011 due to a lack of funding; Iowa's program has ended, however, it still has a loan repayment program for individuals pursuing a graduate degree in dental public health; and Mississippi is no longer taking applicants due to a lack of funding. Additionally, New York's program did not accept applicants for several years, but it resumed in 2017 when it received new funding.
[18] American Dental Education Association, *State and Federal Loan Forgiveness Programs*, (November 2016), *available at*, http://www.adea.org/uploadedFiles/ADEA/Content_Conversion_Final/policy_advocacy/financing_dental_education/ADEA-Summary-of-Loan-Forgiveness-Programs.pdf (last visited January 19, 2018).

Access to Dental Care and Dental Workforce in Florida

In the U.S., there are 18,084 HSPAs, of which 5,866 are dental HSPAs; there are 224 dental HSPAs in Florida.[19] Additionally, there are 4,235 MAUs and MAPs in the U.S.,129 of which are in Florida.[20] Today, there are approximately 57 licensed dentists per 100,000 people in Florida; however, this ratio varies greatly across the state.[21] Most dentists are disproportionately concentrated in the more populous areas of the state. Three counties, Dixie, Glades, and Lafayette, do not have any licensed dentists, while other counties have over 150 dentists per 100,000 residents.[22]

Licensed Dentists per 100,000 Floridians[23]



There is a noticeable shortage of dentists in certain parts of the state, especially the central Panhandle counties and interior counties of south Florida.[24] Lower patient densities, rural income disparities, and lower dental care reimbursement levels make it difficult to recruit and retain dentists in rural communities of the state.[25] Lack of access to dental care can lead to poor oral health and poor overall health. [26] Research has shown a link between poor oral health and diabetes, heart and lung disease, stroke, respiratory illnesses, and adverse birth outcomes including the delivery of pre-term and low birth weight infants.[27]

Effect of Proposed Changes

HB 369 creates the Dental Student Loan Repayment Program (the Program) within the Florida Department of Health (DOH). The Program is subject to funds being appropriated and is intended to promote access to dental care in MUPs by increasing the number of dentists practicing in dental HPSAs or MUAs.

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[19] Health Resources and Services Administration, *HPSA Find Results*, https://datawarehouse.hrsa.gov/tools/analyzers/HpsaFindResults.aspx (last visited January 18, 2018).
[20] Health Resources and Services Administration, *MAU Find Results*, https://datawarehouse.hrsa.gov/tools/analyzers/MuaSearchResults.aspx (last visited January 18, 2018).
[21] Florida Department of Health, Florida CHARTS, *Total Licensed Florida Dentists*, http://www.flhealthcharts.com/charts/OtherIndicators/NonVitalIndNoGrpDataViewer.aspx?cid=0326 (last visited January 19, 2018).
[22] Id.
[23] Id.
[24] Id.
[25] Chris Collins, MSW, *Challenges of Recruitment and Retention in Rural Areas*, North Carolina Medical Journal, Vol. 77 no. 2, (March-April 2016), http://www.ncmedicaljournal.com/content/77/2/99.full (last visited January 22, 2018).
[26] Florida Department of Health, *Florida's Burden of Oral Disease Surveillance Report*, (Aug, 2016), p. 5, *available at*, http://www.floridahealth.gov/programs-and-services/community-health/dental-health/reports/_documents/floridas-burden-oral-disease-surveillance-report.pdf (last visited January 20, 2018).
[27] Id.

A licensed dentist is eligible to participate in the Program if he or she maintains active employment in a public health program that serves Medicaid recipients and other low-income patients and is located in a dental HSPA or a MUA. The bill defines a "public health program" as a county health department, the Children's Medical Services program, a federally funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by DOH.

A participant loses eligibility to receive funding for the Program if:

- The public health program terminates the dentist;
- The HSRA terminates the HPSA or MUA designation for the dentist's practice;
- Florida Medicaid terminates the dentist; or
- The dentist knowingly fails to disclose any participation in fraudulent activity.

The bill authorizes DOH to award up to $50,000 per year for a minimum of one year and a maximum of five years.

The bill requires DOH to adopt rules to administer the Program.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Creates s. 381.4019, F.S., relating to dental student loan repayment program.
Section 2: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill with have a significant negative fiscal impact on DOH. Should DOH award the maximum amount to 10 dentists, the cost would be $570,941 in the first year and $566,467 in the second year.[28]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Participating dentists will be eligible to receive up to $50,000 per year for up to five years.

D. FISCAL COMMENTS:

A new appropriation will be needed to implement the Program.

[28] *Supra*, note 14. *See also,* Email from Bryan P. Wendel, Deputy Director, Office of Legislative Planning, Florida Department of Health, RE: Dental Loan Repayment Legislation, (Dec. 6, 2017) (on file with Health Quality Subcommittee staff).

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

A bill to be entitled

An act relating to the Dental Student Loan Repayment Program; creating s. 381.4019, F.S.; establishing the Dental Student Loan Repayment Program to support dentists who practice in public health programs located in certain underserved areas; providing definitions; requiring the Department of Health to establish the loan program; providing for the award of funds; providing the maximum number of years funds may be awarded; providing eligibility requirements; requiring the department to adopt rules; providing an effective date.

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

Section 1. Section 381.4019, Florida Statutes, is created to read:

381.4019 Dental Student Loan Repayment Program.—Subject to the availability of funds, the Legislature establishes the Dental Student Loan Repayment Program to promote access to dental care by supporting qualified dentists who treat medically underserved populations in dental health professional shortage areas or medically underserved areas. The Legislature recognizes that maintaining good oral health is integral to overall health status and that the good health of residents in this state is an

important contributing factor in state economic development. Better health, including better oral health, increases workplace productivity, reduces the burden of health care costs, and improves the cognitive development of children.

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

(a) "Dental health professional shortage area" means a geographic area designated as such by the Health Resources and Services Administration of the United States Department of Health and Human Services.

(b) "Department" means the Department of Health.

(c) "Loan program" means the Dental Student Loan Repayment Program.

(d) "Medically underserved area" means a geographic area, an area having a special population, or a facility which is designated by department rule as a health professional shortage area as defined by federal regulation and which has a shortage of dental health professionals who serve Medicaid recipients and other low-income patients.

(e) "Public health program" means a county health department, the Children's Medical Services program, a federally funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by the department.

(2) The department shall establish a dental student loan repayment program to benefit state-licensed dentists who

demonstrate, as required by department rule, active employment in a public health program that serves Medicaid recipients and other low-income patients and is located in a dental health professional shortage area or a medically underserved area.

(3) The department shall award funds from the loan program to repay the student loans of a dentist who meets the requirements of subsection (2). An award may not exceed $50,000 per year per eligible dentist.

(4) A participant in the loan program is eligible to receive funds for at least 1 year, up to a maximum of 5 years. The period of obligated service begins when the dentist begins employment as provided in subsection (2).

(5) A dentist is not eligible to participate in the loan program if:

(a) The dentist's employment by a public health program is terminated;

(b) The dentist's practice in a designated health professional shortage area or medically underserved area is terminated;

(c) The dentist's participation in the Florida Medicaid program is terminated; or

(d) The dentist knowingly fails to disclose any participation in fraudulent activity.

(6) The department shall adopt rules to administer the loan program.

Section 2. This act shall take effect July 1, 2018.

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

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 Quality Subcommittee

Representative Burton offered the following:

Amendment

Remove lines 50-73 and insert:

repayment program to benefit Florida-licensed dentists who demonstrate, as required by department rule, active employment in a public health program that serves Medicaid recipients and other low-income patients and is located in a dental health professional shortage area or a medically underserved area.

(3) The department shall award funds from the loan program to repay the student loans of a dentist who meets the requirements of subsection (2).

(a) An award may not exceed $50,000 per year per eligible dentist.

(b) Only loans to pay the costs of tuition, books, dental equipment and supplies, uniforms, and living expenses shall be covered.

(c) All repayments shall be contingent upon continued proof of eligibility and shall be made directly to the holder of the loan. The state shall bear no responsibility for the collection of any interest charges or other remaining balance.

(d) A dentist is eligible to receive funds under the loan program for at least 1 year, up to a maximum of 5 years.

(e) The department shall limit the number of new dentists participating in the loan program to no more than 10 per fiscal year.

(4) A dentist is no longer eligible to receive funds under the loan program if the dentist:

(a) Is no longer employed by a public health program that meets the requirements of subsection (2).

(b) Ceases to participate in the Florida Medicaid program.

(c) Has disciplinary action taken against his or her license by the Board of Dentistry for a violation of s. 466.028.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 579 Infectious Disease Elimination Pilot Programs
SPONSOR(S): Jones and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 800

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In 2016, the Legislature authorized the University of Miami to operate a needle and syringe exchange pilot program in Miami-Dade County. The pilot program offers free, clean, unused needles and syringes to intravenous drug users as a means to prevent the transmission of blood-borne diseases, such as HIV, AIDS, and viral hepatitis. The pilot program must:

- Provide maximum security of the exchange site and equipment;
- Account for the number, disposal, and storage of needles and syringes;
- Adopt measures to control the use and dispersal of sterile needles and syringes;
- Operate a one sterile needle and syringe unit to one used unit exchange ratio;
- Make available educational materials and referrals to educational resources regarding the transmission of HIV, AIDS, viral hepatitis, and other blood-borne diseases;
- Provide HIV and viral hepatitis testing; and
- Provide or refer for drug abuse prevention and treatment.

The program began offering services on December 1, 2016, and has provided 44,497 clean, unused syringes in exchange for used 50,509 syringes. Staff and participants of the pilot program are exempt from prosecution under the Florida Comprehensive Drug Abuse Prevention and Control Act, or any other law for the possession, distribution, and exchange of needles or syringes. However, individuals acting outside the scope of the program are not immune from prosecution.

The pilot program is explicitly prohibited from using state, county, or municipal funds to operate, and may only use grants and donations to fund the program. The pilot project is scheduled to sunset on July 1, 2021.

HB 579 extends the pilot project statewide and retains all of the existing requirements for operation. The bill authorizes the Department of Health (DOH) or an eligible entity designated by DOH to operate a sterile needle and syringe exchange at a fixed location or through a mobile unit. Eligible entities include:

- Hospitals licensed under ch. 395, F.S.;
- Health care clinics licensed under ch. 400, F.S.;
- Substance abuse treatment programs;
- HIV/AIDS service organizations; or
- Other nonprofit entities designated by DOH.

The bill extends the expiration date of the pilot programs from July 1, 2021, to July 1, 2023.

The bill may have an indeterminate, positive fiscal impact on state or local governments, resulting from lower transmission rates of blood-borne diseases. The bill may have an indeterminate negative impact on DOH for the administrative duties required under the bill's provisions.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Needle and Syringe Exchange Programs

Syringe services programs (SSPs)[1] provide sterile needles, syringes, and other injection equipment and facilitate the disposal of used needles and syringes to reduce the transmission of human immunodeficiency virus (HIV) and other blood-borne infections associated with reuse of contaminated needles and syringes by injection-drug users (IDUs).[2] Additionally, these programs may help to: [3]

- Increase the number of drug users who enter treatment for substance use disorder;
- Reduce needlestick injuries among first responders by providing proper disposal;
- Reduce overdose deaths by providing education on overdose prevention and safer injection practices;
- Provide referrals to medical, mental health, and social services; and
- Provide other tools, such as counseling, condoms, and vaccinations, to prevent HIV, Hepatitis C, and sexually transmitted infections.

Approximately 2.6 percent of the U.S. population[4] has injected illicit drugs.[5] During the last decade, there has been increase in drug injection that has been attributed to the use of prescription opioids and heroin among individuals who started using opioids with oral analgesics and transitioned to injection.[6]

The danger of used needles and other sharps, combined with the number of injections of illicit drugs, has prompted communities to try and manage the disposal of sharps within the illicit drug population. In San Francisco in 2000, approximately two million syringes were recovered at SSPs, and an estimated 1.5 million syringes were collected through a pharmacy-based program that provided free-of-charge sharps containers and accepted filled containers for disposal. As a result, an estimated 3.5 million syringes were recovered from community syringe users and safely disposed of as infectious waste.[7] Other SSPs offer methods for safe disposal of syringes after hours. For example, in Santa Cruz, California, the Santa Cruz Needle Exchange Program, in collaboration with the Santa Cruz Parks and Recreation Department, installed 12 steel sharps containers in public restrooms throughout the county.[8]

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[1] Also referred to as syringe exchange programs (SEPs), needle exchange programs (NEPs), or needle and syringe exchange programs (NSEPs).

[2] Centers for Disease Control and Prevention, *Syringe Services Programs – United States, 2008*, Morbidity and Mortality Weekly Report (MMWR) (Nov. 19, 2010), 59(45); 1488-1491, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5945a4.htm/Syringe-Exchange-Programs-United-States-2008 (last visited on December 11, 2017).

[3] Centers for Disease Control and Prevention, *Reducing Harms from Injection Drug Use & Opioid Use Disorder with Syringe Services Programs*, available at https://www.cdc.gov/hiv/pdf/risk/cdchiv-fs-syringe-services.pdf (last visited December 11, 2017).

[4] This population represents persons aged 13 years or older in 2011.

[5] A. Lansky, T. Finlayson, C. Johnson, et. al.; *Estimating the Number of Persons Who Inject Drugs in the United States by Meta-Analysis to Calculate National Rates of HIV and Hepatitis C Virus Infections*; PLoS ONE, May 19, 2014; 9(5), available at http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0097596 (last visited on December 11, 2017).

[6] Centers for Disease Control and Prevention, *Syringe Service for Persons Who Inject Drugs in Urban, Suburban, and Rural Areas – United States, 2013*, Morbidity and Mortality Weekly Report (MMWR) (Dec. 11, 2015), 64(48); 1337-1341, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6448a3.htm (last visited December 15, 2017).

[7] *Supra* note 5. (citing Brad Drda et al., San Francisco Safe Needle Disposal Program, 1991—2001, 42 J. Am Pharm Assoc. S115—6 (2002).

[8] *Centers for Disease Control and Prevention, Update: Syringe Exchange Programs --- United States, 2002,* Morbidity and Mortality Weekly Report (MMWR) (July 15, 2005), 54(27), 673-676, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5427a1.htm (last visited March 4, 2016).

In 2015, five percent (2,392) of the 39,513 new HIV diagnoses and 10 percent (1,804) of the 18,303 AIDS diagnoses in the U.S. were attributed to injection drug use.[9] According to the Centers for Disease Control and Prevention (CDC), SSPs can help prevent blood-borne pathogen transmission by increasing access to sterile syringes among IDUs and enabling safe disposal of used needles and syringes.[10] There are approximately 350 SSP sites operating in the U.S.[11]

A 2012 study compared improper public syringe disposal between Miami, a city without an SSP at the time, and San Francisco, a city with SSPs.[12] Using visual inspection walk-throughs of high drug-use public areas, the study found that Miami was eight times more likely to have syringes improperly disposed of in public areas.[13]

Miami-Dade Infectious Disease Elimination Act (IDEA)

In 2016, the Legislature passed the Miami-Dade Infectious Disease Elimination Act (IDEA), authorizing the University of Miami and its affiliates to establish a needle and syringe exchange pilot program (pilot program) in Miami-Dade County.[14] The pilot program offers free, clean, and unused needles and hypodermic syringes to IDUs to prevent the transmission of blood-borne diseases.

The University of Miami is authorized to operate the pilot program at a fixed location or through a mobile health unit. The pilot program is required to:[15]

- Provide maximum security of the exchange site and equipment;
- Account for the number, disposal, and storage of needles and syringes;
- Adopt any measure to control the use and dispersal of sterile needles and syringes;
- Operate a one sterile needle and syringe unit to one used unit exchange ratio;
- Make available educational materials and referrals to education regarding the transmission of HIV, AIDS, viral hepatitis, and other blood-borne diseases;
- Provide HIV and viral hepatitis testing; and
- Provide or refer for drug abuse prevention and treatment.

The University of Miami must collect data for quarterly, annual, and final reporting purposes, but may not collect any personal identifying information from a participant.[16] The pilot program must issue an annual report to the Department of Health (DOH), as well as a final report on the performance and outcomes of the pilot program to DOH by August 1, 2021. The pilot program expires on July 1, 2021.[17]

The pilot program is expressly prohibited from using state, county, or municipal funds for its operation, and must use grants and donations from private sources to fund the program. [18]

The pilot program began operating on December 1, 2016 as the IDEA Exchange at a fixed location; and as of May 2017, the program began offering services through a mobile unit and provides

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[9] Centers for Disease Control and Prevention, *HIV and Injection Drug Use* (Nov. 2016) available at https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-idu-fact-sheet.pdf (last visited on December 11, 2017). An additional 3 percent (1,202) of the HIV diagnoses and 4% (761) of the AIDS diagnoses were attributable to male-to-male sexual contact and injection drug use.
[10] Id.
[11] North American Syringe Exchange Network, *Directory of Syringe Exchange Programs*, available at https://nasen.org/directory/ (last visited December 15, 2017). The directory provides a list of SSP sites in each state; an SSP may operate more than one site.
[12] Hansel E. Tookes, et al., *A Comparison of Syringe Disposal Practices Among Injection Drug Users in a City with Versus a City Without Needle and Syringe Programs*, 123 Drug & Alcohol Dependence 255 (2012), *available at* http://www.ncbi.nlm.nih.gov/pubmed/22209091 (last visited March 4, 2016).
[13] *Id.* at 255 (finding "44 syringes/1000 census blocks in San Francisco, and 371 syringes/1000 census blocks in Miami.").
[14] Chapter 2016-68, Laws of Fla., codified at s. 381.0038(4), F.S.
[15] Section 381.0038(4)(a), F.S.
[16] Section 381.0038(4)(d), F.S.
[17] Section 381.0038(4)(f), F.S.
[18] Section 381.0038(4)(e), F.S.

backpacking services.[19] As of July 31, 2017, the program has enrolled 409 participants, had 2,426 exchanges, and provided 44,497 syringes in exchange for 50,509 syringes.[20] Additionally, the program achieved the following results:[21]

- Referred 43 individuals for substance use disorder treatment;
- Administered 266 anonymous HIV/Hepatitis C tests;
- Referred 9 individuals for HIV treatment and 35 for Hepatitis C treatment; and
- Provided 251 doses of naloxone[22] to participants and family members, resulting in 73 overdose reversals.

The possession, distribution, or exchange of needles or syringes as part of the pilot program does not violate the Florida Comprehensive Drug Abuse Prevention and Control Act under ch. 893, F.S., or any other law.[23] However, pilot program staff and participants are not immune from prosecution for the possession or redistribution of needles or syringes in any form if acting outside of the pilot program.

Federal Funding of NSEPs

In 2009, Congress passed the FY 2010 Consolidated Appropriations Act, which contained language that removed a ban on federal funding of NSEPs.[24] In July 2010, the U.S. Department of Health and Human Services issued implementation guidelines for programs interested in using federal dollars for NSEPs. [25] On December 23, 2011, President Obama signed the FY 2012 omnibus spending bill[26] that, among other things, reinstated the ban on the use of federal funds for NSEPs; reversing the 111th Congress' 2009 decision that permitted federal funds to be used for NSEPs.[27]

On December 18, 2015, President Obama signed into law the Consolidated Appropriations Act, which prohibits the use of federal funds for the purchase of sterile needles or syringes used to inject illegal drugs.[28] However, the act allows funds to be used for other elements of the program if the state or local health department, in consultation with the CDC, determines that the state or local jurisdiction is, or at risk of, experiencing a significant increase in hepatitis or HIV infection due to intravenous drug use.

Safe Sharps Disposal

Improperly discarded sharps pose a serious risk for injury and infection to sanitation workers and the community. "Sharps" is a medical term for devices with sharp points or edges that can puncture or cut skin.[29] Examples of sharps include:[30]

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[19] IDEA Exchange, Department of Medicine, University of Miami Miller School of Medicine, *IDEA Exchange Annual Report*, (Aug. 1, 2017), (on file with the Health Quality Subcommittee). Backpacking services are services provided on foot.
[20] Id. The program has recovered a surplus of 6,012 syringes through routine exchanges and neighborhood cleanup initiatives.
[21] Id.
[22] Naloxone is an opioid antagonist used to reverse the effects of an opioid overdose by counteracting the depression of the central nervous system and respiratory, allowing an overdose victim to breathe normally. *See* Harm Reduction Coalition, *Understanding Naloxone,* available at: http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/ (last visited December 15, 2017).
[23] Section 381.0038(4)(c), F.S.
[24] Pub. L. No. 111-117.
[25] Matt Fisher, *A History of the Ban on Federal Funding for Syringe Exchange Programs*, The Global Health Policy Center (Feb. 6, 2012), available at http://www.smartglobalhealth.org/blog/entry/a-history-of-the-ban-on-federal-funding-for-syringe-exchange-programs/ (last visited December 15, 2017).
[26] Pub. L. No. 112-74.
[27] *Supra* note 25.
[28] Pub. L. No. 114-113.
[29] Food and Drug Administration, *Safely Using Sharps (Needles and Syringes) at Home, at Work, and on Travel*, (last rev. Mar. 3, 2016), available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/ucm20025647.htm (last visited December 15, 2017).
[30] Id.

- Needles – hollow needles used to inject drugs (medication) under the skin.
- Syringes – devices used to inject medication into or withdraw fluid from the body.
- Lancets, also called "fingerstick" devices – instruments with a short, two-edged blade used to get drops of blood for testing. Lancets are commonly used in the treatment of diabetes.
- Auto Injectors, including epinephrine and insulin pens – syringes pre-filled with fluid medication designed to be self-injected into the body.
- Infusion sets – tubing systems with a needle used to deliver drugs to the body.
- Connection needles/sets – needles that connect to a tube used to transfer fluids in and out of the body, generally used for patients on home hemodialysis.

According to the FDA, used needles and other sharps are dangerous to people and animals if not disposed of safely because they can injure people and spread infections that cause serious health conditions.[31] The most common infections from such injuries are Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV).[32]

Florida Comprehensive Drug Abuse Prevention and Control Act

Section 893.147, F.S., regulates the use or possession of drug paraphernalia. Currently, it is unlawful for any person to use, or to possess with intent to use, drug paraphernalia:

- To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of ch. 893, F.S.; or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of ch. 893, F.S.

Any person who violates the above provision is guilty of a first degree misdemeanor.[33]

Moreover, it is unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used:[34]

- To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of ch. 893, F.S.; or
- To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of ch. 893, F.S.

Any person who violates the above provision is guilty of a third degree felony.[35]

Federal Drug Paraphernalia Statute

Under federal law, it is unlawful for any person to sell or offer for sale drug paraphernalia, use the mails or any other facility of interstate commerce to transport drug paraphernalia or to import or export drug paraphernalia.[36] The penalty for such crime is imprisonment for not more than three years and a fine.[37]

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[31] Id.
[32] *Supra* note 23.
[33] A first-degree misdemeanor is punishable by a term of imprisonment not to exceed 1 year and a $1,000 fine. Sections 775.082 and 775.083, F.S.
[34] Section 893.147(2), F.S.
[35] A third degree felony is punishable by up to five years imprisonment and a $5,000 fine. Sections 775.082 and 775.083, F.S.
[36] 21 U.S.C. § 863(a).
[37] 21 U.S.C. § 863(b).

Persons authorized by local, state, or federal law to possess or distribute drug paraphernalia are exempt from the federal drug paraphernalia statute.[38]

Effect of Proposed

HB 579 expands the existing Miami-Dade Infectious Disease Elimination pilot program to any eligible entity that submits a request to the Department of Health (DOH) to establish a pilot project, regardless of its location within the state.

The bill authorizes DOH or an eligible entity designated by DOH to operate a sterile needle and syringe exchange at a fixed location or through a mobile unit. Eligible entities include:

- Hospitals licensed under ch. 395, F.S.;
- Health care clinics licensed under ch. 400, F.S.;
- Substance abuse treatment programs;
- HIV/AIDS service organizations; or
- Other nonprofit entities designated by DOH.

The bill extends the expiration date of the pilot programs from July 1, 2021 to July 1, 2023.

The bill includes a severability clause[39] and provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Creates an unnumbered section to title the act the "Florida Infectious Disease Elimination Act (IDEA).
Section 2: Amends s. 381.0038, F.S., relating to education; sterile needle and syringe exchange pilot program.
Section 3: Creates an unnumbered section to provide a severability clause.
Section 4: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

In those counties in which a pilot program is operated, the state may realize a cost savings related to the expenditures for the treatment of blood-borne diseases associated with intravenous drug use.[40] The reduction in expenditures for such treatments depends on the extent to which the needle

[38] 21 U.S.C. § 863(f)(1).
[39] A "severability clause" is a provision of a contract or statute that keeps the remaining provisions in force if any portion of that contract or statute is judicially declared void or unconstitutional. Courts may hold a law constitutional in one part and unconstitutional in another. Under such circumstances, a court may sever the valid portion of the law from the remainder and continue to enforce the valid portion. *See Carter v. Carter Coal Co.*, 298 U.S. 238 (1936); *Florida Hosp. Waterman, Inc. v. Buster*, 984 So.2d 478 (Fla. 2008); *Ray v. Mortham*, 742 So.2d 1276 (Fla. 1999); and *Wright v. State*, 351 So.2d 708 (Fla. 1977).
[40] The State of Florida and county governments incur costs for HIV/AIDS treatment through a variety of programs, including Medicaid, the AIDS Drug Assistance Program, and the AIDS Insurance Continuation Program. For a list of patient care programs available in the state, see Department of Health, *Florida HIV/AIDS Patient Care* Programs, available at http://www.floridahealth.gov/diseases-and-conditions/aids/patient-care/_documents/eligibility-information/Appendix.pdf (last visited December 15, 2017). The average lifetime treatment cost of an HIV infection is estimated at $379,668 (in 2010 dollars). Centers for Disease Control and Prevention, *HIV Cost-effectiveness*, (March 7, 2017), available at https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html (last visited December 15, 2017).

and syringe exchange pilot program reduces the transmission of blood-borne diseases among IDUs, their sexual partners, offspring, and others who might be at risk of transmission.

2. Expenditures:

   The bill may have an indeterminate negative fiscal impact on DOH relating to the administration of pilot programs, as well as costs associated with the designation of eligible entities to operate pilot programs.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   A local government entity may realize a cost savings related to the expenditures for the treatment of blood-borne diseases associated with intravenous drug use, if there is a pilot program located in its jurisdiction.[41] The reduction in expenditures for such treatments depends on the extent to which the needle and syringe exchange pilot program reduces the transmission of blood-borne diseases among IDUs, their sexual partners, offspring, and others who might be at risk of transmission.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill authorizes DOH to administer programs; however, there is express prohibition on the use of state funds to operate a pilot project.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[41] Id.

A bill to be entitled

An act relating to infectious disease elimination pilot programs; providing a short title; amending s. 381.0038, F.S.; authorizing the Department of Health to establish sterile needle and syringe exchange pilot programs upon request from eligible entities, rather than a single program established in Miami-Dade County; specifying who may be designated to operate a program; providing for the expiration of all pilot programs; providing for severability; providing an effective date.

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

Section 1. This act may be cited as the "Florida Infectious Disease Elimination Act (IDEA)."

Section 2. Subsection (4) of section 381.0038, Florida Statutes, is amended to read:

381.0038 Education; sterile needle and syringe exchange pilot program.—The Department of Health shall establish a program to educate the public about the threat of acquired immune deficiency syndrome.

(4) The department ~~University of Miami and its affiliates~~ may establish a ~~single~~ sterile needle and syringe exchange pilot program upon request from an eligible entity ~~in Miami-Dade~~

~~County~~. Each pilot program must be administered by the department, or the department may designate one of the following eligible entities to operate the pilot program ~~may operate~~ at a fixed location or through a mobile health unit: a hospital licensed under chapter 395, a health care clinic licensed under part X of chapter 400, a substance abuse treatment program, an HIV or AIDS service organization, or another nonprofit entity designated by the department. Each ~~The~~ pilot program shall offer the free exchange of clean, unused needles and hypodermic syringes for used needles and hypodermic syringes as a means to prevent the transmission of HIV, AIDS, viral hepatitis, or other blood-borne diseases among intravenous drug users and their sexual partners and offspring.

(a) Each ~~The~~ pilot program must:

1. Provide for maximum security of exchange sites and equipment, including an accounting of the number of needles and syringes in use, the number of needles and syringes in storage, safe disposal of returned needles, and any other measure that may be required to control the use and dispersal of sterile needles and syringes.

2. Operate a one-to-one exchange, whereby the participant shall receive one sterile needle and syringe unit in exchange for each used one.

3. Make available educational materials and referrals to education regarding the transmission of HIV, viral hepatitis,

and other blood-borne diseases; provide referrals for drug abuse prevention and treatment; and provide or refer for HIV and viral hepatitis screening.

(b) The possession, distribution, or exchange of needles or syringes as part of each ~~the~~ pilot program established under this subsection is not a violation of any part of chapter 893 or any other law.

(c) A pilot program staff member, volunteer, or participant is not immune from criminal prosecution for:

1. The possession of needles or syringes that are not a part of the pilot program; or

2. The redistribution of needles or syringes in any form, if acting outside the pilot program.

(d) Each ~~The~~ pilot program must collect data for quarterly, annual, and final reporting purposes. The annual report must include information on the number of participants served, the number of needles and syringes exchanged and distributed, the demographic profiles of the participants served, the number of participants entering drug counseling and treatment; the number of participants receiving testing for HIV, AIDS, viral hepatitis, or other blood-borne diseases; and other data necessary for the pilot program. However, personal identifying information may not be collected from a participant for any purpose. Quarterly reports must be submitted to the department ~~of Health in Miami-Dade County~~ by October 15, January

15, April 15, and July 15 of each year. An annual report must be submitted to the department ~~of Health~~ by August 1 every year until the program expires. A final report is due on August 1, 2023 ~~2021~~, to the department ~~of Health~~ and must describe the performance and outcomes of the pilot program and include a summary of the information in the annual reports for all pilot program years.

(e) State, county, or municipal funds may not be used to operate a ~~the~~ pilot program. A ~~The~~ pilot program must ~~shall~~ be funded through grants and donations from private resources and funds.

(f) All ~~The~~ pilot programs ~~program~~ shall expire July 1, 2023 ~~2021~~.

Section 3. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 4. This act shall take effect July 1, 2018.

Amendment No.

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 Quality Subcommittee

Representative Jones offered the following:

Amendment (with title amendment)

Remove lines 23-33 and insert:

(4) An eligible entity ~~The University of Miami and its affiliates~~ may establish a ~~single~~ sterile needle and syringe exchange pilot program ~~in Miami-Dade County~~. Each pilot program must notify the department and provide the pilot program's name and address, the name of the eligible entity operating the program, and the name, address, and telephone number of a contact person. A ~~The~~ pilot program may operate at a fixed location or through a mobile unit by one the following eligible entities: a hospital licensed under chapter 395, a health care clinic licensed under part X of chapter 400, an accredited

medical school, a substance abuse treatment program, or an HIV or AIDS service organization. Each ~~The~~ pilot program shall offer

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

Remove lines 4-9 and insert:

381.0038, F.S.; authorizing eligible entities to establish sterile needle and syringe exchange pilot programs, rather than a single program established in Miami-Dade County; specifying who may operate a pilot program; providing an expiration date of all pilot

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1045 Immunization Registry
SPONSOR(S): Pigman
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Florida law requires children to comply with an immunization schedule established by the Department of Health (DOH), or register a religious objection to immunizations. A parent or guardian must provide a school or child care facility a form signed by administering health care practitioner that shows compliance with the immunization requirements.

Every child born in the state is entered into an electronic database maintain by DOH to record vaccines received by a child; children who are not born in Florida are entered as they are immunized in Florida. A health care practitioner may voluntarily enter immunization records into the database and schools and child care facility may obtain the immunization records of a student as authorized by a parent or guardian. Although all children are listed in the database, a parent or guardian may opt to prohibit access to his or her child's electronic immunization record.

HB 1045 requires physicians, physician assistants, and nurses who administer vaccines to children aged 18 or younger or to students at a Florida college or university health care facility to report the vaccination to the immunization registry. The bill also authorizes automated data uploads to the immunization registry from existing electronic health record systems. The bill repeals the ability of a parent or guardian of a child to opt to exclude his or her child from participating in the immunization registry.

The bill eliminates examples of the types of rules that DOH may promulgate related to the prevention and control of communicable diseases and the immunization registry, but retains DOH's authority to adopt rules as needed to administer the programs.

Effective July 1, 2021, the bill requires that school districts and private schools have a policy that requires each student to have a certification of immunizations on file with the state's immunization registry.

The bill will have no fiscal impact on state or local governments.

The bill has an effective date of July 1, 2018, unless otherwise provided.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Vaccinations

DOH is authorized to implement a program to prevent and control vaccine-preventable diseases, including the immunization of all children in this state and the development of an automated, electronic, and centralized registry of immunizations.[1] For school admission or attendance, a child must obtain the following vaccinations:[2]

- Hepatitis B;
- Diphtheria, tetanus, and pertussis;
- Varicella (Chickenpox);
- Measles, mumps, rubella (MMR);
- Haemophilus influenza type b (Hib); and
- Polio.

Meningococcal meningitis and hepatitis B vaccines are required for individuals residing in on-campus housing of a postsecondary educational institution and are recommended for every student.[3]

All children born in this state are included in the immunization registry and other children are added to the registry as immunizations are provided.[4] A health care practitioner who provides an immunization that is required for school admittance or attendance documents such immunization on a Florida Certification of Immunization Form (immunization form) or submits such information to the Florida State Health Online Tracking System (SHOTS) for electronic certification.[5] Any child entering a preschool, school (K-12), licensed childcare facility, or family daycare home must present an immunization form.[6]

Florida SHOTS

Florida SHOTS is the statewide, online immunization registry employed by DOH to track immunization records.[7] The system is only accessible by authorized health care practitioners, schools, and childcare providers.[8] A health care practitioner voluntarily enrolls to access SHOTS, and once enrolled, may upload his or her patients' immunization history into the system.[9] More than 15,000 practitioners are reporting data to SHOTS.[10] An enrolled school or childcare facility, may access the system to obtain certification of a child's immunizations.

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[1] Section 381.003(1)(e), F.S.
[2] Department of Health, *Immunization Guidelines: Florida Schools, Childcare Facilities, and Family Daycare Homes*, (March 2013), incorporated by reference in r. 64D-3.046, F.A.C., available at http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/_documents/school-guide.pdf (last visited January 7, 2018). The schedule and the number of doses required varies by age.
[3] Section 1006.69, F.S. A student or the parent of a minor who is required to have such vaccines, may refuse by signing a waiver for each vaccine.
[4] Id.
[5] Rule 64D-3.046, F.A.C.
[6] *Supra* note 2. A parent who has a religious objection to the administration of vaccines may apply to DOH for an exemption. A child may also be exempted from immunizations based on medical reasons.
[7] Department of Health, *Frequency Asked Questions*, available at http://www.floridahealth.gov/programs-and-services/immunization/immunization-faq.html (last visited January 7, 2018).
[8] Id.
[9] Id.
[10] Department of Health, *2018 Agency Legislative Bill Analysis for House Bill 1045*, dated December 20, 2017, (on file with the Health Quality Subcommittee).

A parent or guardian may access SHOTS to track their children's immunizations.[11] Authorized users may access and use SHOTS at no charge.[12]

A parent or guardian may opt out of the immunization registry or SHOTS by submitting a request to exclude his or her child from SHOTS.[13] The opt-out does not exempt a child from obtaining required immunizations.[14] The exclusion only prevents the child's immunization record from being accessed electronically; however, the child's record is still maintain in the registry and includes a notation that the parent has opted out of participation.[15]

The immunization registry includes:[16]

- The child's name, date of birth, address, and other unique identifiers necessary;
- The immunization record, including the date, type of vaccine administered, and vaccine lot number; and
- The presence or absence of any adverse reaction or contraindication related to the immunization.

DOH must maintain the confidentiality of such information and any health care practitioner or other agency that obtains such information must maintain the confidentiality.[17]

Effect of Proposed Changes

HB 1045 requires physicians, physician assistants, and nurses who administer vaccines to children aged 18 or younger or to students at a Florida college or university health care facility to report the vaccination to the immunization registry. Vaccinations administered to other individuals may be entered but is not required. The bill authorizes automated data uploads to the immunization registry from existing systems.

The bill eliminates the ability of a parent or guardian of a child to opt to exclude his or her child from participating in the immunization registry. Currently, a parent may opt out of having his or her child's immunization from being accessible by authorized users of the immunization registry. The bill does not affect the ability to object to the administration of vaccines

The bill eliminates examples of the types of rules that DOH may promulgate related to the prevention and control of communicable diseases and the immunization registry, but retains DOH's authority to adopt rules as needed to administer the programs.

Effective July 1, 2021, the bill requires that school districts and private schools have a policy that requires each student to have a certification of immunizations on file with the state's immunization registry.

The bill provides an effective date of July 1, 2018, except as otherwise provided.

B. SECTION DIRECTORY:

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[11] *Supra* note 7. A parent must obtain the identification and certification PIN numbers of their child's immunization record from the child's physician to access the information.
[12] Florida SHOTS, *Frequently Asked Questions*, available at http://flshotsusers.com/resources/frequently-asked-questions (last visited January 14, 2018).
[13] *Supra* note 1.
[14] Id. *See also* Department of Health, *Florida SHOTS Notification and Opt Out Form*, Form DH-1478 (Sept. 3, 2014), available at http://flshotsusers.com/sites/default/files/docs/DH%201478ENGLISH0914.pdf (last visited January 7, 2018).
[15] Rule 64D-3.046(6), F.A.C.
[16] *Supra* note 1.
[17] Id.

Section 1: Amends s. 381.003, F.S., relating to communicable diseases and AIDS prevention and control.
Section 2: Amends s. 1003.22, F.S., relating to school-entry health examinations; immunizations against communicable diseases; exemptions; duties of Department of Health.
Section 3: Provides an effective date of July 1, 2018, except as otherwise provided in the act.

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:

Health care practitioners who do not currently enter vaccination into the system and do not have the technology to do so may experience costs associated with acquiring necessary technological equipment. Health care practitioners who choose to have their electronic health records interface with the SHOTS system may incur costs associated with facilitating such access.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to immunization registry; amending s. 381.003, F.S.; revising provisions relating to the communicable disease prevention and control programs under the Department of Health; providing requirements for electronic availability of immunization records; requiring certain health care practitioners to submit and update data in the immunization registry; requiring the department to adopt rules; amending s. 1003.22, F.S.; revising school-entry health requirements to require students to have a certificate of immunization on file with the Department of Health's immunization registry; providing effective dates.

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

Section 1. Section 381.003, Florida Statutes, is amended to read:

381.003 Communicable disease and AIDS prevention and control.—

(1) The department shall conduct a communicable disease prevention and control program as part of fulfilling its public health mission. A communicable disease is any disease caused by transmission of a specific infectious agent, or its toxic

products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or indirectly. The communicable disease program must include, but need not be limited to:

(a) Programs for the prevention and control of tuberculosis in accordance with chapter 392.

(b) Programs for the prevention and control of human immunodeficiency virus infection and acquired immune deficiency syndrome in accordance with chapter 384 and this chapter.

(c) Programs for the prevention and control of sexually transmissible diseases in accordance with chapter 384.

(d) Programs for the prevention, control, and reporting of communicable diseases of public health significance as provided for in this chapter.

(e) Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children as required by s. 1003.22(3)-(11) and the development of an automated, electronic, and centralized database and ~~or~~ registry of immunizations. The department shall ensure that all children in this state are immunized against vaccine-preventable diseases. The immunization registry shall allow the department to enhance current immunization activities for the purpose of improving the immunization of all children in this state.

1. ~~Except as provided in subparagraph 2.,~~ The department shall include all children born in this state in the

immunization registry by using the birth records from the Office of Vital Statistics. The department shall add other children to the registry as immunization services are provided.

~~2. The parent or guardian of a child may refuse to have the child included in the immunization registry by signing a form obtained from the department, or from the health care practitioner or entity that provides the immunization, which indicates that the parent or guardian does not wish to have the child included in the immunization registry. The decision to not participate in the immunization registry must be noted in the registry.~~

2.~~3.~~ The immunization registry shall allow for immunization records to be electronically available to ~~transferred to~~ entities that are required by law to have such records, including, but not limited to, schools and~~,~~ licensed child care facilities~~, and any other entity that is required by law to obtain proof of a child's immunizations~~.

3.~~4.~~ A ~~Any~~ health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who administers vaccinations or causes vaccinations to be administered to children from birth to 18 years of age or to students at a Florida college or university student health care facility is required to report vaccination data to the immunization registry. Vaccination data for other age ranges may be submitted to the immunization registry on an optional basis. Automated

data upload from existing automated systems is an acceptable method for updating immunization information in the immunization registry. ~~complies with rules adopted by the department to access the immunization registry may, through the immunization registry, directly access immunization records and update a child's immunization history or exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care.~~ The information ~~included~~ in the immunization registry must include the child's name, date of birth, address, and any other unique identifier necessary to correctly identify the child; the immunization record, including the date, type of administered vaccine, and vaccine lot number; and the presence or absence of any adverse reaction or contraindication related to the immunization. Information received by the department for the immunization registry retains its status as confidential medical information and the department must maintain the confidentiality of that information as otherwise required by law. A health care practitioner or other agency that obtains information from the immunization registry must maintain the confidentiality of any medical records in accordance with s. 456.057 or as otherwise required by law.

(2) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section.~~, repeal, and amend rules related to the prevention and control of~~

~~communicable diseases and the administration of the immunization registry. Such rules may include procedures for investigating disease, timeframes for reporting disease, definitions, procedures for managing specific diseases, requirements for followup reports of known or suspected exposure to disease, and procedures for providing access to confidential information necessary for disease investigations. For purposes of the immunization registry, the rules may include procedures for a health care practitioner to obtain authorization to use the immunization registry, methods for a parent or guardian to elect not to participate in the immunization registry, and procedures for a health care practitioner licensed under chapter 458, chapter 459, or chapter 464 to access and share electronic immunization records with other entities allowed by law to have access to the records.~~

Section 2. Effective July 1, 2021, subsection (4) of section 1003.22, Florida Statutes, is amended to read:

1003.22 School-entry health examinations; immunization against communicable diseases; exemptions; duties of Department of Health.—

(4) Each district school board and the governing authority of each private school shall establish and enforce as policy that, prior to admittance to or attendance in a public or private school, grades kindergarten through 12, or any other initial entrance into a Florida public or private school, each

child ~~present or~~ have on file with the state registry of immunizations ~~school~~ a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health and further shall provide for appropriate screening of its students for scoliosis at the proper age. Such certification shall ~~be made on forms approved and provided by the Department of Health and shall~~ become a part of each student's permanent record, to be transferred when the student transfers, is promoted, or changes schools. The transfer of such immunization certification by Florida public schools shall be accomplished using the Florida Automated System for Transferring Education Records and shall be deemed to meet the requirements of this section.

Section 3. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2018.

Amendment No.

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 Quality Subcommittee

Representative Pigman offered the following:

Amendment

Remove everything after the enacting clause and insert:

Section 1. Section 381.003, Florida Statutes, is amended to read:

381.003 Communicable disease and AIDS prevention and control.—

(1) The department shall conduct a communicable disease prevention and control program as part of fulfilling its public health mission. A communicable disease is any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or

indirectly. The communicable disease program must include, but need not be limited to:

(a) Programs for the prevention and control of tuberculosis in accordance with chapter 392.

(b) Programs for the prevention and control of human immunodeficiency virus infection and acquired immune deficiency syndrome in accordance with chapter 384 and this chapter.

(c) Programs for the prevention and control of sexually transmissible diseases in accordance with chapter 384.

(d) Programs for the prevention, control, and reporting of communicable diseases of public health significance as provided for in this chapter.

(e) Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children as required by s. 1003.22(3)-(11) and the development of an automated, electronic, and centralized database and ~~or~~ registry of immunizations. The department shall ensure that all children in this state are immunized against vaccine-preventable diseases. The immunization registry shall allow the department to enhance current immunization activities for the purpose of improving the immunization of all children in this state.

1. ~~Except as provided in subparagraph 2.,~~ The department shall include all children born in this state in the immunization registry by using the birth records from the Office

of Vital Statistics. The department shall add other children to the registry as immunization services are provided.

~~2. The parent or guardian of a child may refuse to have the child included in the immunization registry by signing a form obtained from the department, or from the health care practitioner or entity that provides the immunization, which indicates that the parent or guardian does not wish to have the child included in the immunization registry. The decision to not participate in the immunization registry must be noted in the registry.~~

2.~~3.~~ The immunization registry shall allow for immunization records to be electronically available to ~~transferred to~~ entities that are required by law to have such records, including, but not limited to, schools and~~,~~ licensed child care facilities~~, and any other entity that is required by law to obtain proof of a child's immunizations~~.

3.~~4.~~ A ~~Any~~ health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who administers vaccinations or causes vaccinations to be administered to children from birth to 18 years of age is required to report vaccination data to the immunization registry. A health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who administers vaccinations or causes vaccinations to be administered to college or university students from 19 years of age to 23 years of age at a Florida

college or university student health care facility is required to report vaccination data to the immunization registry. Vaccination data for other age ranges may be submitted to the immunization registry on an optional basis. Automated data upload from existing automated systems is an acceptable method for updating immunization information in the immunization registry. ~~complies with rules adopted by the department to access the immunization registry may, through the immunization registry, directly access immunization records and update a child's immunization history or exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care.~~ The information ~~included~~ in the immunization registry must include the child's name, date of birth, address, and any other unique identifier necessary to correctly identify the child; the immunization record, including the date, type of administered vaccine, and vaccine lot number; and the presence or absence of any adverse reaction or contraindication related to the immunization. Information received by the department for the immunization registry retains its status as confidential medical information and the department must maintain the confidentiality of that information as otherwise required by law. A health care practitioner or other agency that obtains information from the immunization registry must maintain the confidentiality of any medical

records in accordance with s. 456.057 or as otherwise required by law.

(2) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section.~~, repeal, and amend rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for investigating disease, timeframes for reporting disease, definitions, procedures for managing specific diseases, requirements for followup reports of known or suspected exposure to disease, and procedures for providing access to confidential information necessary for disease investigations. For purposes of the immunization registry, the rules may include procedures for a health care practitioner to obtain authorization to use the immunization registry, methods for a parent or guardian to elect not to participate in the immunization registry, and procedures for a health care practitioner licensed under chapter 458, chapter 459, or chapter 464 to access and share electronic immunization records with other entities allowed by law to have access to the records.~~

Section 2. Subsection (4) of section 1003.22, Florida Statutes, is amended to read:

1003.22 School-entry health examinations; immunization against communicable diseases; exemptions; duties of Department of Health.—

(4) Each district school board and the governing authority of each private school shall establish and enforce as policy that, prior to admittance to or attendance in a public or private school, grades kindergarten through 12, or any other initial entrance into a Florida public or private school, each child ~~present or~~ have on file with the state registry of immunizations ~~school~~ a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health and further shall provide for appropriate screening of its students for scoliosis at the proper age. Such certification shall ~~be made on forms approved and provided by the Department of Health and shall~~ become a part of each student's permanent record, to be transferred when the student transfers, is promoted, or changes schools. The transfer of such immunization certification by Florida public schools shall be accomplished using the Florida Automated System for Transferring Education Records and shall be deemed to meet the requirements of this section.

Section 3. Except as otherwise expressly provided in this act, this act shall take effect January 1, 2020.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1047 Department of Health
SPONSOR(S): Gonzalez
TIED BILLS: **IDEN./SIM. BILLS:** SB 1486

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 1047 makes several changes related to programs overseen by Medical Quality Assurance, within the Department of Health (DOH), which licenses and regulates health care practitioners in this state.

The bill:

- Authorizes DOH to request a date of birth on a licensure application;
- Authorizes DOH to adopt rules to implement the Conrad 30 Waiver program;
- Authorizes expedited licensure and fee waivers for the spouse of an active duty military member who holds an active license in another jurisdiction to practice dentistry;
- Repeals a requirement that a Florida-licensed dentist grade the dental licensure examination and that a Florida-licensed dentist or dental hygienist grade the dental hygienist examination;
- Requires dentists and dental hygienist to report adverse incidents to the Board of Dentistry;
- Repeals the licensure of dental laboratories;
- Requires office surgery centers to register with either the Board of Medicine or Board of Osteopathic Medicine and meet certain operational requirements;
- Repeals the voluntary registration of registered chiropractic assistants;
- Authorizes DOH to accept passing scores on the examination for optometry licensure if the examination is taken within 3 years of applying for licensure;
- Authorizes the Board of Optometry to issue a licensure by endorsement;
- Authorizes the Board of Nursing to adopt rules related to standards of care and to issue a licensure by endorsement;
- Establishes standards for permitting and regulating in-state sterile compounding pharmacies and outsourcing facilities;
- Authorizes DOH to issue a single license to a prosthetist-orthotist;
- Requires an athletic trainer to work within his or her scope of practice and revises licensure requirements;
- Limits massage therapy apprenticeships to those in colonic irrigations, and authorizes the Board of Massage Therapy to take action against a massage therapy establishment under certain circumstances;
- Requires a clinical laboratory director to meet federal licensure requirements;
- Updates the name of the accreditation body for psychology programs and revises psychology licensure requirements;
- Authorizes the Board of Clinical Social Work, Marriage and Family Therapists, and Mental Health Counseling to approve a one-time exception to the 60-month limit on an internship registration;
- Revises the licensure requirements for Marriage and Family Therapists;
- Deletes obsolete language and makes technical and conforming changes.

The bill has an indeterminate, positive fiscal impact on DOH, and an insignificant, negative fiscal impact on DOH, which can be absorbed within existing resources. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners.[1] The MQA works in conjunction with 22 boards and 4 councils to license and regulate 7 types of health care facilities and more than 40 health care professions.[2] 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.

General Licensure Requirements

There are general licensure provisions that apply to all licensure applications, regardless of profession. For example, all applicants for licensure must apply in writing on an application form approved by DOH or electronically on a web-based application form.[3] Additionally, an applicant must provide his or her social security number for identification purposes.[4] However, an applicant is not required to provide his or her date of birth as DOH is not currently authorized to collect this information.

Conrad 30 Waiver Program

Federal law requires a foreign physician pursing graduate medical education or training in the United States to obtain a J-1 visa. A holder of a J-1 visa is ineligible to apply for an immigrant visa, permanent residence, or certain nonimmigrant statuses unless he or she has resided and been physically present in his or her country of nationality for at least two years after completion of the J-1 visa program.[5] However, the Conrad 30 Waiver program allows such foreign physicians to apply for a waiver of the two-year residency requirement upon the completion of the J-1 visa program. To be eligible for a Conrad 30 Waiver, the foreign physician must:

- Obtain a contract for full-time employment at a health care facility in an area dedicated as a Health Professional Shortage Area , Medically Underserved Area, or Medically Underserved Population;
- Obtain a "no objection" letter from his or her home country if the home government funded his or her exchange program; and
- Agree to begin employment at the health care facility within 90 days of receipt of the waiver, no later than the date his or her J-1 visa expires.[6]

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[1] 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.
[2] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2016-2017*, available at http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1617.pdf (last visited January 18, 2018).
[3] Section 456.013, F.S. If an applicant does not have a social security number, DOH may issue a unique personal identification number to the applicant.
[4] Id.
[5] Department of Homeland Security, U.S. Citizenship and Immigration Services, *Conrad 30 Waiver Program*, (last rev. May 5, 2014), available at https://www.uscis.gov/working-united-states/students-and-exchange-visitors/conrad-30-waiver-program#Background (last visited January 18, 2018).
[6] Id.

A state may only be issued 30 waivers per year and each state may develop its own applications rules and guidelines. DOH does not currently have statutory authority to develop rules and guidelines for its Conrad 30 program.

Currently, there are 90 physicians practicing in Florida under the Conrad 30 Waiver program.[7] More than 70 percent, or nearly 450 physicians have remained in practice in Florida since the inception of the Conrad 30 Waiver Program.[8] Currently, Florida approves these waivers on a first come basis.

Licensure of Military Spouses

Military Spouses

DOH offers expedited licensing and fee waivers to the spouse of a person serving on active duty with the United States Armed Forces who holds an active license to practice a health care profession in another state or jurisdiction.[9] To qualify for expedited licensure and fee waivers, the military spouse must: [10]

- Submit a complete application;[11]
- Submit evidence of training or experience substantially equivalent to the requirements for licensure in this state for that health care profession and evidence that he or she has obtained a passing score on an appropriate licensing examination, if required for licensure in this state;
- Attest 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;
- Have 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.

Under current law, military spouses who are dentists are not eligible for expedited licensing and fee waivers. No other health care profession is excluded.

The regulatory boards (or DOH if there is no board), are also authorized to issue temporary licenses to the spouse of a member of the U.S. Armed Forces to practice his or her health care profession in Florida, including dentistry.[12] A temporary license is valid for one year and is not renewable.[13] To be eligible for a temporary license, a military spouse must:[14]

- Submit a completed application and application fee;[15]
- Provide proof that he or she is married to a member of the U.S. Armed Forces serving on active duty in this state pursuant to official military orders;
- Provide proof of a valid license from another state or jurisdiction to practice the health profession for which he or she is applying and that such license is not subject to any disciplinary proceeding;

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[7] E-mail correspondence with the Department of Health, dated January 22, 2018 (on file with the Health Quality Subcommittee).
[8] Department of Health, *2017 Physician Workforce Annual Report*, (November 2017), available at http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1617.pdf (last visited January 18, 2018).
[9] Section 456.024(3), F.S. The application fee, licensure fee, and unlicensed activity fee is waived for such applicants.
[10] Section 456.024(3)(b), F.S.
[11] DOH operates the Veterans Application for Licensure Online Response System (VALOR) to provide expedited licensing for active duty military members, honorably discharged veterans, and spouses of active duty military members with an active license in another state. *See* http://www.flhealthsource.gov/valor (last visited January 18, 2018).
[12] Section 456.024(4), F.S.
[13] Section 456.024(4)(f), F.S.
[14] Section 456.024(4)(a)-(d), F.S.
[15] Pursuant to rule 64B-4.007, F.A.C., the application fee is $65.

- Provide proof that he or she would otherwise be entitled to full licensure and is eligible to take the respective licensure examination as required in this state; and
- Pass a criminal background screening.

A military spouse who holds a temporary license to practice dentistry must practice under the indirect supervision[16] of a dentist who holds an active license to practice in this state.[17] This requirement does not apply to any other profession.

Office Surgeries

The Board of Medicine and the Board of Osteopathic Medicine (collectively, Boards) have authority to adopt rules to regulate practice of medicine and osteopathic medicine, respectively. The Boards have authority to establish, by rule, standards of practice and standards of care for particular settings.[18] Such standards may include education and training, medications including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.[19]

The Boards set forth the standards of care that must be met for office surgeries. An office surgery is any surgery that is performed outside a facility licensed under ch. 390, F.S., or ch. 395, F.S.[20] There are several levels of office surgeries that are governed rules adopted by the Boards, which sets forth the scope of each level of office surgeries, the equipment and medications that must be available, and the training requirements for personnel present during the surgery:

- Level I involves the most minor of surgeries, which require minimal sedation or local or topical anesthesia, and have a remote the chance of complications requiring hospitalization.[21]
- Level II office surgeries involve moderate sedation and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office.[22]
- Level IIA office surgeries are those Level II surgeries with a maximum planned duration of 5 minutes or less and in which chances of complications requiring hospitalization are remote.[23]
- Level III office surgeries are the most complex and require deep sedation or general anesthesia; the physician performing the surgery must have staff privileges to perform the same procedure in a hospital as that being performed in the office setting.[24]

Prior to performing any surgery, the physician must evaluate the risk of anesthesia and of the surgical procedure to be performed.[25] The physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.[26]

Registration

The Boards require a licensed physician who performs certain liposuction procedures, Level II procedures planned to last more than 5 minutes, and Level III procedures to register the office with

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[16] Section 466.003(9), F.S., defines indirect supervision as supervision whereby a Florida-licensed dentist authorizes the procedure and a Florida-licensed dentist is on the premises while the procedures are performed.
[17] Section 456.024(4)(j), F.S.
[18] Sections 458.331(v) and 459.015(z), F.S.
[19] Id.
[20] Rules 64B8-9.009(1)(d) and 64B15-14.007(1)(d), F.A.C. Abortion clinics are licensed under ch. 390, F.S., and facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgery centers, mobile surgical facilities, and certain intensive residential treatment programs.
[21] Rules 64B8-9.009(3) and 64B15-14.007(3), F.A.C.
[22] Rules 64B8-9.009(4) and 64B15-14.007(4), F.A.C.
[23] Rules 64B-9.009(5) and 64B15-14.007(5), F.A.C.
[24] Rules 64B8-9.009(6) and 64B15-14.007(6), F.A.C.
[25] Rules 64B8-9.009(2) and 64B15-14.007(2), F.A.C.
[26] Id.

DOH.[27] A physician who performs surgery in an office setting must ensure that the office is registered with DOH, regardless of whether other physicians practice in the office or the office is not owned by a physician.[28] The registration requires a physician to document compliance with transfer agreement[29] and training requirements as required in rule and pass an inspection by DOH or have the office accredited by a national accreditation organization. There are currently 556 offices registered with DOH.[30]

Adverse Incident Reporting

A physician must report any adverse incident that occurs in an office practice setting to DOH within 15 days after the occurrence any adverse incident.[31] An adverse incident in an office setting is defined as an event over which the physician or licensee could exercise control and which is associated with a medical intervention and results in one of the following patient injuries:[32]

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- If the procedure results in death; brain or spinal damage; permanent disfigurement; the fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory functions; or any condition that required the transfer of a patient, the performance of:
    - A wrong-site surgical procedure;
    - A wrong surgical procedure; or
    - A surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed consent process;
- A procedure to remove unplanned foreign objects remaining from a surgical procedure; or
- Any condition that required the transfer of a patient to a hospital from an ambulatory surgical center or any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

DOH must review each adverse incident report to determine if discipline against the practitioner's license is warranted.[33]

Chiropractic Assistants

There are two types of chiropractic assistants: certified and registered.[34] A certified chiropractic assistant is an allied health professional who, under supervision, performs tasks or a combination of tasks traditionally performed by a chiropractic physician.[35] A registered chiropractic assistant is a professional, multi-skilled person dedicated to assisting in all aspects of chiropractic medical practice under the direct supervision of a chiropractic physician or certified chiropractic assistant.[36]

A registered chiropractic assistant voluntarily registers with the board.[37] There are no educational or eligibility standards set in rule or statute for such registration. However, a person who becomes a

[27] Rule 64B8-9.0091 and 64B15-14.0076, F.A.C.
[28] Rule 64B8-9.0091(1) and 64B15-14.0076(1), F.A.C.
[29] A physician or the facility where a surgical procedure is being performed must have a transfer agreement with a licensed hospital within a reasonable proximity or within 30 minutes transport time to the hospital. *See* Rules 64B8-9.009 and 64B15-14.007, F.A.C.
[30] Department of Health, *2018 Agency Legislative Bill Analysis for House Bill 1047*, (Dec. 19, 2017), on file with the Health Quality Subcommittee.
[31] Sections 458.351 and 459.026, F.S.
[32] Sections 458.351(4) and 459.026(4), F.S.
[33] Sections 458.351(5) and 459.026(5), F.S.
[34] Sections 460.4165 and 460.4166, F.S.
[35] Rule 64B2-18(5), F.A.C.
[36] Section 460.4166(1), F.S.
[37] Section 460.4166(3), F.S.

registered chiropractic assistant must adhere to ethical and legal standards of professional practice, recognize and respond to emergencies, and demonstrate professional characteristics.[38] A registered chiropractic assistant may:[39]

- Prepare patients for the chiropractic physician's care;
- Take vital signs;
- Observe and report patients' signs and symptoms;
- Administer basic first aid;
- Assist with patient examinations or treatments other than manipulations or adjustments;
- Operate office equipment;
- Collect routine laboratory specimens as directed by the chiropractic physician or certified chiropractic assistant;
- Administer nutritional supplements as directed by the chiropractic physician or certified chiropractic assistant; and
- Perform office procedures under the direct supervision of by the chiropractic physician or certified chiropractic assistant.

As of June 30, 2017, there were 3,800 active registered chiropractic assistants.[40] DOH does not regulate the practice of registered chiropractic assistants.[41]

Optometry

Optometry Licensure

The practice of optometry includes the diagnosis of conditions of the human eye and its appendages; the use of objective and subjective means or methods to determine the refractive powers of the human eye or any visual, muscular neurological, or anatomic anomalies of the human eye or its appendages; and the prescribing and use of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, or other means to correct, remedy, or relieve any insufficiencies or abnormal conditions of the eyes and their appendages.[42]

The Board of Optometry (Board) regulates the practice of optometry in this state.[43] Any person seeking to be licensed as an optometrist must apply to DOH to take the licensure and certification examinations.[44] To qualify for licensure, an applicant must:[45]

- Be 18 years of age or older;
- Have graduated from an accredited school or college of optometry approved by rule of the Board;
- Be of good moral character;
- Have successfully completed at least 110 hours of transcript-quality coursework and clinical training in general and ocular pharmacology; and
- Have completed at least 1 year of supervised experience in differential diagnosis of eye disease or disorders as part of the optometric training or in a clinical setting as part of the optometric experience.

[38] *Supra* note 36.
[39] Section 460.4166, F.S.
[40] *Supra* note 30.
[41] Id.
[42] Section 463.002(7), F.S.
[43] Section 463.005, F.S.
[44] Section 463.006, F.S.
[45] Id.

In addition, an applicant must pass the Florida licensure examination, which consists of:[46]

- Part I – the Applied Basic Science (ABS) portion of the examination developed by the National Boards of Examiners in Optometry (NBEO);
- Part II – the Patient Assessment and Management (PAM) portion of the examination developed by NBEO, which includes an embedded Treatment of Ocular Disease (TMOD) examination;
- Part III – the Clinical Skills portion of the examination developed by NBEO; and
- Part IV – A written examination on applicable Florida laws and rules governing the practice of optometry.

An applicant for licensure must pass all 4 parts of the examination.[47] An applicant who fails to pass any part of the licensure examination may retake the applicable part; however, the reexamination must occur within 18 months of the date of the original failure.[48]

Administrative Challenge to Licensure Rule

Prior to 2017, an individual licensed as an optometrist in another state could apply for a Florida license without having to sit for a licensure examination if the applicant passed the NBEO examination within the 7 years preceding the application.[49] In 2016, two out-of-state optometrists applying for licensure in Florida petitioned the Board to waive the rule requirement to retake the NBEO examination since more than seven years had passed since they received passing scores.[50] One of the optometrists was licensed in Nevada and had passed the NBEO in 2007; the other was licensed in Michigan and had passed the NBEO in 1998.[51] The Board denied both requests, and each applicant filed a petition with the Division of Administrative Hearings (DOAH) to invalidate the rule.[52]

DOAH held that the look-back provision of the rule was an invalid exercise of delegated legislative authority because it enlarged the authority the Board was given under statute being implemented, s. 463.006(1), F.S. Specifically, the administrative law judge found that s. 463.006(1), F.S., requires applicants to submit the application for licensure before taking the NEO examination, and that the plain language of the section would prohibit the Board from accepting any scores from an NBEO examination taken before an individual files an application for licensure.[53]

Eleven out of 23 accredited schools of optometry in the United States require students to take some or all of the NBEO examination prior to graduation, including optometry schools in Florida.[54] As a result of the DOAH decision, graduating students applying for licensure are required to retake examinations they have previously passed while in school or college, and all out-of-state applicants must retake the examination.[55]

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[46] Rule 64B13-4.001, F.A.C., and Department of Health, Board of Pharmacy, *Certified Optometrist Licensing Requirements*, available at http://floridasoptometry.gov/licensing/certified-optometrist/ (last visited January 19, 2018).
[47] Id.
[48] Rule 64B13-4.002, F.A.C. The Board of Optometry may grant a 1 year extension to allow an additional retake based on medical disability.
[49] Rule 68B13-4.001(2), F.A.C. At that time, the relevant part of the rule read: "Given constant advances in research, developing knowledge in the area of basic and clinical science as applied to the diagnosis, correction, remedy, and relief of insufficiencies or abnormal conditions of the human eyes and their appendages, variances the scope of optometric practice among the states, and the importance of fundamental clinical skills to patient health and safety, passing scores on Part I, Part II, Part III and Part IV of the licensure examination must be obtained within the seven (7) year period immediately preceding licensure application."
[50] *Yontz and Johnson v. Department of Health, Board of Optometry*, Case No. 16-6663RX (Fla. DOAH Apr. 14, 2017). After the DOAH order was issued, DOH repealed this provision from r. 64B13-4.001(2), F.A.C.
[51] Id.
[52] *Johnson v. Florida Board of Optometry*, Case No. 15-5655 and *Yontz v. Florida Board of Optometry and the Florida Optometric Ass'n,* Case No. 16-6123. The cases were consolidated, see footnote 50.
[53] *Supra* note 50 at pp. 32-33.
[54] Department of Health, *2018 Agency Legislative Bill Analysis for Senate Bill 520*, (Oct. 12, 2017), on file with the Health and Human Services Committee. SB 520 is substantively similar to the PCB.
[55] Id.

Board of Nursing

Rulemaking Authority

The Board of Nursing has authority to adopt rules to implement ch. 464, F.S., which regulates the practice of nursing in this state.[56] The Board of Nursing oversees the licensure and practice of certified nursing assistants, licensed practical nurses, registered nurses, and advanced registered nurse practitioners.

In 2011, the Board of Nursing proposed a rule that adopted standards related to moderate sedation in a rule that addressed unprofessional conduct. The Joint Administrative Procedures Committee (JAPC) opined that the proposed rule may enlarge the Board of Nursing's authority to adopt rules because the rule established separate and specific education and training to practice professional, creating an unauthorized level of licensure for nurses.[57]

The Florida Medical Association, the Florida Osteopathic Association, and the Florida Podiatric Medical Association filed a petition with the Division of Administrative Hearings (DOAH) alleging the Board of Nursing exceeded its delegated legislative authority.[58] The administrative law judge (ALJ) ultimately held that although the Board of Nursing is granted general rulemaking authority in ch. 464, F.S., the Legislature had not expressly granted the Board of Nursing authority to promulgate nursing standards of practice.[59] The ALJ noted that other practice acts, such as ch. 458, F.S., which regulates allopathic physicians, and ch. 459, F.S., which regulates osteopathic physicians specifically grant those Boards authority to define standards of practice.[60] The ALJ found the rule to be invalid. Subsequently, the First District Court of Appeals upheld the DOAH decision.[61]

Certified Nursing Assistants

Certified Nursing Assistants (CNAs) provide care and assist individuals with tasks relating to the activities of daily living, such as those associated with personal care, nutrition and hydration, maintaining mobility, toileting, safety and cleaning, end-of-life care, cardiopulmonary resuscitation and emergency care.[62] An applicant for certification as a CNA must complete an approved training program, pass a competency examination, and pass a background screening.[63] A CNA who is certified in another state, is listed on that state's CNA registry,[64] and has not been found to have committed abuse, neglect, or exploitation in that state, is eligible for certification by endorsement in Florida. However, a CNA from a territory of the United States or the District of Columbia, is not eligible for certification by endorsement.

The Board of Nursing may discipline a CNA for:

- Obtaining or attempting to obtain certification or an exemption, or possessing or attempting to possess certification or letter of exemption, by bribery, misrepresentation, deceit, or through an error of the board; or

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[56] Section 464.006, F.S.
[57] *Florida Medical Ass'n, Inc., Florida Osteopathic Medical Ass'n, and Florida Podiatric Ass'n v. Department of Health, Florida Ass'n of Nurse Anesthetists, and Florida Nurses Ass'n*, Case No. 12-1545RP (Fla. DOAH Nov. 2, 2012).
[58] Id.
[59] Id. at 80.
[60] Id.
[61] *Department of Health Board of Nursing v. Florida Medical Ass'n, Inc., et al*, 132 So.3d 225 (Fla. 1d DCA 2014); *Florida Ass'n of Nurse Anesthetists v. Florida Medical Ass'n, Inc. et al*, 132 So.3d 225 (Fla. 1d DCA 2014); and *Florida Nurse Ass' n v. Florida Medical Ass'n, Inc. et al,* 132 So.3d 225 (Fla. 1d DCA 2014).
[62] Section 464.201(5), F.S.
[63] Section 464.203, F.S. *See also* Department of Health, Board of Nursing, *Certified Nursing Assistant (CNA) by Examination*, available at http://floridasnursing.gov/licensing/certified-nursing-assistant-examination/ (last visited January 19, 2018). An applicant who fails the competency examination 3 times, may not take the exam again until he or she completes an approved training program.
[64] A CNA Registry is a listing of CNAs who received certification and maintain an active certification. (Rule 64B9-15.004, F.A.C.)

- Intentionally violating any provision of ch. 464, F.S., the practice act for nursing professions, ch. 456, F.S., the general licensing act, or the rules adopted by the Board of Nursing.

Pharmacy Regulation

Chapter 465, F.S., regulates pharmacies in Florida and contains the minimum requirements for safe practice.[65] A person who wants to operate a pharmacy in Florida must one of the following DOH-issued permits:

- Community pharmacy - A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[66]
- Institutional pharmacy - A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[67]
- Nuclear pharmacy - A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.[68]
- Special pharmacy - A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.[69]
- Internet pharmacy - A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.[70]

All licensed pharmacies must pass an on-site inspection before DOH will issue an initial permit; an on-site inspection is also required any time a pharmacy changes its ownership or address.[71]

Compounding

Compounding is the professional act by a pharmacist or other practitioner authorized by law, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent.[72]

There are two types of compounding: sterile and non-sterile. Sterile compounding is the preparation of a custom medication or product in a sterile environment to prevent contamination and protect patient safety.[73] Nonsterile compounding includes capsules, ointments, creams, gels, and suppositories that do not require a sterile preparation environment.[74]

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[65] Section 465.002, F.S.
[66] Sections 465.003(11)(a)1. and 465.018, F.S.
[67] Sections 465.003(11)(a)2. and 465.019, F.S.
[68] Sections 465.003(11)(a)3. and 465.0193, F.S.
[69] Sections 465.003(11)(a)4. and 465.0196, F.S.
[70] Sections 465.003(11)(a)5. and 465.0197, F.S.
[71] Rule 64B16-28(1)(d), F.A.C.
[72] Rule 64B16-27.700, F.A.C.
[73] U.S. Dept. of Health and Human Services, Office of Inspector General, *Memorandum Report: High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them, OEI-01-13-00150*, (April 10, 2013), available at https://oig.hhs.gov/oei/reports/oei-01-13-00150.pdf (last visited January 19, 2018).
[74] National Conference of State Legislatures, *Legisbrief: Regulating Compounding Pharmacies*, (June 2015), available at http://www.ncsl.org/research/health/regulating-compounding-pharmacies-lb-june-2015.aspx (last visited January 19, 2018).

Special Sterile Compounding Permit

Current law does not expressly provide for an in-state sterile compounding permit. However, s. 456.0196, F.S. grants DOH rule-making authority to create and issue special pharmacy permits. Under that authority, DOH has adopted rules for the issuance of a special sterile compounding permit to regulate in-state pharmacies and outsourcing facilities that perform sterile compounding. Rule 64B-28.802, F.A.C., requires that a pharmacy engaging in the preparation of compounded sterile products in this state must obtain a Special Sterile Compounding Permit (SSCP). The Board of Pharmacy has adopted standards of practice in rule for compounding sterile products, including the Current Good Manufacturing Practices and specific chapters of the United States Pharmacopoeia.[75] Stand-alone special parenteral/enteral pharmacies and special parenteral/enteral extended scope pharmacies are not required to obtain the SSCP.[76]

Applications for new establishments submitted after March 21, 2014, must be accompanied with a $255 application fee. However, pharmacies holding a sterile compounding permit prior to that date do not have to pay such fee. The SSCP is issued in addition to the pharmacy permit (.i.e. community pharmacy or institutional pharmacy).[77]

Nonresident Sterile Compounding Permit

All out-of-state pharmacies or outsourcing facilities must obtain a nonresident sterile compounding permit prior to shipping, mailing, delivering, or dispensing a compound sterile product[78] into this state. Any compounded product sent into this state must meet or exceed Florida's standards for sterile compounding.[79] To obtain the permit, a registered nonresident pharmacy or outsourcing facility must submit an application and a $255 fee to DOH. The application must include:

- Proof of registration with the U.S. Food and Drug Administration (FDA) as an outsourcing facility;[80]
- Proof of registration as a nonresident pharmacy under s. 465.0156, F.S., or, if the applicant is not a pharmacy, proof of an active and unencumbered license, registration, or permit issued by the state, territory, or district where the applicant is located, which is required to compound sterile products in that jurisdiction;
- An attestation by an owner or officer and the prescription department manager or the pharmacist in charge that:
    - They have read and understand Florida law and rules governing sterile compounding;
    - Any sterile compounded product shipped or otherwise introduced into this state will meet or exceed Florida law and rules governing sterile compounding; and
    - Any sterile compounded product shipped or otherwise introduced has not been, and will not be, compounded in violation of laws and rules governing sterile compounding where the applicant is located.

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[75] Rule 64B16-28.797, F.A.C. The Current Good Manufacturing Practice regulation is the main regulatory standard used by the Food and Drug Administration to ensure pharmaceutical quality by assuring proper design, monitoring, and control of manufacturing processes and facilities. *See* U.S. Food and Drug Administration, *Facts about the Current Good Manufacturing Practices (CGMPs)*, available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm (last visited January 19, 2018). The U.S. Pharmacopeia sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. *See* U.S. Pharmacopeial Convention, *About USP*, available at http://www.usp.org/about-usp (last visited January 19, 2018).

[76] Rule 64B16-28.100, F.A.C.

[77] Rule 64B16-28.802, F.A.C.

[78] Section 465.003(20), F.S., defines "compounded sterile product" as a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug or product that is required to be sterile under federal or state law or rule, which is produced through compounding, but is not approved by the FDA.

[79] Section 465.0158, F.S.

[80] To register with the FDA as an outsourcing facility, the facility must comply with Current Good Manufacturing Practices, be inspected by the FDA according to a risk-based schedule, and meet certain other conditions such as adverse event reporting and providing the FDA with certain information about the products they compound.

- Copies of existing policies and procedures governing sterile compounding that meet certain standards; and
- A current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state, territory or district where the applicant is located.[81]

The Board of Pharmacy has authority to administratively discipline a nonresident sterile compounding permittee for violation of laws or rules governing pharmacies and entities licensed under MQA.

In-state sterile compounding pharmacies and outsourcing facilities are not statutorily required to obtain a permit for compounding in a manner similar to out-of-state compounding pharmacies or outsourcing facilities.

Dentistry

Examination for Licensure

Any person wishing to practice dentistry in this state must apply to DOH and meet specified requirements. Section 466.006, F.S., requires dentistry licensure applicants to sit for and pass the following licensure examinations:

- The National Board of Dental Examiners dental examiner (NBDE);
- A written examination on Florida laws and rules regulating the practice of dentistry; and
- A practical examination, which is the American Dental Licensing Examination developed by the American Board of Dental Examiners, Inc., and graded by a Florida-licensed dentist employed by DOH for such purpose.[82]

To qualify to take the Florida dental licensure examination, an applicant must be 18 years of age or older, be a graduate of a dental school accredited by the American Dental Association or be a student in the final year of a program at an accredited institution, and have successfully completed the NBDE dental examination.

Any person wishing to be licensed as a dental hygienist must apply to DOH and meet the following qualifications:

- Be 18 years of age or older;
- Be a graduate of an accredited dental hygiene college or school;[83] and
- Obtain a passing score on the:
    - Dental Hygiene National Board Examination;
    - Dental Hygiene Licensing Examination developed by the American Board of Dental Examiners, Inc., which is graded by a Florida-licensed dentist or dental hygienist employed by DOH for such purpose; and
    - A written examination on Florida laws and rules regulating the practice of dental hygiene.

Adverse Incident Reporting

Dentists and dental hygienist certified by DOH to administer anesthesia must report, in writing, any adverse incident that occurs to the Board of Dentistry within 48 hours by registered mail.[84] An adverse

[81] Section 465.0158 (3), F.S.
[82] A passing score is valid for 365 days after the date the official examination results are published. A passing score on an examination obtained in another jurisdiction must be completed on or after October 1, 2011.
[83] If the school is not accredited, the applicant must have completed a minimum of 4 years of postsecondary dental education and received a dental school diploma which
is comparable to a D.D.S. or D.M.
[84] Rule 64B5-14.006, F.A.C.

incident in an office setting is defined as any mortality that occurs during or as the result of a dental procedure, or an incident that results in a temporary or permanent physical or mental injury the requires hospitalization or emergency room treatment of a patient as a direct result of the use of general anesthesia,[85] deep sedation,[86] moderate sedation,[87] pediatric moderate sedation,[88] minimal sedation,[89] nitrous oxide,[90] or local anesthesia.[91] The dentist must file a complete written report with the Board of Dentistry within 30 days.[92] Since 2014, 23 adverse incident reports have been filed with DOH.[93] Of those, 17 were closed without discipline, 1 was issued a letter of guidance, 4 are currently being prosecuted, and 1 is still under investigation.[94]

Dental Laboratories

A dental laboratory is a facility that supplies or manufactures artificial substitutes for natural teeth, or that furnishes, supplies, constructs, reproduces, or repairs a prosthetic denture, bridge, or appliance to be worn in the human mouth or that otherwise holds itself out as a dental laboratory.[95] Dental laboratories must biennially register with DOH, and the owner or at least one employee must complete 18 hours on continuing education each biennium.[96] A dental laboratory is subject to inspection by DOH and must:[97]

- Maintain and make available to DOH a copy of the laboratory's registration;
- Be clean and in good repair;
- Properly dispose of all waste materials at the end of each day in accordance with local restrictions;
- Maintain the original or a copy of a prescription from a dentist for each appliance or artificial restorative oral device authorizing its construction or repair for 4 years;
- Maintain a written policy and procedure manual on sanitation; and
- Have a designated receiving area.

A dental laboratory may not have dental chairs, x-ray machines, or anesthetics, sedatives, or medicinal drugs.[98] A dental laboratory may not solicit or advertise to the general public.[99]

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[85] General anesthesia is a controlled state of unconsciousness, produced by a pharmacologic agent, accompanied by a partial or complete loss of protective reflexes, including inability to independently maintain an airway and respond purposefully to physical stimulation or verbal command. (Rule 64B5-14.001(2), F.A.C.)
[86] Deep sedation is a controlled state of depressed consciousness accompanied by partial loss of protective reflexes, including either or both the inability to continually maintain an airway independently or to respond appropriately to physical stimulation or verbal command, produced by pharmacologic or non-pharmacologic method or combination thereof. (Rule 64B5-14.001(3), F.A.C.)
[87] Moderate sedation is a depressed level of consciousness produced by the administration of pharmacologic substances, that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command. (Rule 64B5-14.001(4), F.A.C.)
[88] Pediatric moderate sedation is a depressed level of consciousness produced by the administration of pharmacologic substances, that retains a child patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command. (Rule 64B5-14.001(5), F.A.C.)
[89] Minimal sedation involves the perioperative use of medication to relieve anxiety before or during a dental procedure and does not produce a depressed level of consciousness and maintains the patient's ability to maintain an airway independently and to respond appropriately to physical and verbal stimulation. (Rule 64B5-14.001(10), F.A.C.)
[90] The use of nitrous oxide produces an altered level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command. (Rule 64B5-14.001(6), F.A.C.)
[91] Local anesthesia involves the loss of sensation of pain in a specific area of the body. (Rule 64B5-14.001(7), F.A.C.)
[92] *Supra* note 84.
[93] *Supra* note 30.
[94] Id.
[95] Section 466.031, F.S.
[96] Section 466.032, F.S.
[97] Rule 64B27-1.001, F.A.C.
[98] Id. Personal prescriptions are permissible.
[99] Section 466.035, F.S.

There are currently 12 states, including Florida that regulate dental laboratories in some way,[100] of which 7 require dental laboratories to be registered.[101] Since 2012, 6 administrative complaints were filed against dental laboratories in Florida, 4 of those resulted in disciplinary cases.[102]

Athletic Trainers

Athletic trainers provide service and care to individuals related to the prevention, recognition, evaluation, management, disposition, treatment, or rehabilitation of a physically active person who sustained an injury, illness, or other condition involving exercise, sport, recreation, or related physical activity.[103] To be licensed as an athletic trainer, an applicant must:[104]

- Hold a bachelor's degree or higher from an accredited athletic training degree program and pass the national examination to be certified by the Board of Certification;[105]
- If graduated before 2004, hold a current certification from the Board of Certification;
- Hold a current certification in both cardiopulmonary resuscitation and the use of an automated external defibrillator at the professional rescue level; and
- Pass a background screening.

An athletic trainer must practice under the direction of an allopathic, osteopathic, or chiropractic physician,[106] and may provide care such as:[107]

- Injury prevention, recognition, and evaluation;
- First aid and emergency care;
- Injury management and treatment;
- Rehabilitation through the use of safe and appropriate physical rehabilitation practices;
- Conditioning;
- Performance of tests and measurements to prevent, evaluate, and monitor acute and chronic injuries;
- Therapeutic exercises;
- Massage;
- Cryotherapy and thermotherapy;
- Therapy using other agents such as water, electricity, light, or sound; and
- The application of topical prescription medications at the direction of a physician.

Orthotists and Prosthetists

The Board of Orthotists and Prosthetists oversees the licensure and regulation of orthotists[108] and prosthetists.[109] A person applying for licensure must first apply to DOH to take the appropriate licensure examination. The board may accept the exam results of a national orthotic or prosthetic, standards

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[100] National Association of Dental Laboratories, *State Regulation*, available at http://dentallabs.org/state-regulation/ (last visited January 20, 2018). The other 11 states are Illinois, Kentucky, Minnesota, Missouri, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas, and Virginia.
[101] Id. These include Florida, Kentucky, Minnesota, Oklahoma, Pennsylvania, South Carolina, and Texas.
[102] *Supra* note 30.
[103] Section 468.701(2), F.S.
[104] Section 468.707, F.S.
[105] The Board of Certification is a not-for-profit credentialing agency to provide a certification program for the entry level athletic training profession. *See* Board of Certification for the Athletic Trainer, *What is the BOC?*, available at http://www.bocatc.org/about-us#what-is-the-boc (last visited January 20, 2018).
[106] Section 468.713, F.S.
[107] Rule 64B33-4.001, F.A.C.
[108] An orthotist is a health care professional who evaluates, formulates treatment, measures, designs, fabricates, assembles, fits, adjusts, services or provides necessary training to accomplish the fitting of an orthosis or pedorthics. (Section 486.80(9)-(10), F.S)
[109] An orthotist is a health care professional who evaluates, formulates treatment, measures, designs, fabricates, assembles, fits, adjusts, services or provides necessary training to accomplish the fitting of a prosthesis. (S. 486.80(15)-(16), F.S.)

organization in lieu of administering the state exam.[110] The board must verify that an applicant for licensure examination meets the following requirements:

- Has completed the application form and paid all applicable fees;
- Is of good moral character;
- Is 18 years of age or older;
- Has completed the appropriate educational preparation, including practical training requirements; and
- Has successfully completed an appropriate clinical internship in the professional area for which the license is sought.[111]

In addition to the requirements listed above, an applicant must meet the following requirements for each license he or she is seeking:

- A Bachelor of Science degree in Orthotics and Prosthetics from a regionally accredited college or university from an accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs, or a bachelor's degree with a certificate in orthotics or prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent;
- An internship of one year of qualified experience or a residency program recognized by the board;
- Completion of the mandatory classes;[112] and
- Passage of the state orthotic examination or board-approved orthotic examination if applying for an orthotist license, or the state prosthetic examination or board-approved examination if applying for a prosthetist license.[113]

Currently, a person who qualifies to be licensed as both an orthotist and a prosthetist must obtain two separate licenses.

Massage Therapy

The "Massage Practice Act" (Act), governs the practice of massage in Florida.[114] A significant portion of the Act is dedicated to regulating massage establishments, which are sites or premises, or portion thereof, wherein a massage therapist practices massage.[115] Massage establishments must be licensed by DOH in accordance with rules adopted by Board of Massage Therapy.[116] A massage establishment must:[117]

- Have all individuals with an ownership interest, or for a corporation with more than $250,000 in assets, the owner, officer, or management pass a background screening;
- Provide proof of property damage and bodily injury liability insurance coverage;
- Comply with local building code requirements;
- Provide a bathroom with at least one toilet and one sink with running water for its clients to use;
- Maintain toilet facilities in the common area of the establishment;

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[110] Section 486.803(4), F.S. The Board has approved the American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC) exam for orthotist and prosthetist applicants (r. 64B14-4.001, F.A.C.)
[111] Section 486.803(2), F.S.
[112] Pursuant to r. 64B14-5.005, F.A.C., mandatory courses include two hours on Florida laws and rules, two hours on the prevention of medical errors, one hour on infection disease control, and a CPR certification course.
[113] Section 486.803(5), F.S. Licenses must be renewed biennially.
[114] Chapter 480, F.S.
[115] Section 480.033(7), F.S.
[116] Section 480.043, F.S. Registration requirements do not apply to an allopathic, osteopathic, or chiropractic physician who employs a licensed massage therapist to perform massage on the physician's patients at the physician's practice location.
[117] Id. and r. 64B7-26.003, F.A.C.

- Have a massage therapist on the premises if a client is in a treatment room for the purpose of receiving massage therapy;
- Maintain certain safety and sanitary requirements; and
- Pass initial and periodic inspections by DOH.

DOH must deny an application for a license or renewal of a license if a person with an ownership interest has been convicted or found guilty of, or entered a plea of nolo contedere to a crime related to prostitution or a felony offense related to certain other crimes, such as human trafficking or kidnapping.[118]

Massage Therapists

To be licensed as a massage therapist, an applicant must:[119]

- Be at least 18 years of age or have received a high school diploma or graduate equivalency diploma;
- Complete a course of study at a board-approved massage school or apprentice program;
- Pass an examination; and
- Pass a background screening.

DOH must deny an application if the applicant has been convicted or found guilty of, or entered a plea of nolo contedere to a crime related to prostitution or a felony offense related to certain other crimes.[120] In the 2016-2017 fiscal year, 2,076 individuals applied for licensure by examination, 12 of which qualified for licensure by completing an approved Florida apprenticeship program.[121]

Colonic Irrigation Apprenticeship Programs

A massage therapist, a massage apprentice, or a student in a board-approved massage therapy school may study colonic irrigation under the direct supervision of a sponsor.[122] The sponsor must be licensed to practice massage, authorized to practice colonic irrigation, and have practiced colonic irrigation for at least 3 years.[123] The apprenticeship must be completed within 12 months of commencement[124] and must consist of a minimum of 100 hours of training, including 45 hours of clinical practicum with a minimum of 20 treatments given.[125]

Clinical Laboratory Directors

A clinical laboratory performs services to provide information for use in the diagnosis, prevention, or treatment of a disease or identification or assessment of a medical or physical condition.[126] The Agency for Health Care Administration regulates clinical laboratories and DOH regulates clinical laboratory personnel, including clinical laboratory directors, supervisors, technologists, and technicians.[127]

A clinical laboratory director is responsible for the overall operation and administration of a clinical laboratory.[128] A director may not direct more than 5 clinical laboratories and may delegate the performance of certain duties to licensed clinical supervisors, except that the director may not delegate the approval, signing, and dating of an initial procedure review or a substantive change in existing

[118] Section 480.043(8), F.S.
[119] Section 480.041, F.S.
[120] Id.
[121] *Supra* note 30.
[122] Rule 64B7-29.001, F.A.C.
[123] Id.
[124] Rule 64B7-29.007, F.A.C.
[125] Rule 64B7-25.001, F.A.C.
[126] Section 483.041, F.S.
[127] *See generally*, ch. 483, F.S.
[128] Rule 64B3-13.001(1), F.A.C.

procedure.[129] However, the clinical laboratory director remains responsible that all duties of the laboratory are performed properly.[130] An applicant for licensure as a clinical laboratory director must meet the qualifications for a High Complexity Laboratory Director, which requires the applicant be either:[131]

- A licensed allopathic or osteopathic physician; and
- Be certified in anatomic or clinical pathology, or both;

  or
- A licensed allopathic, osteopathic, or podiatric physician; and
- Have at least 1 year of laboratory training during medical residency or have at least 2 years' experience directing or supervising high complexity testing;

  or
- Hold a doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and
- Be certified by a board approved by the federal Department Health and Human Services or meet specified training and experience requirements.

A clinical laboratory director must have at least 2 years' experience in the specialty to be directed or hold a national board certification in such specialty.[132]

Psychologists

The Board of Psychology oversees the licensure and regulation of psychologists.[133] To receive a license to practice psychology, an individual must:[134]

- Have received a doctoral-level psychological education from an accredited school in the United States or Canada;[135]
- Complete 2 years or 4,000 hours of supervised experience;
- Pass the Examination for Professional Practice in Psychology;[136] and
- Pass an examination on Florida laws and rules.

An applicant who holds an active, valid license in another state may also qualify for licensure in this state if at the time the license was issued, the requirements were substantially equivalent to or more stringent than those in Florida at that time.[137]

Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling

Intern Registration

To be licensed as a clinical social worker, marriage and family therapist, or mental health counselor, an applicant must meet educational requirements, complete at least 2 years of postgraduate or postmaster's clinical practice supervised by a licensed practitioner, and pass a theory and practice examination.[138] During the time in which an applicant is completing the required supervised clinical experience or internship, he or she must register with the DOH as an intern.[139] The supervised clinical

[129] Rule 64B3-13.001(4)-(5), F.A.C.
[130] Rule 64B3-13.001(5), F.A.C.
[131] 42 C.F.R. s. 489.1443.
[132] *See* s. 483.824, F.S., and r. 64B3-5.007, F.A.C.
[133] Section 490.004, F.S.
[134] Section 490.005, F.S.
[135] Section 490.003(3), F.S., defines doctoral-level education as a Psy.D, an Ed.D., or a Ph.D in psychology from an accredited educational institution.
[136] Rule 64B19-11.001, F.A.C.
[137] Section 490.006, F.S.
[138] Section 491.005, F.S. A procedure for licensure by endorsement is provided in s. 491.006, F.S.
[139] Section 491.0045, F.S.

experience may be met by providing at least 1,500 hours of face-to-face psychotherapy with clients, which may not be accrued in less than 100 weeks.[140]

An applicant seeking registration as an intern must:[141]

- Submit a completed application form and the nonrefundable fee to the DOH;
- Complete education requirements;
- Submit an acceptable supervision plan for meeting the practicum, internship, or field work required for licensure that was not satisfied by graduate studies; and
- Identify a qualified supervisor.

An intern registration expires 60 months after the date of issue and may only be renewed if the candidate has passed the theory and practice examination required for full licensure.[142]

Marriage and Family Therapists

Marriage and family therapy incorporates marriage and family therapy, psychotherapy, hypnotherapy, sex therapy, counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients.[143] An applicant seeking licensure as a mental health counselor must:[144]

- Possess a master's degree from an accredited program;
- Complete 36 semester hours of graduate coursework that includes a minimum of 3 semester hours of graduate-level coursework in:
    - The dynamics of marriage and family systems;
    - Marriage therapy and counseling theory;
    - Family therapy and counseling theory and techniques;
    - Individual human development theories throughout the life cycle;
    - Personality or general counseling theory and techniques;
    - Psychosocial theory; and
    - Substance abuse theory and counseling techniques.
- Complete at least one graduate level course of 3 semester hours in legal, ethical, and professional standards;
- Complete as least one graduate level course of 3 semester hours in diagnosis, appraisal, assessment, and testing for individual or interpersonal disorder or dysfunction;
- Complete at least one graduate level course of 3 semester hours in behavioral research;
- Complete at least one supervised clinical practicum, internship, or field experience in a marriage and family counseling setting, during which the student provided 180 direct client contact hours of marriage and family therapy services;
- Complete two years of post-master's supervised experience under the supervision of a licensed marriage and family therapist with five years of experience or the equivalent who is qualified as a supervisor by board;
- Pass a board approved examination; and
- Demonstrate knowledge of laws and rules governing the practice.

An individual may apply for a marriage and family therapy dual license if he or she passes an examination in marriage and family therapy and holds an active license for at least three years as a

[140] Rule 64B4-2.001, F.A.C.
[141] Section 491.0045(2), F.S.
[142] Section 491.0045(6), F.S.
[143] Id.
[144] Section 491.005(3), F.S.

psychologist, clinical social worker, mental health counselor, or advanced registered nurse practitioner who is determined by the Board of Nursing to be a specialist in psychiatric mental health.[145]

Mental Health Counselors

A mental health counselor is an individual who uses scientific and applied behavioral science theories, methods, and techniques to describe, prevent, and treat undesired behavior and enhance mental health and human develop and is based on research and theory in personality, family, group, and organizational dynamics and development, career planning, cultural diversity, human growth and development, human sexuality, normal and abnormal behavior, psychopathology, psychotherapy, and rehabilitation.[146] Mental health counselors are regulated by the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, within DOH. To qualify for licensure as a mental health counselor, an individual must:[147]

- Have a master's degree from a mental health counseling program accredited by the Council of the Accreditation of Counseling and Related Educational Programs, or a program related to the practice of mental health counseling that includes coursework and a 1,000-hoour practicum, internship, or fieldwork of at least 60 semester hours that meet certain requirements;
- Have at least two years of post-master's supervised clinical experience in mental health counseling;
- Pass an examination from the Professional Examination Service for the National Academy of Certified Clinical Mental Health Counselors; and
- Pass an eight-hour course on Florida laws and rules approved by the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling.[148]

Currently, an applicant for a mental health counselor license must, by rule, pass the National Clinical Mental Health Counseling Examination. Current law refers to an outdated mental health counseling examination.

Effect of Proposed Changes

General Licensure Requirements

The bill requires the application for licensure to include the applicant's date of birth, in addition to the currently required social security number. This will provide DOH an additional method of verify the identity of an individual applicant.

Conrad 30 Program

The bill authorizes DOH to adopt rules to implement the Conrad 30 Waiver program in this state. This allows DOH to set guidelines in addition to those required by federal law.

Dentistry

Military Spouses

The bill expands the expedited licensure application process to include the spouse of an active duty military member who holds an active license to practice dentistry in another state or jurisdiction and waives the application, licensure, unlicensed activity fees. The bill also repeals a provision that requires

[145] Section 491.0057, F.S.
[146] Sections 491.003(6) and (9), F.S.
[147] Section 491.005(4), F.S.
[148] Section 491.005(4), F.S., and r. 64B4-3.0035, F.A.C.

the spouse of a member of the U.S. Armed Forces serving on active duty in this state who holds a temporary license to practice dentistry to practice under the supervision of a Florida-licensed dentist.

These provisions allow dentistry to be treated in the same manner as all other health professions for which a military spouse may pursue licensure in this state.

Dental Licensure Exams

The bill repeals a requirement that a Florida-licensed dentist grade the American Dental Licensing Examination, and that either a Florida-licensed dentist or dental hygienist grade Dental Hygienist Examination produced by the American Board of Dental Examiners, Inc., for applicants for licensure in this state.

Dental Adverse Incidents

Dentists and dental hygienist are currently required to submit adverse incidents related to the administration of anesthesia under rules adopted by the Board of Dentistry. The bill statutorily requires a dentist to report an adverse incident that occurs in his or her office to DOH in writing by certified mail and postmarked within 48 hours after the incident occurs. An adverse incident is any death that occurs during or as a result of a dental procedure, or a temporary or permanent physical or mental injury that requires hospitalization or emergency room treatment as a result of the use of general anesthesia, deep sedation, conscious sedation, pediatric conscious sedation, oral sedation, minimal sedation, nitrous oxide, or local anesthesia.

A dentist must also report any death or other adverse incident that occurs in the dentist's outpatient facility to the Board of Dentistry in writing by certified mail within 48 hours of such occurrence. Within 30 days, the dentist must file a complete report with the Board of Pharmacy.

A certified dental hygienist who holds a certificate to administer local anesthesia must notify the Board of Dentistry in writing by registered mail within 48 hours of an adverse incident that was related to or the result of the administration of local anesthesia. The dental hygienist must file a complete report with the Board of Dentistry within 30 days.

DOH must review each adverse incident report to determine whether the incident involved conduct by a health care practitioner that warrants disciplinary action by the applicable regulatory board. A dentist or dental hygienist who fails to timely and completely report adverse incidents as required will be subject to disciplinary action by the Board of Dentistry.

Dental Laboratories

The bill repeals the regulation of dental laboratories.

Office Surgery Centers

The bill authorizes the Board of Medicine and Board of Osteopathic Medicine to regulate an office surgery center, which is facilities where a physician performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat are removed, level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an office setting, or any facility at which surgical procedures are performed that is not licensed under ch. 390, F.S., or ch. 395, F.S. Office surgeries are currently regulated under rules adopted by the Boards.

The bill requires office surgery centers to register with DOH unless the facility is licensed pursuant to ch. 395, F.S., or affiliated with an accredited medical school at which medical students, residents, or fellows are trained. Each office surgery center must registered, regardless of whether the center is operated under the same business name or management as another center. If the ownership of the

office surgery center changes, a new registration. DOH must deny or revoke the registration of an office surgery center if it is:

- Not fully owned by a Florida-licensed physician or a group of Florida-licensed physicians;
- Not a licensed health care center;[149] or
- Owned by or in any contractual or employment relationship with a Florida-licensed physician who:
    - Had hospital privileges revoked in the past 5 years;
    - Does not have a clear and active Florida license; or
    - Had a license suspended in Florida or another jurisdiction in the last 5 years for an offense related to standard of care.

The bill directs DOH to revoke the registration if it finds the office surgery center does not meet the requirements for registration or is directly or indirectly owned by a person who does not meet the requirements for registration. If a registration is revoked or suspended, the designated physician, owner or lessor of the property, manager, and proprietor must:

- Cease operation of the facility as of the effective date of the suspension or revocation;
- Remove all signs and symbols identifying the facility as an office surgery center; and
- Advise DOH of the disposition of the medicinal drugs located at the facility, and such disposition may be subject to the supervision and approval of DOH.

If the registration is revoked, any person named on the registration is barred from operating an office surgery center for 5 years after the registration is revoked. DOH may prescribe the period of suspension of registration; however, a suspension may not exceed 2 years.

The bill requires an office surgery center must designate a Florida-licensed physician as the designated physician. The designated physician must practice at the office surgery center and is responsible for ensuring that office surgery center complies with all registration and operation requirements. The office surgery center must notify DOH within 10 days of a change in the designated physician. If an office surgery center fails to have a designated physician, DOH may suspend its registration. A designated physician must notify DOH within 10 days of her or his termination of employment with the facility.

Under the bill, DOH must annually inspect office surgery centers, which includes a review of patient records, unless the office surgery center is accredited by a nationally recognized accrediting agency or a Board-approved accrediting agency.[150] DOH must make a reasonable attempt to discuss any violations found during an inspection with the designated physician. DOH may revoke the registration of an office surgery center and prohibit all physicians associated with the center from practicing at that location based on the findings of an annual inspection. The owner or designated physician must document any action taken to correct a violation, which will be verified by DOH during a follow-up visit.

The bill requires the designated physician to:

- Ensure that the facility maintains an ongoing quality assurance program that objectively and systematically:
    - Monitors and evaluates the quality and appropriateness of the patient care provided;
    - Evaluates methods to ensure patient care;
    - Identifies and corrects deficiencies;
    - Alerts the designated physician to identify and resolve recurring problems; and

[149] Health care centers are licensed under part X of ch. 400, F.S.

[150] There are approximately 190 accredited office surgery centers in Florida. Office surgery centers may be accredited by American Association for Accreditation of Ambulatory Surgery Facilities, Accreditation Association for Ambulatory Health Care, or the Joint Commission on Accreditation of Healthcare Organizations (*supra* note 30).
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    - Provides opportunities to improve the facility's performance and to enhance and improve the quality of care provided;
- Establish a quality assurance program that:
    - Identifies, investigates, and analyze the frequency and cause of adverse incidents;
    - Identifies trends or patterns of adverse incidents;
    - Develops measures to correct, reduce, minimize, or eliminate the risk of adverse incidents; and
    - Documents and reviews, at least quarterly, the information required above;
- Report all adverse incidents to DOH.

The bill prohibits a physician from practicing in an office surgery center unless the facility is registered with DOH. If a physician practices at an unregistered facility, he or she is subject to discipline by the appropriate regulatory board. A physician practicing in an office surgery center must notify the appropriate regulatory board, in writing, within 10 days of beginning or ending her or his practice at the facility.

The bill requires every physician practicing at an office surgery center to be responsible for ensuring that the facility complies with:

- Facility and physical operations requirements, including:
    - Being located and operated at a publicly accessible fixed location;
    - Publicly displaying a visible printed sign that clearly identifies the name, hours of operations, and street address;
    - Maintaining a publicly-listed telephone number and other methods of communication;
    - Emergency lighting and communications;
    - A reception and waiting area;
    - A restroom;
    - An administrative area, including room for storing medical records, supplies, and equipment;
    - Private patient examination rooms;
    - Treatment rooms; if needed;
    - Publicly displaying a visible printed sign located in a conspicuous place in the waiting area with the name and contact information of the facility's designated physician and the names of all the physicians practicing in the facility; and
    - Compliance with laws governing the storage of prescription drugs and associated recordkeeping;
- Infection control requirements, including:
    - Maintaining equipment and supplies to support infection prevention and control activities;
    - Identifying infection risks based on:
        - Geographic location, community, and population served;
        - The provided care, treatment, and services; and
        - An analysis of its infection surveillance and control data;
    - Maintaining written infection prevention policies and procedures that address:
        - Unprotected exposure to pathogens;
        - Transmission of infections associated with procedures performed at the facility; and
        - Transmission of infections associated with the use of medical equipment, devices, and supplies; and
- Health and safety requirements, including:
    - Being structurally sound, in good repair, clean, and free from health and safety hazards;
    - Having evacuation procedures in the event of an emergency;
    - Having a written facility-specific disaster plan setting forth actions that will be taken in the event of facility closure due to unforeseen circumstances;

- Having at least one employee on the premises during patient care hours who is certified in Basic Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrives.

All physicians must maintain the standard of care, skill, and treatment as required by law.

The bill authorizes DOH to impose a fine of up to $5,000 per violation if an office surgery center violates applicable state or federal laws or administrative rules, including those related to registrations, prescription drugs, and controlled substances. In determining whether to impose a penalty or the amount of the penalty to be imposed, DOH must consider:

- The gravity of the violation, including the probability of death or serious physical or emotional harm to a patient has resulted or could have resulted, the severity of the action or potential harm, and the extent to which the applicable laws or rules were violated;
- What actions, if any, the owner or designated physician took to correct the violation;
- Whether there were any previous violations at the facility; and
- The financial benefit that the facility derived from committing or continuing to commit the violation.

Each day a violation continues after the date is fixed for correction constitute a separate and distinct violation. DOH may impose a fine and, in the case of an owner-operated facility, revoke or deny the facility's registration if the designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

The bill also authorizes DOH to impose a fine of $10,000 on the owner of an office surgery center fails to register as required when there is a change of ownership. If an owner or designated physician concurrently operates an unregistered office surgery center, DOH may fine the owner or physician $5,000 per day.

The bill authorizes the Board of Medicine and the Board of Osteopathic Medicine to adopt rules related to the registration and inspection of office surgery centers. Such rules must also set forth training requirements for health care practitioners who are not regulated by another regulatory board.

Chiropractic Physician Assistants

The bill repeals the voluntary registration of registered chiropractic assistants.

Optometry

The bill requires optometry applicants to apply to DOH for licensure, rather than applying to take the licensure examination. This will allow applicants to take all or a portion of the licensure examination prior to applying to DOH. The bill requires an applicant to have obtained a passing score on licensure examination of the National Board of Examiners in Optometry or similar exam approved by the Board of Optometry. The bill repeals language related to the topics that must be tested on the licensure exam and authorizes DOH to use a national examination.

Currently, an out-of-state optometrist must take the licensure examination to be licensed in Florida. The bill creates licensure by endorsement for optometrists who are licensed in another jurisdiction. DOH may charge a nonrefundable application fee or no more than $250 and a licensure fee of no more the $325. For licensure by endorsement, an applicant must have:

- Graduated from an accredited school or college of optometry;
- Passed the licensure examination of National Board of Examiners in Optometry or other national examination approved by the Board of Optometry;

- An active license to practice optometry in another jurisdiction for at least 5 of the immediately preceding 7 years; or successful completion of a board-approved clinical competency examination within the year preceding the filing of an application for licensure;
- Successfully completed the clinical skills portion of the examination developed by the National Board of Examiners in Optometry, and achieved a score of at least 75 percent on each of the biomicroscopy, binocular indirect ophthalmoscopy, and dilated biomicroscopy and noncontact fundus lens evaluation skills individually;
- Successfully completed a written examination on the applicable general laws and rules governing the practice of optometry;
- Obtained a passing score on either the Treatment and Management of Ocular Disease examination in the Patient Assessment and Management portion of the examination developed by the National Board of Examiners in Optometry or the stand alone Treatment and Management of Ocular Disease examination; and
- Completed at least 30 hours of board-approved continuing education for the 2 calendar years immediately preceding application.

DOH may not issue a license by endorsement if the applicant is under investigation in any jurisdiction for an act or offense that would constitute a licensure violation in Florida until the investigation is complete. If the applicant has such violation license or does not otherwise meet the requirements of licensure, the Board of Optometry may:

- Refuse to certify the application for licensure or certification to DOH;
- Certify the application for licensure or certification to DOH with restrictions on the scope of practice; or
- Certify the application for licensure or certification to DOH with a probationary period subject to conditions specified by the Board of Optometry.

Nursing

The bill authorizes the Board of Nursing to adopt rules related to the standards of care for licensed practical nurses, registered nurses, advanced registered nurse practitioners, and CNAs. The bill authorizes CNA applicants who are licensed in other territories or the District of Columbia to qualify for licensure by endorsement. The bill authorizes the Board of Nursing to discipline CNAs for any violation of a law or rule regulating CNA practice. The bill removes the requirement that a violation must be intentional to be subject to disciplinary action.

Pharmacy

In-state Sterile Compounding

Current law does not expressly provide for an in-state sterile compounding permit as it does for out-of-state pharmacies and outsourcing facilities that perform sterile compounding. However, s. 465.0196, F.S. grants the Board of Pharmacy rule-making authority to create and issue special pharmacy permits. Under that authority, the Board of Pharmacy has adopted rules for the issuance of a special sterile compounding permit to regulate in-state pharmacies and outsourcing facilities that perform sterile compounding. The bill expressly gives DOH authority to issue an in-state sterile compounding permit.

The bill requires a pharmacy or outsourcing facility located in this state that dispenses, creates, delivers, ships, or mails a compound sterile product to obtain a sterile compounding permit. If, upon receipt of an application, the Board of Pharmacy verifies that the application complies with the laws and rules governing pharmacies, DOH must issue the permit. Within 90 days before issuing the permit, DOH must conduct an onsite inspection. General requirements and disciplinary guidelines for pharmacies will apply to in-state sterile compounding permittees.

A licensed pharmacist must supervise the compounding and dispensing of all drugs. A permittee must notify DOH within 10 days of a change in the supervising physician. A permittee must have a written policy and procedural manual specifying the duties, tasks, and functions a registered pharmacy technician is allowed to perform, if it uses registered pharmacy technicians.

The bill authorizes the Board of Pharmacy to adopt rules for the standards of practice for sterile compounding. In adopting such rules, the Board of Pharmacy must consider the U.S. Pharmacopeia; and for outsourcing facilities, the Board of Pharmacy must consider the Current Good Manufacturing Practice regulations by the FDA. Other authoritative professional standards may also be considered.

On-site inspections

Currently, DOH performs onsite inspections prior to issuing any new pharmacy permit or a permit for a change of location pursuant to rules adopted by the Board of Pharmacy. The bill expressly requires DOH to perform such inspections within 90 days before the issuance of a permit.

Athletic Trainers

The bill requires athletic trainers to work within her or his scope of practice as defined by Board of Athletic Training in rule. The bill adds another route to licensure by authorizing individuals who hold a bachelor's degree, completed a Board of Certification internship, and holds a certification from the Board of Certification to be eligible for licensure.

The bill establishes that a licensed athletic trainer must maintain his or her certification from the Board of Certification in good standing to be eligible for licensure renewal. The bill requires the Board of Athletic Training to establish rules for the supervision of an athletic training student.

Orthotics and Prosthetics

The bill authorizes the Board of Orthotists and Prosthetists to issue a single license for prosthetics and orthotics practice. Currently, an individual must hold two separate licenses: one as a prosthetist and one as an orthotist. To qualify for the single license, an individual must hold a Bachelor of Science degree or higher in orthotics and prosthetics from an accredited college or university. The bill also authorizes the completion of a dual residency program to qualify for licensure.

Massage Therapy

The bill limits apprenticeships to only those in colonic irrigations. A licensed massage therapist must supervise a colonic irrigation apprentice.

The bill authorizes the Board of Massage Therapy to designate a national examination for licensure and repeals provisions requiring DOH to develop a licensure examination.

The bill eliminates a massage therapy apprenticeship as a path to licensure. However, if an individual has been issued a license as a massage therapy apprentice before July 1, 2018, he or she may continue to perform massage therapy until the license expires. A massage therapist apprentice may apply for full licensure upon completion of the apprenticeship and before July 1, 2021.

The bill authorizes the Board of Massage Therapy to revoke, suspend, or deny the licensure of a massage establishment that is owned by an individual who previously had a prior establishment license revoked if:

- The license was obtained by fraud or misrepresentation;
- The licensee is proven to be guilty of fraud, deceit, gross negligence, incompetence, or misconduct in the operation of the licensed establishment; or

- The owner of the massage therapy establishment or any person providing massage therapy services at the establishment has had 3 convictions of, or pleas of guilty or nolo contendere to, or dismissals of a criminal action after a successful completion of a pretrial intervention, diversion, or substance abuse program for any misdemeanor or felony, regardless of adjudication, or a crime related to prostitution and related acts that occur at or within the establishment.

DOH may not issue a license to an establishment disciplined under this provision unless there is change of ownership.

Clinical Laboratory Directors

The bill requires a clinical laboratory director to be licensed as clinical laboratory director under federal law to qualify for licensure in this state. A clinical laboratory director may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel or may delegate such duties as authorized under federal law.

Psychologists

The bill repeals obsolete provisions related to applicants for licensure prior to July 1, 1999. The bill requires psychology programs within educational institutions to be accredited by the American Psychological Association (APA), which is recognized as the national accrediting authority for professional education and training in psychology by the U.S. Department of Education and the Council for Higher Education Accreditation.[151] The bill replaces references to the Commission on Recognition of Postsecondary Accreditation to its successor organization, the Council for Higher Education Accreditation.[152] For applicants for licensure who obtained their education in Canada, the bill authorizes those applicants to demonstrate that they have completed a program comparable to APA-accredited programs.

The bill eliminates a provision that allowed an applicant for licensure by endorsement to hold a license from another state that has licensure standards that are equivalent or more stringent than Florida to qualify for licensure. However, an individual may apply for licensure by endorsement if he or she has a doctoral degree in psychology and has practiced for at least 10 years of the last 25 years, rather than 20 years as required in current law.

Licensed Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling

Intern Registration

The bill authorizes the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling to make a one-time exception to the 60-month limit on an internship registration. Such exceptions may only be granted in an emergency or hardship case, as defined by rule. The bill deletes obsolete language related to biennial renewals of intern registrations.

Marriage and Family Therapists

The bill requires that an applicant for licensure hold a master's degree with an emphasis in marriage and family therapy from a program accredited by the Commission of Accreditation for Marriage and Family Therapy Education or a Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs. An applicant may also qualify for licensure if he or she holds a master's degree in a closely related field and has completed graduated courses approved by

[151] American Psychological Association, *Understanding APA Accreditation*, available at http://www.apa.org/ed/accreditation/about/index.aspx (last visited January 20, 2018).
[152] U.S. Department of Education, *Accreditation in the U.S.*, available at https://www2.ed.gov/admins/finaid/accred/accredus.html (last visited July 20, 2018).

the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling. The bill eliminates specified the coursework and clinical experience required for licensure that is currently enumerated in statute.

The bill updates the name of the licensure examination for mental health counseling licensure applicants to the National Clinical Mental Health Counseling Examination administered by the National Board for Certified Counselors or its successors. This will conform the law to current practice.[153] The bill reduces the number of hours required for the clinical practicum or internship from 1,000 hours to 700 hours.

To be licensed as a marriage and family therapist s. 491.005(3), F.S., requires an applicant to complete two years of clinical experience. However, later in the same paragraph, it states the clinical experience required is three years. The bill corrects the scrivener's error in the paragraph.

The bill clarifies that DOH is deny or impose penalties on the license of a marriage and family therapist who violates the practice act or ch. 456, F.S., the general regulatory statute. This will alleviate confusion regarding the authority of DOH to impose such discipline or deny a license.

Licensure by endorsement

The bill deletes educational requirements for applicants for licensure by endorsement. Such applicant qualifies for licensure if he or she holds a valid, active license to practice in another state for 3 of the 5 years preceding the date of application, pass an equivalent licensure examination, and is not under investigation for and has not been found to have committed any act that would constitute a licensure violation in Florida.

The bill makes other conforming changes.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.4018, F.S., relating to physician workforce assessment and development.
Section 2: Amends s. 456.013, F.S., relating to department; general licensing provisions.
Section 3: Amends s. 456.024, F.S., relating to members of Armed Forces in good standing with administrative boards or the department; spouses; licensure.
Section 4: Amends s. 458.309, F.S., relating to rulemaking authority.
Section 5: Creates s. 458.3266, F.S., relating to office surgery centers.
Section 6: Amends s. 459.005, F.S., relating to rulemaking authority.
Section 7: Creates s. 459.0138, F.S., relating to office surgery centers.
Section 8: Repeals s. 460.4166, F.S., relating to certified chiropractic physician's assistants.
Section 9: Amends s. 463.006, F.S., relating to licensure and certification by examination.
Section 10: Creates s. 463.0061, F.S., relating to licensure by endorsement; requirements; fees.
Section 11: Amends s. 464.006, F.S., relating to rulemaking authority.
Section 12: Amends s. 464.202, F.S., relating to duties and powers of the board.
Section 13: Amends s. 464.203, F.S., relating to certified nursing assistants; certification requirement.
Section 14: Amends s. 464.204, F.S., relating to denial, suspension, or revocation of certification; disciplinary actions.
Section 15: Amends s. 465.019, F.S., relating to institutional pharmacies; permits.
Section 16: Amends s. 465.0193, F.S., relating to nuclear pharmacy permits.
Section 17: Creates s. 465.0195, F.S., relating to pharmacy or outsourcing facility; sterile compounding permit.
Section 18: Amends s. 465.0196, F.S., relating to special pharmacy permits.
Section 19: Amends s. 465.0197, F.S., relating to internet pharmacy permits.

[153] *Supra* note 30.

Section 20: Amends s. 466.006, F.S., relating to examination of dentists.
Section 21: Amends s. 466.007, F.S., relating to examination of dental hygienists.
Section 22: Amends s. 466.017, F.S., relating to prescription of drugs; anesthesia.
Section 23: Repeals ss. 466.032, 466.033, 466.034, 466.035, 466.036, 466.037, 466.038, and 466.039, F.S., relating to registration; registration certificates; change of ownership or address; advertising; information; periodic inspections; equipment and supplies; suspension and revocation; administrative fine; rules; and violations.
Section 24: Amends s. 468.701, F.S., relating to definitions.
Section 25: Amends s. 468.707, F.S., relating to licensure requirements.
Section 26: Amends s. 468.711, F.S., relating to renewal of license; continuing education.
Section 27: Amends s. 468.723, F.S., relating to exemptions.
Section 28: Amends s. 468.803, F.S., relating to license, registration, and examination requirements.
Section 29: Amends s. 480.033, F.S., relating to definitions.
Section 30: Amends s. 480.041, F.S., relating to massage therapists; qualifications; licensure; endorsement.
Section 31: Repeals s. 480.042, F.S., relating to examinations.
Section 32: Amends s. 480.046, F.S., relating to grounds for disciplinary action by the board.
Section 33: Amends s. 483.824, F.S., relating to qualifications of clinical laboratory director.
Section 34: Amends s. 490.003, F.S., relating to definitions.
Section 35: Amends s. 490.005, F.S., relating to licensure by examination.
Section 36: Amends s. 490.006, F.S., relating to licensure by endorsement.
Section 37: Amends s. 491.0045, F.S., relating to intern registration; requirements.
Section 38: Amends s. 491.005, F.S., relating to licensure by examination.
Section 39: Amends s. 491.006, F.S., relating to licensure or certification by endorsement.
Section 40: Amends s. 491.007, F.S., relating to renewal of license, registration, or certificate.
Section 41: Amends s. 491.009, F.S., relating to discipline.
Section 42: Amends s. 463.0057, F.S., relating to optometric faculty certificate.
Section 43: Amends s. 491.0046, F.S., relating to provisional license; requirements.
Section 44: Amends s. 945.42, F.S., relating to definitions; ss. 945.40-945.49.
Section 45: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill may have an indeterminate, positive fiscal impact on DOH due to the repeal of the regulation of registered chiropractic assistants and dental laboratories.

2. Expenditures:

   The bill will have an insignificant, negative fiscal impact on DOH, which can be absorbed within existing resources.[154] The bill requires DOH or the appropriate regulatory board to adopt rules related to the Conrad 40 waiver program, office surgery centers, standards of care for nurses, and the supervision of athletic training students. DOH may need to repeal adopted rules related to the deregulation of registered chiropractic assistants and dental laboratories. DOH may experience a loss of revenue related to the exemption of dentists who are military spouses from the payment of application and licensure fees and elimination the temporary license for dentists.

[154] E-mail correspondence with DOH, dated January 22, 2018 (on file with the Health Quality Subcommittee).

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Individuals who operate office surgery centers will have to pay registration and inspection fees. Dentists who are spouses of active duty military members and currently hold temporary licenses will no longer have to pay fees associated with the temporary license and indirect supervision by a Florida-licensed dentist. Individuals who voluntary registered as chiropractic assistants or were required to be licensed as dental laboratory will no longer have fees associated with such registration or licensure.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority for DOH or the applicable regulatory boards to adopt rules related to the Conrad 40 waiver program, office surgery centers, standards of care for nurses, and the supervision of athletic training students.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the Department of Health; amending s. 381.4018, F.S.; authorizing the Department of Health to adopt rules to implement a federal program to further encourage qualified physicians to relocate to and practice in underserved areas; amending s. 456.013, F.S.; revising health care practitioner licensure application requirements; amending s. 456.024, F.S.; revising licensure eligibility requirements; amending s. 458.309, F.S.; deleting a provision requiring certain physicians to register the office with the Department of Health; removing departmental responsibilities; creating s. 458.3266, F.S.; providing definitions; requiring office surgery centers to register with the Department of Health under certain circumstances; providing registration requirements; providing responsibilities for office surgery center physicians; requiring the department to inspect office surgery centers; providing an exception; providing rulemaking authority to the Board of Medicine; providing penalties; amending s. 459.005, F.S.; deleting a provision requiring certain physicians to register the office with the Department of Health; removing departmental responsibilities; creating s. 459.0138, F.S.; providing definitions;

requiring office surgery centers to register with the Department of Health under certain circumstances; providing registration requirements; providing responsibilities for office surgery center physicians; requiring the department to inspect office surgery centers; providing an exception; providing rulemaking authority to the Board of Medicine; providing penalties; repealing s. 460.4166, F.S., relating to registered chiropractic assistants; amending s. 463.006, F.S.; revising examination requirements for licensure and certification by examination; creating s. 463.0061, F.S.; authorizing licensure of optometry by endorsement and providing requirements therefor; defining the term "active licensed practice of optometry" amending s. 464.006, F.S.; authorizing the board to establish certain standards of care; amending s. 464.202, F.S.; requiring the board to establish discipline and standards of care under the scope of practice of certified nursing assistants; amending s. 464.203, F.S.; revising certification requirements for nursing assistants; amending s. 464.204, F.S.; revising grounds for board-imposed disciplinary sanctions; amending s. 465.019, F.S.; requiring an institutional pharmacy to pass inspection by the board for certain permits; amending s. 465.0193, F.S.;

requiring a nuclear pharmacy to pass a specified inspection by the department within a specified time before issuance of certain permits; creating s. 465.0195, F.S.; requiring certain pharmacies and outsourcing facilities to obtain a permit in order to create, ship, mail, deliver, or dispense compounded sterile products into this state; providing application requirements; providing inspection requirements; providing permit requirements; authorizing the board to adopt rules; providing applicability; amending s. 465.0196, F.S.; requiring a special pharmacy to pass inspection by the board for certain permits; amending s. 465.0197, F.S.; requiring an Internet pharmacy to pass inspection by the board for certain permits; amending s. 466.006, F.S.; revising certain requirements for examinations completed by applicants seeking dental licensure; amending s. 466.007, F.S.; revising requirements for examinations of a dental hygienist; amending s. 466.017, F.S.; providing adverse incident reporting requirements; defining the term "adverse incident"; providing for disciplinary action by the board; authorizing the Board of Dentistry to adopt rules; repealing s. 466.032, F.S., relating to registration; repealing s. 466.033, F.S., relating to registration

certificates; repealing s. 466.034, F.S., relating to change of ownership or address; repealing s. 466.035, F.S., relating to advertising; repealing s. 466.036, F.S., relating to information, periodic inspections, and equipment and supplies; repealing s. 466.037, F.S., relating to suspension and revocation and administrative fines; repealing s. 466.038, F.S., relating to rules; repealing s. 466.039, F.S., relating to violations; amending s. 468.701, F.S.; revising a definition; amending s. 468.707, F.S.; revising athletic trainer licensure requirements; amending s. 468.711, F.S.; revising requirements for the renewal of license related to continuing education; amending s. 468.723, F.S.; revising a definition; amending s. 468.803, F.S.; revising orthotic, prosthetic, and pedorthic licensure, registration, and examination requirements; amending s. 480.033, F.S.; revising a definition; amending s. 480.041, F.S.; revising qualifications for licensure as a massage therapist; repealing s. 480.042, F.S., relating to examinations; amending s. 480.046, F.S.; revising instances under which disciplinary action may be taken against massage establishments; amending s. 483.824, F.S.; revising qualification requirements for a clinical laboratory director; amending s. 490.003,

F.S.; revising definitions; amending s. 490.005, F.S.; revising examination requirements for licensure of a psychologist; amending s. 490.006, F.S.; revising requirements for licensure by endorsement of certain psychologists; amending s. 491.0045, F.S.; providing an exemption for intern registration requirements under certain circumstances; amending s. 491.005, F.S.; revising education requirements for the licensure of marriage and family therapists; revising examination requirements for the licensure of mental health counselors; amending s. 491.006, F.S.; revising requirements for licensure or certification by endorsement for certain professions; amending s. 491.007, F.S.; removing a biennial intern registration fee; amending s. 491.009, F.S.; authorizing the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling to enter an order denying licensure or imposing penalties against an applicant for licensure under certain circumstances; providing penalties; amending ss. 463.0057, 491.0046, and 945.42, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Paragraph (f) of subsection (3) of section 381.4018, Florida Statutes, is amended to read:

381.4018 Physician workforce assessment and development.—

(3) GENERAL FUNCTIONS.—The department shall maximize the use of existing programs under the jurisdiction of the department and other state agencies and coordinate governmental and nongovernmental stakeholders and resources in order to develop a state strategic plan and assess the implementation of such strategic plan. In developing the state strategic plan, the department shall:

(f) Develop strategies to maximize federal and state programs that provide for the use of incentives to attract physicians to this state or retain physicians within the state. Such strategies should explore and maximize federal-state partnerships that provide incentives for physicians to practice in federally designated shortage areas. Strategies shall also consider the use of state programs, such as the Medical Education Reimbursement and Loan Repayment Program pursuant to s. 1009.65, which provide for education loan repayment or loan forgiveness and provide monetary incentives for physicians to relocate to underserved areas of the state. To further encourage qualified physicians to relocate to and practice in underserved areas, the department, following federal requirements, shall adopt any rules necessary for the implementation of the Conrad 30 Waiver Program established under s. 214(1) of the Immigration

and Nationality Act.

Section 2. Paragraph (a) of subsection (1) of section 456.013, Florida Statutes, is amended to read:

456.013 Department; general licensing provisions.—

(1)(a) Any person desiring to be licensed in a profession within the jurisdiction of the department shall apply to the department in writing ~~to take the licensure examination~~. The application shall be made on a form prepared and furnished by the department. The application form must be available on the World Wide Web and the department may accept electronically submitted applications beginning July 1, 2001. The application shall require the social security number and date of birth of the applicant, except as provided in paragraphs (b) and (c). The form shall be supplemented as needed to reflect any material change in any circumstance or condition stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department. If an application is submitted electronically, the department may require supplemental materials, including an original signature of the applicant and verification of credentials, to be submitted in a nonelectronic format. An incomplete application shall expire 1 year after initial filing. In order to further the economic development goals of the state, and notwithstanding any law to the contrary, the department may enter into an

agreement with the county tax collector for the purpose of appointing the county tax collector as the department's agent to accept applications for licenses and applications for renewals of licenses. The agreement must specify the time within which the tax collector must forward any applications and accompanying application fees to the department.

Section 3. Paragraphs (a) and (b) of subsection (3) and paragraph (j) of subsection (4) of section 456.024, Florida Statutes, are amended to read:

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

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

1. 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. 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~~, other than a dentist,~~ in another state, the District of Columbia, or a possession or territory of the United States and is the spouse of a person serving on active duty with the United States Armed Forces.

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) The board, or the 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 he or she is a member of the United States Armed Forces, the United States Reserve Forces, or the National Guard, submits proof that he or she has received 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 he or she 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 he or she 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~~, excluding dentistry,~~ for which licensure in another state or jurisdiction is not required, if he or she 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 he or she 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 of the application, the subject of a disciplinary proceeding in a jurisdiction in which he or she holds a license or by the United States Department of Defense for reasons related to the practice of the profession for which he or she is applying.

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

6. Submits a set of fingerprints for a background screening pursuant to s. 456.0135, if required for the

profession for which he or she is applying.

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

(4)

~~(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 4. Subsection (3) of section 458.309, Florida Statutes, is amended to read:

458.309 Rulemaking authority.—

~~(3) A physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.~~

Section 5. Section 458.3266, Florida Statutes, is created to read:

458.3266 Office surgery centers.—

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

(a) "Designated physician" means a physician licensed under this chapter or chapter 459 that practices at the office surgery center location for which the physician has assumed responsibility for complying with all requirements related to registration and operation of the center in this section and rules of the board.

(b) "Office surgery center" means any facility where a physician performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat are removed, level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an office setting, or any facility in which surgery is performed outside of any facility licensed under chapter 390 or chapter 395.

(2) REGISTRATION.—

(a) An office surgery center must register with the department unless the center is:

1. Licensed as a facility pursuant to chapter 395; or

2. Affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.

(b) Office surgery center locations shall be registered

separately regardless of whether the center is operated under the same business name or management as another center. The actual costs for registration shall be paid by the person seeking to register and operate the office center in which office surgery is performed.

(c) As a part of registration, an office surgery center must have a designated physician. Within 10 days after termination of a designated physician, the center must notify the department of the identity of another designated physician for that center. Failing to have a designated physician practicing at the location of the registered center may result in the suspension of the center's certificate of registration, as described in s. 456.073(8) or agency action under s. 120.60(6).

(d) The department shall deny registration to an office surgery center that is:

1. Not fully owned by a physician licensed under this chapter or chapter 459 or a group of physicians licensed under this chapter or chapter 459;

2. Not a health care center licensed under part X of chapter 400; or

3. Owned by or in any contractual or employment relationship with a physician licensed under this chapter or chapter 459 who:

a. Had hospital privileges revoked in the last 5 years.

b. Does not have a clear and active license with the department; or

c. Had a license disciplined by the department or another jurisdiction in the last 5 years for an offense related to standard of care.

(e) If the department finds that an office surgery center does not meet the requirements of paragraph (c) or is owned, directly or indirectly, by a person meeting criteria listed in paragraph (d), the department shall revoke the certificate of registration previously issued by the department.

(f) The department may revoke the office surgery center's certificate of registration and prohibit all physicians associated with the center from practicing at that location based upon an annual inspection and evaluation of the factors described in subsection (4).

(g) If the certificate of registration is revoked or suspended, the designated physician of the center, the owner or lessor of the center property, the manager, and the proprietor shall:

1. Cease to operate the facility as an office surgery center as of the effective date of the suspension or revocation.

2. Be responsible for removing all signs and symbols identifying the premises as an office surgery center.

(h) Upon the effective date of the suspension or revocation, the designated physician of the office surgery

center shall advise the department of the disposition of the medicinal drugs located on the premises. The disposition is subject to the supervision and approval of the department. Medicinal drugs that are purchased or held by a center that is not registered may be deemed adulterated pursuant to s. 499.006.

(i) If the office surgery center's registration is revoked, any person named in the registration documents of the center, including persons owning or operating the center, may not, as an individual or as a part of a group, apply to operate an office surgery center for 5 years after the date the registration is revoked.

(j) The period of suspension for the registration of an office surgery center shall be prescribed by the department, but may not exceed 2 years.

(k) A change of ownership of a registered office surgery center requires submission of a new registration application. An office surgery registration may not be transferred.

(3) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in an office surgery center as required in subsection (2).

(a)1. A physician may not practice medicine in an office surgery center, as described in subsection (5), if the office surgery center is not registered with the department as required by this section. A physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical

regulatory board.

2. Surgical procedures performed in an office surgery center may not include any procedure that may result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin; require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; involve major blood vessels performed with direct visualization by open exposure of the major vessel, except for percutaneous endovascular intervention; or are generally emergent or life threatening in nature.

(b) The designated physician of an office surgery center shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his or her employment with a center registered under subsection (2). Each physician practicing in an office surgery center shall advise the board, in writing, within 10 calendar days after beginning or ending his or her practice at an office surgery center.

(c) Each physician practicing in an office surgery center is responsible for ensuring compliance with the following:

1. Facility and physical operations requirements, including:

a. An office surgery center which shall be located and operated at a publicly accessible fixed location.

b. The public display of a visible printed sign that clearly identifies the name, hours of operations, and the street address of the center.

c. Maintaining a publicly listed telephone number and other methods of communication available to the public.

d. Emergency lighting and communications.

e. A reception and waiting area.

f. A restroom.

g. An administrative area, including room for storage of medical records, supplies, and equipment.

h. Private patient examination rooms.

i. Treatment rooms, if treatment is being provided to the patients.

j. The public display of a visible printed sign located in a conspicuous place in the waiting room with the name and contact information of the center's designated physician and the names of all physicians practicing in the center.

k. Compliance with ss. 499.0121 and 893.07, if the center stores and dispenses prescription drugs.

2. Infection control requirements, including:

a. The maintenance of equipment and supplies to support infection prevention and control activities.

b. The identification of infection risks that shall be based on the following:

(I) Geographic location, community, and population served.

(II) The provided care, treatment, and services.

(III) An analysis of its infection surveillance and control data.

c. Center maintenance of written infection prevention policies and procedures that address prioritized risks and limit the following:

(I) Unprotected exposure to pathogens.

(II) Transmission of infections associated with procedures performed in the center.

(III) Transmission of infections associated with the center's use of medical equipment, devices, and supplies.

3. Health and safety requirements, including:

a. Being structurally sound, in good repair, clean, and free from health and safety hazards, including its grounds, buildings, furniture, appliances, and equipment.

b. Having evacuation procedures in the event of an emergency, which shall include provisions for the evacuation of disabled patients and employees.

c. Having a written facility-specific disaster plan setting forth actions that will be taken in the event of center closure due to unforeseen disasters and shall include provisions for the protection of medical records and any controlled substances.

d. Having at least one employee on the premises during patient care hours who is certified in Basic Life Support and is

trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.

(d) The designated physician of an office surgery center is responsible for ensuring the center complies with the following quality assurance requirements:

1. The center shall maintain an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the designated physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public.

2. The designated physician shall establish a quality assurance program that includes the following components:

a. Identification, investigation, and analysis of the frequency and causes of adverse incidents to patients.

b. Identification of trends or patterns of incidents.

c. Development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients.

d. Documentation of the functions provided in this subparagraph and periodic review no less than quarterly of such information by the designated physician.

(e) The designated physician for each office surgery

center shall report all adverse incidents to the department as set forth in s. 458.351.

This section does not excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care or rules adopted by the board. This section does not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(4) INSPECTION.—

(a) The department shall inspect the office surgery center annually, including a review of the patient records, to ensure that it complies with this section and the rules of the board adopted pursuant to subsection (5) unless the center is accredited by a nationally recognized accrediting agency or an accrediting organization approved by the board.

(b) The actual costs for inspection or accreditation shall be paid by the person seeking to register and operate the office center in which office surgery is performed.

(c) During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or designated physician of the office surgery center before issuing a formal written notification.

(d) Any action taken to correct a violation shall be documented in writing by the owner or designated physician of

the office surgery center and verified by follow-up visits by departmental personnel.

(5) RULEMAKING.—The board shall adopt rules:

(a) Necessary to administer the registration and inspection of office surgery centers which establish the specific requirements, procedures, forms, and fees.

(b) Setting forth training requirements for all facility health care practitioners who are not regulated by another board.

(6) PENALTIES; ENFORCEMENT.—

(a) The department may impose an administrative fine on an office surgery center of up to $5,000 per violation for violating the requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act; or the rules of the department.

(b) In determining whether a penalty is to be imposed upon a center, and in determining the amount of the fine, the department shall consider the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the center's actions or the actions of the physician, the severity of the action or

potential harm, and the extent to which the provisions of the applicable laws or rules were violated.

2. What actions, if any, the owner or designated physician took to correct the violations.

3. Whether there were any previous violations at the center.

4. The financial benefits that the center derived from committing or continuing to commit the violation.

(c) Each day a violation continues after the date fixed for termination of the violation as ordered by the department constitutes an additional, separate, and distinct violation.

(d) The department may impose a fine and, in the case of an owner-operated office surgery center, revoke or deny a center's registration if the center's designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

(e) An owner or designated physician of an office surgery center who concurrently operates an unregistered center is subject to an administrative fine of $5,000 per day.

(f) If the owner of an office surgery center that requires registration fails to apply to register the center upon a change of ownership and operates the center under the new ownership, the owner is subject to a fine of $10,000.

Section 6. Subsection (2) of section 459.005, Florida Statutes, is amended to read:

459.005 Rulemaking authority.—

~~(2) A physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.~~

Section 7. Section 459.0138, Florida Statutes, is created to read:

459.0138 Office surgery centers.-

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

(a) "Designated physician" means a physician licensed under this chapter or chapter 459 that practices at the office surgery center location for which the physician has assumed responsibility for complying with all requirements related to registration and operation of the center in this section and rules of the board.

(b) "Office surgery center" means any facility where a

physician performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat are removed, level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an office setting, or any facility in which surgery is performed outside of any facility licensed under chapter 390 or chapter 395.

(2) REGISTRATION.—

(a) An office surgery center must register with the department unless the center is:

1. Licensed as a facility pursuant to chapter 395; or

2. Affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.

(b) Office surgery center locations shall be registered separately regardless of whether the center is operated under the same business name or management as another center. The actual costs for registration shall be paid by the person seeking to register and operate the office center in which office surgery is performed.

(c) As a part of registration, an office surgery center must have a designated physician. Within 10 days after termination of a designated physician, the center must notify the department of the identity of another designated physician for that center. Failing to have a designated physician practicing at the location of the registered center may result

in the suspension of the center's certificate of registration as described in s. 456.073(8) or agency action under s. 120.60(6).

(d) The department shall deny registration to an office surgery center that is:

1. Not fully owned by a physician licensed under this chapter or chapter 459 or a group of physicians licensed under this chapter or chapter 459;

2. Not a health care center licensed under part X of chapter 400; or

3. Owned by or any contractual or employment relationship with a physician licensed under this chapter or chapter 459 who:

a. Had hospital privileges revoked in the last 5 years.

b. Does not have a clear and active license with the department; or

c. Had a license disciplined by the department or another jurisdiction in the last 5 years for an offense related to standard of care.

(e) If the department finds that an office surgery center does not meet the requirements of paragraph (c) or is owned, directly or indirectly, by a person meeting criteria listed in paragraph (d), the department shall revoke the certificate of registration previously issued by the department.

(f) The department may revoke the office surgery center's certificate of registration and prohibit all physicians associated with the center from practicing at that location

based upon an annual inspection and evaluation of the factors described in subsection (4).

(g) If the registration is revoked or suspended, the designated physician of the center, the owner or lessor of the center property, the manager, and the proprietor shall:

1. Cease to operate the facility as an office surgery center as of the effective date of the suspension or revocation.

2. Be responsible for removing all signs and symbols identifying the premises as an office surgery center.

(h) Upon the effective date of the suspension or revocation, the designated physician of the office surgery center shall advise the department of the disposition of the medicinal drugs located on the premises. The disposition is subject to the supervision and approval of the department. Medicinal drugs that are purchased or held by a center that is not registered may be deemed adulterated pursuant to s. 499.006.

(i) If the office surgery center's registration is revoked, any person named in the registration documents of the center, including persons owning or operating the center, may not, as an individual or as a part of a group, apply to operate an office surgery center for 5 years after the date the registration is revoked.

(j) The period of suspension for the registration of an office surgery center shall be prescribed by the department, but may not exceed 2 years.

(k) A change of ownership of a registered office surgery center requires submission of a new registration application. An office surgery registration may not be transferred.

(3) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in an office surgery center as required in subsection (2).

(a)1. A physician may not practice medicine in an office surgery center, as described in subsection (5), if the office surgery center is not registered with the department as required by this section. A physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

2. Surgical procedures performed in an office surgery center may not include any procedure that may result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin; require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; involve major blood vessels performed with direct visualization by open exposure of the major vessel, except for percutaneous endovascular intervention; or are generally emergent or life threatening in nature.

(b) The designated physician of an office surgery center shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his

or her employment with a center registered under subsection (2). Each physician practicing in an office surgery center shall advise the board, in writing, within 10 calendar days after beginning or ending his or her practice at an office surgery center.

(c) Each physician practicing in an office surgery center is responsible for ensuring compliance with the following:

1. Facility and physical operations requirements, including:

a. An office surgery center which shall be located and operated at a publicly accessible fixed location.

b. The public display of a visible printed sign that clearly identifies the name, hours of operations, and the street address of the center.

c. Maintaining a publicly listed telephone number and other methods of communication available to the public.

d. Emergency lighting and communications.

e. A reception and waiting area.

f. A restroom.

g. An administrative area, including room for storage of medical records, supplies, and equipment.

h. Private patient examination rooms.

i. Treatment rooms, if treatment is being provided to the patients.

j. The public display of a visible printed sign located in

a conspicuous place in the waiting room with the name and contact information of the center's designated physician and the names of all physicians practicing in the center.

k. Compliance with ss. 499.0121 and 893.07, if the center stores and dispenses prescription drugs.

2. Infection control requirements, including:

a. The maintenance of equipment and supplies to support infection prevention and control activities.

b. The identification of infection risks that shall be based on the following:

(I) Geographic location, community, and population served.

(II) The provided care, treatment, and services.

(III) An analysis of its infection surveillance and control data.

c. Center maintenance of written infection prevention policies and procedures that address prioritized risks and limit the following:

(I) Unprotected exposure to pathogens.

(II) Transmission of infections associated with procedures performed in the center.

(III) Transmission of infections associated with the center's use of medical equipment, devices, and supplies.

3. Health and safety requirements, including:

a. Being structurally sound, in good repair, clean, and free from health and safety hazards, including its grounds,

buildings, furniture, appliances, and equipment.

b. Having evacuation procedures in the event of an emergency, which shall include provisions for the evacuation of disabled patients and employees.

c. Having a written facility-specific disaster plan setting forth actions that will be taken in the event of center closure due to unforeseen disasters and shall include provisions for the protection of medical records and any controlled substances.

d. Having at least one employee on the premises during patient care hours who is certified in Basic Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.

(d) The designated physician of an office surgery center is responsible for ensuring the center complies with the following quality assurance requirements:

1. The center shall maintain an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the designated physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public.

2. The designated physician shall establish a quality assurance program that includes the following components:

a. Identification, investigation, and analysis of the frequency and causes of adverse incidents to patients.

b. Identification of trends or patterns of incidents.

c. Development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients.

d. Documentation of the functions provided in this subparagraph and periodic review no less than quarterly of such information by the designated physician.

(e) The designated physician for each office surgery center shall report all adverse incidents to the department as set forth in s. 458.351.

This section does not excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care or rules adopted by the board. This section does not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(4) INSPECTION.—

(a) The department shall inspect the office surgery center annually, including a review of the patient records, to ensure that it complies with this section and the rules of the board adopted pursuant to subsection (5) unless the center is

accredited by a nationally recognized accrediting agency approved by the board.

(b) The actual costs for inspection or accreditation shall be paid by the person seeking to register and operate the office center in which office surgery is performed.

(c) During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or designated physician of the office surgery center before issuing a formal written notification.

(d) Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the office surgery center and verified by follow-up visits by departmental personnel.

(5) RULEMAKING.—The board shall adopt rules:

(a) Necessary to administer the registration and inspection of office surgery centers which establish the specific requirements, procedures, forms, and fees.

(b) Setting forth training requirements for all facility health care practitioners who are not regulated by another board.

(6) PENALTIES; ENFORCEMENT.—

(a) The department may impose an administrative fine on an office surgery center of up to $5,000 per violation for violating the requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the

Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act; or the rules of the department.

(b) In determining whether a penalty is to be imposed upon a center, and in determining the amount of the fine, the department shall consider the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the center's actions or the actions of the physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.

2. What actions, if any, the owner or designated physician took to correct the violations.

3. Whether there were any previous violations at the center.

4. The financial benefits that the center derived from committing or continuing to commit the violation.

(c) Each day a violation continues after the date fixed for termination of the violation as ordered by the department constitutes an additional, separate, and distinct violation.

(d) The department may impose a fine and, in the case of an owner-operated office surgery center, revoke or deny a center's registration if the center's designated physician

knowingly and intentionally misrepresents actions taken to correct a violation.

(e) An owner or designated physician of an office surgery center who concurrently operates an unregistered center is subject to an administrative fine of $5,000 per day.

(f) If the owner of an office surgery center that requires registration fails to apply to register the center upon a change of ownership and operates the center under the new ownership, the owner is subject to a fine of $10,000.

Section 8. Section 460.4166, Florida Statutes, is repealed.

Section 9. Section 463.006, Florida Statutes, is amended to read:

463.006 Licensure and certification by examination.—

(1) Any person desiring to be a licensed practitioner pursuant to this chapter shall apply to the department ~~to take the licensure and certification examinations~~. The department shall license ~~examine~~ each applicant who the board determines has:

(a) Completed the application forms as required by the board, remitted an application fee for certification not to exceed $250, ~~remitted an examination fee for certification not to exceed $250,~~ and remitted a ~~an examination~~ fee for licensure not to exceed $325, all as set by the board.

(b) Submitted proof satisfactory to the department that

she or he:

1. Is at least 18 years of age.

2. Has graduated from an accredited school or college of optometry approved by rule of the board.

~~3. Is of good moral character.~~

3.~~4.~~ Has successfully completed at least 110 hours of transcript-quality coursework and clinical training in general and ocular pharmacology as determined by the board, at an institution that:

a. Has facilities for both didactic and clinical instructions in pharmacology; and

b. Is accredited by a regional or professional accrediting organization that is recognized and approved by the Commission on Recognition of Postsecondary Accreditation or the United States Department of Education.

4.~~5.~~ Has completed at least 1 year of supervised experience in differential diagnosis of eye disease or disorders as part of the optometric training or in a clinical setting as part of the optometric experience.

5. Has obtained a passing score, as established by rule of the board, on the licensure examination of the National Board of Examiners in Optometry or a similar nationally recognized examination approved by the board.

~~(2) The examination shall consist of the appropriate subjects, including applicable state laws and rules and general~~

~~and ocular pharmacology with emphasis on the use and side effects of ocular pharmaceutical agents. The board may by rule substitute a national examination as part or all of the examination and may by rule offer a practical examination in addition to the written examination.~~

(2)~~(3)~~ Each applicant who successfully passes the examination and otherwise meets the requirements of this chapter is entitled to be licensed as a practitioner and to be certified to administer and prescribe ocular pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 10. Section 463.0061, Florida Statutes, is created to read:

463.0061 Licensure by endorsement; requirements; fees.—

(1) Any person desiring to be a licensed practitioner pursuant to this chapter shall apply to the department. The department shall issue a license by endorsement to any applicant who, upon applying to the department on forms furnished by the department and remitting a nonrefundable application fee set by the board not to exceed $250 and a licensure fee not to exceed $325, the board certifies:

(a) Has graduated from an accredited school or college of optometry accredited by a regional or professional accrediting organization that is recognized and approved by the Commission on Recognition of Postsecondary Accreditation or the United States Department of Education.

(b) Has obtained an overall passing score, as established by rule of the board, on the licensure examination of the National Board of Examiners in Optometry or a similar nationally recognized examination approved by the board.

(c) Has submitted evidence of an active, licensed practice of optometry in another jurisdiction, for at least 5 of the immediately preceding 7 years, or evidence of successful completion of a board-approved clinical competency examination within the year preceding the filing of an application for licensure. For purposes of this paragraph, "active licensed practice of optometry" means that practice of optometry by optometrists, including those employed by any federal or state governmental entity in community or public health.

(d) Has successfully completed the clinical skills portion of the examination developed by the National Board of Examiners in Optometry. In addition to an overall passing score on the clinical skills portion, an applicant must obtain a score of 75 percent or better on each of the biomicroscopy, binocular indirect ophthalmoscopy, and dilated biomicroscopy and noncontact fundus lens evaluation skills individually.

(e) Has successfully completed a written examination on applicable general laws and rules governing the practice of optometry.

(f) Has obtained a passing score on either the Treatment and Management of Ocular Disease examination in the Patient

Assessment and Management portion of the examination developed by the National Board of Examiners in Optometry or the stand alone Treatment and Management of Ocular Disease examination developed by the National Board of Examiners in Optometry.

(2) The applicant shall submit evidence of completing a total of at least 30 hours of board-approved continuing education for the 2 calendar years immediately preceding application.

(3) The department shall not issue a license by endorsement to any applicant who is under investigation in any jurisdiction for an act or offense which would constitute a violation of this chapter until such time as the investigation is complete, at which time the provisions of s. 463.016 shall apply. Furthermore, the department may not issue an unrestricted license to any individual who has committed any act or offense in any jurisdiction constituting the basis for disciplining an optometrist pursuant to s. 463.016. If the board finds that an individual has committed an act or offense constituting the basis for disciplining an optometrist pursuant to s. 463.016, the board may enter an order imposing one or more of the terms set forth in subsection (4).

(4) When the board determines that an applicant for licensure by endorsement has failed to satisfy each of the appropriate requirements in this section, it may enter an order requiring one or more of the following:

(a) Refusal to certify to the department an application for licensure or certification;

(b) Certify to the department an application for licensure or certification with restrictions on the scope of practice of the licensee; or

(c) Certify to the department an application for licensure or certification with a probationary period subject to conditions specified by the board, including, but not limited to, requiring the optometrist to submit to treatment, attend continuing education courses, submit to reexamination, or work under the supervision of another licensed optometrist.

Section 11. Section 464.006, Florida Statutes, is amended to read:

464.006 Rulemaking authority.—The board may ~~has authority to~~ adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this part conferring duties upon it and establish standards of care.

Section 12. Section 464.202, Florida Statutes, is amended to read:

464.202 Duties and powers of the board.—The board shall maintain, or contract with or approve another entity to maintain, a state registry of certified nursing assistants. The registry must consist of the name of each certified nursing assistant in this state; other identifying information defined by board rule; certification status; the effective date of

certification; other information required by state or federal law; information regarding any crime or any abuse, neglect, or exploitation as provided under chapter 435; and any disciplinary action taken against the certified nursing assistant. The registry shall be accessible to the public, the certificateholder, employers, and other state agencies. The board shall adopt by rule testing procedures for use in certifying nursing assistants and shall adopt rules regulating the practice of certified nursing assistants, including discipline and establishing standards of care and specifying the scope of practice authorized and the level of supervision required for the practice of certified nursing assistants. The board may contract with or approve another entity or organization to provide the examination services, including the development and administration of examinations. The board shall require that the contract provider offer certified nursing assistant applications via the Internet, and may require the contract provider to accept certified nursing assistant applications for processing via the Internet. The board shall require the contract provider to provide the preliminary results of the certified nursing examination on the date the test is administered. The provider shall pay all reasonable costs and expenses incurred by the board in evaluating the provider's application and performance during the delivery of services, including examination services and procedures for maintaining

the certified nursing assistant registry.

Section 13. Paragraph (c) of subsection (1) of section 464.203, Florida Statutes, is amended to read:

464.203 Certified nursing assistants; certification requirement.—

(1) The board shall issue a certificate to practice as a certified nursing assistant to any person who demonstrates a minimum competency to read and write and successfully passes the required background screening pursuant to s. 400.215. If the person has successfully passed the required background screening pursuant to s. 400.215 or s. 408.809 within 90 days before applying for a certificate to practice and the person's background screening results are not retained in the clearinghouse created under s. 435.12, the board shall waive the requirement that the applicant successfully pass an additional background screening pursuant to s. 400.215. The person must also meet one of the following requirements:

(c) Is currently certified in another state <u>or territory, and the District of Columbia</u>; is listed on that state's certified nursing assistant registry; and has not been found to have committed abuse, neglect, or exploitation in that state.

Section 14. Subsection (1) of section 464.204, Florida Statutes, is amended to read:

464.204 Denial, suspension, or revocation of certification; disciplinary actions.—

(1) The following acts constitute grounds for which the board may impose disciplinary sanctions as specified in subsection (2):

(a) Obtaining or attempting to obtain certification or an exemption, or possessing or attempting to possess certification or a letter of exemption, by bribery, misrepresentation, deceit, or through an error of the board.

(b) ~~Intentionally~~ Violating any provision of this chapter, chapter 456, or the rules adopted by the board.

Section 15. Subsection (7) is added to section 465.019, Florida Statutes, to read:

465.019 Institutional pharmacies; permits.—

(7) An institutional pharmacy must pass an onsite inspection by the department as a prerequisite to the issuance of an initial permit or a permit for a change of location. The inspection must be completed within 90 days before the issuance of the permit.

Section 16. Section 465.0193, Florida Statutes, is amended to read:

465.0193 Nuclear pharmacy permits.—Any person desiring a permit to operate a nuclear pharmacy shall apply to the department. If the board certifies that the application complies with applicable law, the department shall issue the permit. No permit shall be issued unless a duly licensed and qualified nuclear pharmacist is designated as being responsible for

activities described in s. 465.0126. A nuclear pharmacy must pass an onsite inspection by the department as a prerequisite to the issuance of an initial permit or a permit for a change of location. The inspection must be completed within 90 days before the issuance of the permit. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for the compounding and dispensing of nuclear pharmaceuticals.

Section 17. Section 465.0195, Florida Statutes, is created to read:

465.0195 Pharmacy or outsourcing facility; sterile compounding permit.—Before a pharmacy or outsourcing facility located in this state dispenses, creates, delivers, ships, or mails, in any manner, a compounded sterile product, the pharmacy or outsourcing facility must hold a sterile compounding permit.

(1) An application for a sterile compounding permit shall be submitted on a form furnished by the board. The board may require such information as it deems reasonably necessary to carry out the purposes of this section.

(2) If the board certifies that the application complies with applicable laws and rules of the board governing pharmacies, the department shall issue the permit.

(3) A pharmacy or outsourcing facility must pass an onsite inspection by the department as a prerequisite to the issuance of an initial permit or a permit for a change of location. The

inspection must be completed within 90 days prior to the issuance of the permit. The board may adopt by rule, standards for the conducting of an onsite inspection for issuance of a sterile compounding permit.

(4) A permit may not be issued unless a licensed pharmacist is designated to undertake the professional supervision of the compounding and dispensing of all drugs dispensed by the permittee.

(5) A permittee must notify the department within 10 days after any change of the licensed pharmacist under subsection (4). Each permittee that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is authorized to perform.

(6) The board may adopt by rule, standards of practice for sterile compounding. In adopting such rules, the board shall give due consideration to the standards and requirements provided in chapter 797 of the United States Pharmacopeia, or other professionally accepted standards deemed authoritative by the board. In adopting such rules for an outsourcing facility, the board shall consider the standards and requirements of current good manufacturing practices as set forth by federal law and any other professionally accepted standards deemed authoritative by the board.

(7) All provisions relating to pharmacy permits found in

ss. 465.022 and 465.023, are applicable to permits issued pursuant to this section.

Section 18. Section 465.0196, Florida Statutes, is amended to read:

465.0196 Special pharmacy permits.—Any person desiring a permit to operate a special pharmacy shall apply to the department for a special pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. A special pharmacy must pass an onsite inspection by the department as a prerequisite to the issuance of an initial permit or a permit for a change of location. The inspection must be completed within 90 days before the issuance of the permit. A permit may not be issued unless a licensed pharmacist is designated to undertake the professional supervision of the compounding and dispensing of all drugs dispensed by the pharmacy. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs occurs. The permittee shall notify the department within 10 days after any change of the licensed pharmacist responsible for such duties. Each permittee that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions

that a registered pharmacy technician is allowed to perform.

Section 19. Subsection (2) of section 465.0197, Florida Statutes, is amended to read:

465.0197 Internet pharmacy permits.—

(2) An Internet pharmacy must obtain a permit under this section to sell medicinal drugs to persons in this state. An Internet pharmacy must pass an onsite inspection by the department as a prerequisite to the issuance of an initial permit or a permit for a change of location. The inspection must be completed within 90 days prior to the issuance of the permit.

Section 20. Subsection (4) of section 466.006, Florida Statutes, is amended to read:

466.006 Examination of dentists.—

(4) Notwithstanding any other provision of law in chapter 456 pertaining to the clinical dental licensure examination or national examinations, to be licensed as a dentist in this state, an applicant must successfully complete the following:

(a) A written examination on the laws and rules of the state regulating the practice of dentistry;

(b)1. A practical or clinical examination, which shall be the American Dental Licensing Examination produced by the American Board of Dental Examiners, Inc., or its successor entity, if any, that is administered in this state ~~and graded by dentists licensed in this state and employed by the department for just such purpose~~, provided that the board has attained, and

continues to maintain thereafter, representation on the board of directors of the American Board of Dental Examiners, the examination development committee of the American Board of Dental Examiners, and such other committees of the American Board of Dental Examiners as the board deems appropriate by rule to assure that the standards established herein are maintained organizationally. A passing score on the American Dental Licensing Examination administered in this state ~~and graded by dentists who are licensed in this state~~ is valid for 365 days after the date the official examination results are published.

2.a. As an alternative to the requirements of subparagraph 1., an applicant may submit scores from an American Dental Licensing Examination previously administered in a jurisdiction other than this state after October 1, 2011, and such examination results shall be recognized as valid for the purpose of licensure in this state. A passing score on the American Dental Licensing Examination administered out-of-state shall be the same as the passing score for the American Dental Licensing Examination administered in this state ~~and graded by dentists who are licensed in this state~~. The examination results are valid for 365 days after the date the official examination results are published. The applicant must have completed the examination after October 1, 2011.

b. This subparagraph may not be given retroactive application.

3. If the date of an applicant's passing American Dental Licensing Examination scores from an examination previously administered in a jurisdiction other than this state under subparagraph 2. is older than 365 days, then such scores shall nevertheless be recognized as valid for the purpose of licensure in this state, but only if the applicant demonstrates that all of the following additional standards have been met:

a.(I) The applicant completed the American Dental Licensing Examination after October 1, 2011.

(II) This sub-subparagraph may not be given retroactive application;

b. The applicant graduated from a dental school accredited by the American Dental Association Commission on Dental Accreditation or its successor entity, if any, or any other dental accrediting organization recognized by the United States Department of Education. Provided, however, if the applicant did not graduate from such a dental school, the applicant may submit proof of having successfully completed a full-time supplemental general dentistry program accredited by the American Dental Association Commission on Dental Accreditation of at least 2 consecutive academic years at such accredited sponsoring institution. Such program must provide didactic and clinical education at the level of a D.D.S. or D.M.D. program accredited by the American Dental Association Commission on Dental Accreditation;

c. The applicant currently possesses a valid and active dental license in good standing, with no restriction, which has never been revoked, suspended, restricted, or otherwise disciplined, from another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico;

d. The applicant submits proof that he or she has never been reported to the National Practitioner Data Bank, the Healthcare Integrity and Protection Data Bank, or the American Association of Dental Boards Clearinghouse. This sub-subparagraph does not apply if the applicant successfully appealed to have his or her name removed from the data banks of these agencies;

e.(I) In the 5 years immediately preceding the date of application for licensure in this state, the applicant must submit proof of having been consecutively engaged in the full-time practice of dentistry in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico, or, if the applicant has been licensed in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico for less than 5 years, the applicant must submit proof of having been engaged in the full-time practice of dentistry since the date of his or her initial licensure.

(II) As used in this section, "full-time practice" is

defined as a minimum of 1,200 hours per year for each and every year in the consecutive 5-year period or, where applicable, the period since initial licensure, and must include any combination of the following:

(A) Active clinical practice of dentistry providing direct patient care.

(B) Full-time practice as a faculty member employed by a dental or dental hygiene school approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(C) Full-time practice as a student at a postgraduate dental education program approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(III) The board shall develop rules to determine what type of proof of full-time practice is required and to recoup the cost to the board of verifying full-time practice under this section. Such proof must, at a minimum, be:

(A) Admissible as evidence in an administrative proceeding;

(B) Submitted in writing;

(C) Submitted by the applicant under oath with penalties of perjury attached;

(D) Further documented by an affidavit of someone unrelated to the applicant who is familiar with the applicant's

practice and testifies with particularity that the applicant has been engaged in full-time practice; and

(E) Specifically found by the board to be both credible and admissible.

(IV) An affidavit of only the applicant is not acceptable proof of full-time practice unless it is further attested to by someone unrelated to the applicant who has personal knowledge of the applicant's practice. If the board deems it necessary to assess credibility or accuracy, the board may require the applicant or the applicant's witnesses to appear before the board and give oral testimony under oath;

f. The applicant must submit documentation that he or she has completed, or will complete, prior to licensure in this state, continuing education equivalent to this state's requirements for the last full reporting biennium;

g. The applicant must prove that he or she has never been convicted of, or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession in any jurisdiction;

h. The applicant must successfully pass a written examination on the laws and rules of this state regulating the practice of dentistry and must successfully pass the computer-based diagnostic skills examination; and

i. The applicant must submit documentation that he or she has successfully completed the National Board of Dental

Examiners dental examination.

Section 21. Paragraph (b) of subsection (4) and paragraph (a) of subsection (6) of section 466.007, Florida Statutes, are amended to read:

466.007 Examination of dental hygienists.—

(4) Effective July 1, 2012, to be licensed as a dental hygienist in this state, an applicant must successfully complete the following:

(b) A practical or clinical examination approved by the board. The examination shall be the Dental Hygiene Examination produced by the American Board of Dental Examiners, Inc. (ADEX) or its successor entity, if any, if the board finds that the successor entity's clinical examination meets or exceeds the provisions of this section. The board shall approve the ADEX Dental Hygiene Examination if the board has attained and continues to maintain representation on the ADEX House of Representatives, the ADEX Dental Hygiene Examination Development Committee, and such other ADEX Dental Hygiene committees as the board deems appropriate through rulemaking to ensure that the standards established in this section are maintained organizationally. The ADEX Dental Hygiene Examination or the examination produced by its successor entity is a comprehensive examination in which an applicant must demonstrate skills within the dental hygiene scope of practice on a live patient and any other components that the board deems necessary for the

applicant to successfully demonstrate competency for the purpose of licensure. ~~The ADEX Dental Hygiene Examination or the examination by the successor entity administered in this state shall be graded by dentists and dental hygienists licensed in this state who are employed by the department for this purpose.~~

(6)(a) A passing score on the ADEX Dental Hygiene Examination administered out of state shall be considered the same as a passing score for the ADEX Dental Hygiene Examination administered in this state ~~and graded by licensed dentists and dental hygienists~~.

Section 22. Subsections (9) through (15) are added to section 466.017, Florida Statutes, to read:

466.017 Prescription of drugs; anesthesia.—

(9) Any adverse incident that occurs in an office maintained by a dentist must be reported to the department. The required notification to the department must be submitted in writing by certified mail and postmarked within 48 hours after the incident occurs.

(10) A dentist practicing in this state must notify the board in writing by certified mail within 48 hours of any mortality or other adverse incident that occurs in the dentist's outpatient facility. A complete written report must be filed with the board within 30 days after the mortality or other adverse incident.

(11) For purposes of notification to the department

pursuant to this section, the term "adverse incident" means any mortality that occurs during or as the result of a dental procedure, or an incident that results in the temporary or permanent physical or mental injury that requires hospitalization or emergency room treatment of a dental patient that occurred during or as a direct result of the use of general anesthesia, deep sedation, conscious sedation, pediatric conscious sedation, oral sedation, minimal sedation (anxiolysis), nitrous oxide, or local anesthesia.

(12) Any certified registered dental hygienist administering local anesthesia must notify the board, in writing by registered mail within 48 hours of any adverse incident that was related to or the result of the administration of local anesthesia. A complete written report must be filed with the board within 30 days after the mortality or other adverse incident.

(13) A failure by the dentist or dental hygienist to timely and completely comply with all the reporting requirements in this section is the basis for disciplinary action by the board pursuant to s. 466.028(1).

(14) The department shall review each incident and determine whether it involved conduct by a health care professional subject to disciplinary action, in which case s. 456.073 applies. Disciplinary action, if any, shall be taken by the board under which the health care professional is licensed.

(15) The board may adopt rules to administer this section.

Section 23. Sections 466.032, 466.033, 466.034, 466.035, 466.036, 466.037, 466.038, and 466.039, Florida Statutes, are repealed.

Section 24. Subsection (1) of section 468.701, Florida Statutes, is amended to read:

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

(1) "Athletic trainer" means a person licensed under this part who has met the requirements under this part, including education requirements as set forth by the Commission on Accreditation of Athletic Training Education or its successor and necessary credentials from the Board of Certification. An athletic trainer must work within his or her scope of practice as established in the rules adopted by the board under s. 468.705. An individual who is licensed as an athletic trainer may not otherwise provide, offer to provide, or represent that he or she is qualified to provide any care or services beyond his or her scope of practice, or that he or she lacks the education, training, or experience to provide, or that he or she is otherwise prohibited by law from providing.

Section 25. Section 468.707, Florida Statutes, is amended to read:

468.707 Licensure requirements.—Any person desiring to be licensed as an athletic trainer shall apply to the department on a form approved by the department. An applicant shall also

provide records or other evidence, as determined by the board, to prove he or she has met the requirements of this section. The department shall license each applicant who:

(1) Has completed the application form and remitted the required fees.

(2) ~~For a person who applies on or after July 1, 2016,~~ Has submitted to background screening pursuant to s. 456.0135. The board may require a background screening for an applicant whose license has expired or who is undergoing disciplinary action.

(3)(a) Has obtained a baccalaureate or higher degree from a college or university professional athletic training degree program accredited by the Commission on Accreditation of Athletic Training Education or its successor recognized and approved by the United States Department of Education or the Commission on Recognition of Postsecondary Accreditation, approved by the board, or recognized by the Board of Certification, and has passed the national examination to be certified by the Board of Certification, or~~.~~

(b)~~(4)~~ Has obtained, at a minimum, a bachelor's degree and has completed the Board of Certification internship requirements and ~~If graduated before 2004,~~ has a current certification from the Board of Certification.

(4)~~(5)~~ Has current certification in both cardiopulmonary resuscitation and the use of an automated external defibrillator set forth in the continuing education requirements as determined

by the board pursuant to s. 468.711.

(5)~~(6)~~ Has completed any other requirements as determined by the department and approved by the board.

Section 26. Subsection (3) of section 468.711, Florida Statutes, is amended to read:

468.711 Renewal of license; continuing education.—

(3) If initially licensed after January 1, 1998, the licensee must be currently certified by the Board of Certification or its successor agency and maintain that certification in good standing without lapse.

Section 27. Subsection (2) of section 468.723, Florida Statutes, is amended to read:

468.723 Exemptions.—This part does not prevent or restrict:

(2) An athletic training student acting under the direct supervision of a licensed athletic trainer. For purposes of this subsection, "direct supervision" means the physical presence of an athletic trainer so that the athletic trainer is immediately available to the athletic training student and able to intervene on behalf of the athletic training student. The supervision must be in accordance with rules adopted by the board ~~the standards set forth by the Commission on Accreditation of Athletic Training Education or its successor~~.

Section 28. Subsections (1), (3), and (4) of section 468.803, Florida Statutes, are amended to read:

468.803 License, registration, and examination requirements.—

(1) The department shall issue a license to practice orthotics, prosthetics, or pedorthics, or a registration for a resident to practice orthotics or prosthetics, to qualified applicants. Licenses shall be granted independently in orthotics, prosthetics, or pedorthics, but a person may be licensed in more than one such discipline, and a prosthetist-orthotist license may be granted to persons meeting the requirements for both a prosthetist and an orthotist license. Registrations shall be granted independently in orthotics or prosthetics, and a person may be registered in both fields at the same time or jointly in orthotics and prosthetics as a dual registration.

(3) A person seeking to attain the required orthotics or prosthetics experience in this state must be approved by the board and registered as a resident by the department. Although a registration may be held in both practice fields, for independent registrations the board shall not approve a second registration until at least 1 year after the issuance of the first registration. Notwithstanding subsection (2), an applicant for independent registrations who has been approved by the board and registered by the department in one practice field may apply for registration in the second practice field without an additional state or national criminal history check during the

period in which the first registration is valid. Each <u>independent</u> registration <u>or dual registration</u> is valid for 2 years from the date of issuance unless otherwise revoked by the department upon recommendation of the board. The board shall set a registration fee not to exceed $500 to be paid by the applicant. A registration may be renewed once by the department upon recommendation of the board for a period no longer than 1 year, as such renewal is defined by the board by rule. The registration renewal fee shall not exceed one-half the current registration fee. To be considered by the board for approval of registration as a resident, the applicant must have:

(a) A Bachelor of Science or higher-level postgraduate degree in Orthotics and Prosthetics from a regionally accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs or, at a minimum, a bachelor's degree from a regionally accredited college or university and a certificate in orthotics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board; ~~or~~

(b) A Bachelor of Science or higher-level postgraduate degree in Orthotics and Prosthetics from a regionally accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs or, at a minimum, a bachelor's degree from a regionally accredited

college or university and a certificate in prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board; or

(c) A Bachelor of Science or higher-level postgraduate degree in Orthotics and Prosthetics from a regionally accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs or, at a minimum, a bachelor's degree from a regionally accredited college or university and a dual certificate in both orthotics and prosthetics from programs recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board.

(4) The department may develop and administer a state examination for an orthotist or a prosthetist license, or the board may approve the existing examination of a national standards organization. The examination must be predicated on a minimum of a baccalaureate-level education and formalized specialized training in the appropriate field. Each examination must demonstrate a minimum level of competence in basic scientific knowledge, written problem solving, and practical clinical patient management. The board shall require an examination fee not to exceed the actual cost to the board in developing, administering, and approving the examination, which fee must be paid by the applicant. To be considered by the board

for examination, the applicant must have:

(a) For an examination in orthotics:

1. A Bachelor of Science or higher-level postgraduate degree in Orthotics and Prosthetics from a regionally accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs or, at a minimum, a bachelor's degree from a regionally accredited college or university and a certificate in orthotics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board; and

2. An approved orthotics internship of 1 year of qualified experience, as determined by the board, or an orthotic residency program or dual residency program recognized by the board.

(b) For an examination in prosthetics:

1. A Bachelor of Science or higher-level postgraduate degree in Orthotics and Prosthetics from a regionally accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs or, at a minimum, a bachelor's degree from a regionally accredited college or university and a certificate in prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board; and

2. An approved prosthetics internship of 1 year of

qualified experience, as determined by the board, or a prosthetic residency program or dual residency program recognized by the board.

Section 29. Subsection (5) of section 480.033, Florida Statutes, is amended to read:

480.033 Definitions.—As used in this act:

(5) "Apprentice" means a person approved by the board to study colonic irrigation ~~massage~~ under the instruction of a licensed massage therapist practicing colonic irrigation.

Section 30. Subsections (1) and (2) of section 480.041, Florida Statutes, are amended, and subsection (8) is added to that section, to read:

480.041 Massage therapists; qualifications; licensure; endorsement.—

(1) Any person is qualified for licensure as a massage therapist under this act who:

(a) Is at least 18 years of age or has received a high school diploma or high school equivalency diploma;

(b) Has completed a course of study at a board-approved massage school ~~or has completed an apprenticeship program~~ that meets standards adopted by the board; and

(c) Has received a passing grade on a national ~~an~~ examination designated ~~administered~~ by the board ~~department~~.

(2) Every person desiring to be examined for licensure as a massage therapist shall apply to the department in writing

upon forms prepared and furnished by the department. Such applicants shall be subject to the provisions of s. 480.046(1). ~~Applicants may take an examination administered by the department only upon meeting the requirements of this section as determined by the board.~~

(8) A person issued a license as a massage apprentice before July 1, 2018, may continue that apprenticeship and perform massage therapy as permitted under that license until it expires. Upon completion of the apprenticeship, before July 1, 2021, a massage apprentice may apply to the board for full licensure and be granted a license if all other applicable licensure requirements are met.

Section 31. Section 480.042, Florida Statutes, is repealed.

Section 32. Subsection (3) of section 480.046, Florida Statutes, is amended, and subsection (5) is added to that section, to read:

480.046 Grounds for disciplinary action by the board.—

(3) The board may ~~shall have the power to~~ revoke or suspend the license of a massage establishment licensed under this act, or ~~to~~ deny subsequent licensure of such an establishment, if the establishment is owned by an individual or entity who has a prior establishment license revoked, in either of the following cases:

(a) Upon proof that a license has been obtained by fraud

or misrepresentation.

(b) Upon proof that the holder of a license is guilty of fraud or deceit or of gross negligence, incompetency, or misconduct in the operation of the establishment so licensed.

(c) Upon proof that the owner of a massage establishment or any individual or individuals providing massage therapy services within the establishment, in the aggregate or individually, have had three convictions of, or pleas of guilty or nolo contendere to, or dismissals of a criminal action after a successful completion of a pretrial intervention, diversion, or substance abuse program for any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction related to prostitution and related acts as defined in s. 796.07, which occurred at or within the establishment.

(5) An establishment may not apply for relicensure if disciplined under this section unless there is a change in ownership.

Section 33. Section 483.824, Florida Statutes, is amended to read:

483.824 Qualifications of clinical laboratory director.—A clinical laboratory director must qualify as a clinical laboratory director according to Title 42, part 493, Code of Federal Regulations, must be a currently licensed laboratory director, have 4 years of clinical laboratory experience with 2 years of experience in the specialty to be directed or be

nationally board certified in the specialty to be directed, and must meet one of the following requirements:

(1) Be a physician licensed under chapter 458 or chapter 459;

(2) Hold an earned doctoral degree in a chemical, physical, or biological science from a regionally accredited institution and maintain national certification requirements equal to those required by the federal Centers for Medicare and Medicaid Services or the federal Health Care Financing Administration; or

(3) For the subspecialty of oral pathology, be a physician licensed under chapter 458 or chapter 459 or a dentist licensed under chapter 466. The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 42 C.F.R. ss. 493.1447, 493.1453, 493.1459, and 493.1487.

Section 34. Subsection (3) of section 490.003, Florida Statutes, is amended to read:

490.003 Definitions.—As used in this chapter:

(3) ~~(a) Prior to July 1, 1999, "doctoral-level psychological education" and "doctoral degree in psychology" mean a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from:~~

~~1. An educational institution which, at the time the applicant was enrolled and graduated, had institutional accreditation from an agency recognized and approved by the United States Department of Education or was recognized as a member in good standing with the Association of Universities and Colleges of Canada; and~~

~~2. A psychology program within that educational institution which, at the time the applicant was enrolled and graduated, had programmatic accreditation from an accrediting agency recognized and approved by the United States Department of Education or was comparable to such programs.~~

~~(b)~~ Effective July 1, 1999, "doctoral-level psychological education" and "doctoral degree in psychology" mean a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from:

(a)~~1.~~ An educational institution which, at the time the applicant was enrolled and graduated, had institutional accreditation from an agency recognized and approved by the United States Department of Education or was recognized as a member in good standing with the Association of Universities and Colleges of Canada; and

(b)~~2.~~ A psychology program within that educational institution which, at the time the applicant was enrolled and graduated, had programmatic accreditation from the American Psychological Association ~~an agency recognized and approved by the United States Department of Education~~.

Section 35. Paragraph (b) of subsection (1) and paragraph (b) of subsection (2) of section 490.005, Florida Statutes, are amended to read:

490.005 Licensure by examination.—

(1) Any person desiring to be licensed as a psychologist shall apply to the department to take the licensure examination. The department shall license each applicant who the board certifies has:

(b) Submitted proof satisfactory to the board that the applicant has:

1. Received doctoral-level psychological education, as defined in s. 490.003(3);

2. Received the equivalent of a doctoral-level psychological education, as defined in s. 490.003(3), from a program at a school or university located outside the United States of America ~~and Canada~~, which was officially recognized by the government of the country in which it is located as an institution or program to train students to practice professional psychology. The burden of establishing that the requirements of this provision have been met shall be upon the applicant;

~~3. Received and submitted to the board, prior to July 1, 1999, certification of an augmented doctoral-level psychological education from the program director of a doctoral-level psychology program accredited by a programmatic agency~~

~~recognized and approved by the United States Department of Education; or~~

~~4. Received and submitted to the board, prior to August 31, 2001, certification of a doctoral-level program that at the time the applicant was enrolled and graduated maintained a standard of education and training comparable to the standard of training of programs accredited by a programmatic agency recognized and approved by the United States Department of Education. Such certification of comparability shall be provided by the program director of a doctoral-level psychology program accredited by a programmatic agency recognized and approved by the United States Department of Education.~~

(2) Any person desiring to be licensed as a school psychologist shall apply to the department to take the licensure examination. The department shall license each applicant who the department certifies has:

(b) Submitted satisfactory proof to the department that the applicant:

1. Has received a doctorate, specialist, or equivalent degree from a program primarily psychological in nature and has completed 60 semester hours or 90 quarter hours of graduate study, in areas related to school psychology as defined by rule of the department, from a college or university which at the time the applicant was enrolled and graduated was accredited by an accrediting agency recognized and approved by the Council for

Higher Education Accreditation, its successor, ~~Commission on Recognition of Postsecondary Accreditation~~ or an institution which is publicly recognized as a member in good standing with the Association of Universities and Colleges of Canada.

2. Has had a minimum of 3 years of experience in school psychology, 2 years of which must be supervised by an individual who is a licensed school psychologist or who has otherwise qualified as a school psychologist supervisor, by education and experience, as set forth by rule of the department. A doctoral internship may be applied toward the supervision requirement.

3. Has passed an examination provided by the department.

Section 36. Subsection (1) of section 490.006, Florida Statutes, is amended to read:

490.006 Licensure by endorsement.—

(1) The department shall license a person as a psychologist or school psychologist who, upon applying to the department and remitting the appropriate fee, demonstrates to the department or, in the case of psychologists, to the board that the applicant:

~~(a) Holds a valid license or certificate in another state to practice psychology or school psychology, as applicable, provided that, when the applicant secured such license or certificate, the requirements were substantially equivalent to or more stringent than those set forth in this chapter at that time; and, if no Florida law existed at that time, then the~~

~~requirements in the other state must have been substantially equivalent to or more stringent than those set forth in this chapter at the present time;~~

(a) ~~(b)~~ Is a diplomate in good standing with the American Board of Professional Psychology, Inc.; or

(b) ~~(c)~~ Possesses a doctoral degree in psychology ~~as described in s. 490.003~~ and has at least 10 ~~20~~ years of experience as a licensed psychologist in any jurisdiction or territory of the United States within 25 years preceding the date of application.

Section 37. Subsection (6) of section 491.0045, Florida Statutes, as amended by chapter 2016-80 and chapter 2016-241, Laws of Florida, is reenacted to read:

491.0045 Intern registration; requirements.—

(6) A registration issued on or before March 31, 2017, expires March 31, 2022, and may not be renewed or reissued. Any registration issued after March 31, 2017, expires 60 months after the date it is issued. The board may make a one-time exception from the requirements of this section in emergency or hardship cases, as defined by board rule, if ~~A subsequent intern registration may not be issued unless~~ the candidate has passed the theory and practice examination described in s. 491.005(1)(d), (3)(d), and (4)(d).

Section 38. Subsections (3) and (4) of section 491.005, Florida Statutes, are amended to read:

491.005 Licensure by examination.—

(3) MARRIAGE AND FAMILY THERAPY.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual cost ~~to the department~~ for the purchase of the examination from the Association of Marital and Family Therapy Regulatory Board, or similar national organization, the department shall issue a license as a marriage and family therapist to an applicant who the board certifies:

(a) Has submitted an application and paid the appropriate fee.

(b)1. Has a minimum of a master's degree with major emphasis in marriage and family therapy from a program accredited by the Commission of Accreditation for Marriage and Family Therapy Education or from a Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs, or a closely related field, and graduate courses approved by the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling. ~~has completed all of the following requirements:~~

~~a. Thirty-six semester hours or 48 quarter hours of graduate coursework, which must include a minimum of 3 semester hours or 4 quarter hours of graduate-level course credits in each of the following nine areas: dynamics of marriage and family systems; marriage therapy and counseling theory and techniques; family therapy and counseling theory and techniques;~~

~~individual human development theories throughout the life cycle; personality theory or general counseling theory and techniques; psychopathology; human sexuality theory and counseling techniques; psychosocial theory; and substance abuse theory and counseling techniques. Courses in research, evaluation, appraisal, assessment, or testing theories and procedures; thesis or dissertation work; or practicums, internships, or fieldwork may not be applied toward this requirement.~~

~~b. A minimum of one graduate-level course of 3 semester hours or 4 quarter hours in legal, ethical, and professional standards issues in the practice of marriage and family therapy or a course determined by the board to be equivalent.~~

~~c. A minimum of one graduate-level course of 3 semester hours or 4 quarter hours in diagnosis, appraisal, assessment, and testing for individual or interpersonal disorder or dysfunction; and a minimum of one 3-semester-hour or 4-quarter-hour graduate-level course in behavioral research which focuses on the interpretation and application of research data as it applies to clinical practice. Credit for thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.~~

~~d. A minimum of one supervised clinical practicum, internship, or field experience in a marriage and family counseling setting, during which the student provided 180 direct client contact hours of marriage and family therapy services~~

~~under the supervision of an individual who met the requirements for supervision under paragraph (c). This requirement may be met by a supervised practice experience which took place outside the academic arena, but which is certified as equivalent to a graduate-level practicum or internship program which required a minimum of 180 direct client contact hours of marriage and family therapy services currently offered within an academic program of a college or university accredited by an accrediting agency approved by the United States Department of Education, or an institution which is publicly recognized as a member in good standing with the Association of Universities and Colleges of Canada or a training institution accredited by the Commission on Accreditation for Marriage and Family Therapy Education recognized by the United States Department of Education. Certification shall be required from an official of such college, university, or training institution.~~

2. If the course title which appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant shall be required to provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course.

The required master's degree must have been received in an institution of higher education which at the time the applicant graduated was: fully accredited by a regional accrediting body

recognized by the Commission on Recognition of Postsecondary Accreditation; publicly recognized as a member in good standing with the Association of Universities and Colleges of Canada; or an institution of higher education located outside the United States and Canada, which at the time the applicant was enrolled and at the time the applicant graduated maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by a regional accrediting body recognized by the Commission on Recognition of Postsecondary Accreditation. Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as professional marriage and family therapists or psychotherapists. The burden of establishing that the requirements of this provision have been met shall be upon the applicant, and the board shall require documentation, such as, but not limited to, an evaluation by a foreign equivalency determination service, as evidence that the applicant's graduate degree program and education were equivalent to an accredited program in this country. An applicant with a master's degree from a program which did not emphasize marriage and family therapy may complete the coursework requirement in a training institution fully accredited by the Commission on Accreditation for Marriage and

Family Therapy Education recognized by the United States Department of Education.

(c) Has had at least 2 years of clinical experience during which 50 percent of the applicant's clients were receiving marriage and family therapy services, which must be at the post-master's level under the supervision of a licensed marriage and family therapist with at least 5 years of experience, or the equivalent, who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If a graduate has a master's degree with a major emphasis in marriage and family therapy or a closely related field that did not include all the coursework required under subparagraph (b)1. ~~sub-subparagraphs (b)1.a.-c.~~, credit for the post-master's level clinical experience shall not commence until the applicant has completed a minimum of 10 of the courses required under subparagraph (b)1. ~~sub-subparagraphs (b)1.a.-c.~~, as determined by the board, and at least 6 semester hours or 9 quarter hours of the course credits must have been completed in the area of marriage and family systems, theories, or techniques. Within the 2 ~~3~~ years of required experience, the applicant shall provide direct individual, group, or family therapy and counseling, to include the following categories of cases: unmarried dyads, married couples, separating and divorcing couples, and family

groups including children. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

(d) Has passed a theory and practice examination provided by the department for this purpose.

(e) Has demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

(f) For the purposes of dual licensure, the department shall license as a marriage and family therapist any person who meets the requirements of s. 491.0057. Fees for dual licensure shall not exceed those stated in this subsection.

(4) MENTAL HEALTH COUNSELING.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual per applicant cost to the department for purchase of the examination from the National Board of Certified Counselors or its successor ~~Professional Examination Service for the National Academy of Certified Clinical Mental Health Counselors or a similar national organization~~, the department shall issue a license as a mental health counselor to an applicant who the board certifies:

(a) Has submitted an application and paid the appropriate

fee.

(b)1. Has a minimum of an earned master's degree from a mental health counseling program accredited by the Council for the Accreditation of Counseling and Related Educational Programs that consists of at least 60 semester hours or 80 quarter hours of clinical and didactic instruction, including a course in human sexuality and a course in substance abuse. If the master's degree is earned from a program related to the practice of mental health counseling that is not accredited by the Council for the Accreditation of Counseling and Related Educational Programs, then the coursework and practicum, internship, or fieldwork must consist of at least 60 semester hours or 80 quarter hours and meet the following requirements:

a. Thirty-three semester hours or 44 quarter hours of graduate coursework, which must include a minimum of 3 semester hours or 4 quarter hours of graduate-level coursework in each of the following 11 content areas: counseling theories and practice; human growth and development; diagnosis and treatment of psychopathology; human sexuality; group theories and practice; individual evaluation and assessment; career and lifestyle assessment; research and program evaluation; social and cultural foundations; counseling in community settings; and substance abuse. Courses in research, thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.

b. A minimum of 3 semester hours or 4 quarter hours of graduate-level coursework in legal, ethical, and professional standards issues in the practice of mental health counseling, which includes goals, objectives, and practices of professional counseling organizations, codes of ethics, legal considerations, standards of preparation, certifications and licensing, and the role identity and professional obligations of mental health counselors. Courses in research, thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.

c. The equivalent, as determined by the board, of at least 700 ~~1,000~~ hours of university-sponsored supervised clinical practicum, internship, or field experience as required in the accrediting standards of the Council for Accreditation of Counseling and Related Educational Programs for mental health counseling programs. This experience may not be used to satisfy the post-master's clinical experience requirement.

2. If the course title which appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant shall be required to provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course.

Education and training in mental health counseling must have been received in an institution of higher education which at the

time the applicant graduated was: fully accredited by a regional accrediting body recognized by the Commission on Recognition of Postsecondary Accreditation; publicly recognized as a member in good standing with the Association of Universities and Colleges of Canada; or an institution of higher education located outside the United States and Canada, which at the time the applicant was enrolled and at the time the applicant graduated maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by a regional accrediting body recognized by the Commission on Recognition of Postsecondary Accreditation. Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as mental health counselors. The burden of establishing that the requirements of this provision have been met shall be upon the applicant, and the board shall require documentation, such as, but not limited to, an evaluation by a foreign equivalency determination service, as evidence that the applicant's graduate degree program and education were equivalent to an accredited program in this country.

(c) Has had at least 2 years of clinical experience in mental health counseling, which must be at the post-master's level under the supervision of a licensed mental health

counselor or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If a graduate has a master's degree with a major related to the practice of mental health counseling that did not include all the coursework required under sub-subparagraphs (b)1.a.-b., credit for the post-master's level clinical experience shall not commence until the applicant has completed a minimum of seven of the courses required under sub-subparagraphs (b)1.a.-b., as determined by the board, one of which must be a course in psychopathology or abnormal psychology. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

(d) Has passed a theory and practice examination provided by the department for this purpose.

(e) Has demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

Section 39. Paragraph (b) of subsection (1) of section 491.006, Florida Statutes, is amended to read:

491.006 Licensure or certification by endorsement.—

(1) The department shall license or grant a certificate to a person in a profession regulated by this chapter who, upon applying to the department and remitting the appropriate fee, demonstrates to the board that he or she:

(b)1. Holds an active valid license to practice and has actively practiced the profession for which licensure is applied in another state for 3 of the last 5 years immediately preceding licensure.

~~2. Meets the education requirements of this chapter for the profession for which licensure is applied.~~

2.~~3.~~ Has passed a substantially equivalent licensing examination in another state or has passed the licensure examination in this state in the profession for which the applicant seeks licensure.

3.~~4.~~ Holds a license in good standing, is not under investigation for an act that would constitute a violation of this chapter, and has not been found to have committed any act that would constitute a violation of this chapter. The fees paid by any applicant for certification as a master social worker under this section are nonrefundable.

Section 40. Subsection (3) of section 491.007, Florida Statutes, is amended to read:

491.007 Renewal of license, registration, or certificate.—

~~(3) The board or department shall prescribe by rule a method for the biennial renewal of an intern registration at a~~

~~fee set by rule, not to exceed $100.~~

Section 41. Subsection (2) of section 491.009, Florida Statutes, is amended to read:

491.009 Discipline.—

(2) The board ~~department~~, or, in the case of certified master social workers ~~psychologists~~, the department ~~board~~, may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).

Section 42. Subsection (3) of section 463.0057, Florida Statutes, is amended to read:

463.0057 Optometric faculty certificate.—

(3) The holder of a faculty certificate may engage in the practice of optometry as permitted by this section but may not administer or prescribe topical ocular pharmaceutical agents unless the certificateholder has satisfied the requirements of s. 463.006(1)(b)3. and 4. ~~s. 463.006(1)(b)4. and 5~~. If a certificateholder wishes to administer or prescribe oral ocular pharmaceutical agents, the certificateholder must also satisfy the requirements of s. 463.0055(1)(b).

Section 43. Paragraph (c) of subsection (2) of section 491.0046, Florida Statutes, is amended to read:

491.0046 Provisional license; requirements.—

(2) The department shall issue a provisional clinical social worker license, provisional marriage and family therapist license, or provisional mental health counselor license to each applicant who the board certifies has:

(c) Has met the following minimum coursework requirements:

1. For clinical social work, a minimum of 15 semester hours or 22 quarter hours of the coursework required by s. 491.005(1)(b)2.b.

2. For marriage and family therapy, 10 of the courses required by s. 491.005(3)(b)1. ~~s. 491.005(3)(b)1.a.-c.~~, as determined by the board, and at least 6 semester hours or 9 quarter hours of the course credits must have been completed in the area of marriage and family systems, theories, or techniques.

3. For mental health counseling, a minimum of seven of the courses required under s. 491.005(3)(b)1. ~~s. 491.005(4)(b)1.a.-c.~~

Section 44. Subsection (11) of section 945.42, Florida Statutes, is amended to read:

945.42 Definitions; ss. 945.40-945.49.—As used in ss. 945.40-945.49, the following terms shall have the meanings ascribed to them, unless the context shall clearly indicate otherwise:

(11) "Psychological professional" means a behavioral practitioner who has an approved doctoral degree in psychology

as defined in s. 490.003(3) ~~s. 490.003(3)(b)~~ and is employed by the department or who is licensed as a psychologist pursuant to chapter 490.

Section 45. This act shall take effect July 1, 2018.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 1047 (2018)

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 Quality Subcommittee

Representative Gonzalez offered the following:

Amendment (with title amendment)

Remove lines 261-834

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

Remove lines 10-33 and insert:

requirements; repealing s. 460.4166, F.S., relating to

Amendment No. 2

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 Quality Subcommittee

Representative Gonzalez offered the following:

Amendment (with title amendment)

Between lines 1354 and 1355, insert:

Section 1. Paragraph (n) is added to subsection (1) of section 468.505, Florida Statutes, to read:

468.505 Exemptions; exceptions.—

(1) Nothing in this part may be construed as prohibiting or restricting the practice, services, or activities of:

(n) A person who furnishes nutrition information, provides recommendations or advice concerning nutrition, or markets food, food materials, or dietary supplements for remuneration, if that person does not represent that he or she is a dietitian, licensed dietitian, registered dietitian, licensed nutritionist,

nutrition counselor, licensed nutrition counselor, or any other words, letters, symbols, or insignia indicating or implying that he or she is a dietitian, nutritionist, or nutrition counselor.

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

Remove line 84 and insert:

relating to violations; amending s. 468.505, F.S.; providing an exception to licensure; amending s. 468.701, F.S.;

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1155 Anatomical Gifts
SPONSOR(S): La Rosa
TIED BILLS: **IDEN./SIM. BILLS:** SB 1086

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Gilani	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Part V of ch. 765, F.S., regulates the procurement, donation, and use of anatomical gifts. An anatomical gift is the donation of all or part of a human body after the donor's death, which is only used for transplantation, therapy, research, or education.

Any person may make an anatomical gift by executing a document or using some other mechanism to verify the intent to do so. Examples include a signed organ and tissue card, registering online with the donor registry, a driver's license signifying an intent to donate, or an executed will.

Currently, only the following entities may receive an anatomical gift:

- Any procurement organization (e.g. tissue bank, eye bank) or accredited medical or dental school, college, or university for education, research, therapy, or transplantation.
- Any individual specified by name for therapy or transplantation needed by that individual.
- The anatomical board or a nontransplant anatomical donation organization (a tissue bank or other organization that facilitates nontransplant anatomical donations) for donation of the whole body for medical or dental education or research.

Donors may specify by name which of these entities they wish to donate their human remains.

HB 1155 expands the list of entities that may receive anatomical gifts to include a nonprofit surgical training center for education, research, or training. The bill defines nonprofit surgical training center as a facility or department owned by a licensed hospital, which offers multidisciplinary learning opportunities, including continuing medical education courses. The bill prohibits a nonprofit surgical training center from giving an anatomical gift to another facility.

The bill has no fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Anatomical Gifts

Part V of ch. 765, F.S., regulates the procurement, donation, and use of anatomical gifts. An anatomical gift is the donation of all or part of a human body after the donor's death, which is to only be used for transplantation, therapy, research, or education.[1]

Any person may make an anatomical gift by:[2]

- Signing an organ and tissue donor card.
- Registering online with the donor registry.
- Signifying an intent to donate on his or her driver license or an identification card issued by the Department of Highway and Motor Vehicles.[3]
- Expressing a wish to donate in a living will or other advance directive.
- Executing a will that includes a provision indicating that the testator wishes to make an anatomical gift.[4]
- Expressing a wish to donate in a document other than a will, so long as the document is signed by the donor in the presence of two witnesses who also sign the document in the donor's presence; If the donor cannot sign, the document may be signed for him or her at the donor's direction and in his or her presence and the presence of two witnesses who must also sign the document in the donor's presence.

Section 765.513(1), F.S., limits the persons or entities that may receive an anatomical gift and the conditions for such gift:

- Any procurement organization[5] or accredited medical or dental school, college, or university for education, research, therapy, or transplantation.
- Any individual specified by name for therapy or transplantation needed by him or her.
- The anatomical board or a nontransplant anatomical donation organization[6] for donation of the whole body for medical or dental education or research.

Donors may select by name which eligible person or entity to whom they gift their human remains.[7] Donors who list multiple purposes for their human remains in their gifting document[8] will have their donation prioritized first for transplantation or therapy, if suitable, and then for research or education.[9]

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[1] S. 765.511(2), F.S.
[2] S. 765.512(1), S. 765.514(1), F.S.
[3] Revocation, suspension, expiration, or cancellation of the driver license or identification card does not invalidate the gift, s. 765.514(c), F.S.
[4] The gift becomes effective upon the death of the testator without waiting for probate. If the will is not probated or declared invalid for testamentary purposes, the gift is nevertheless valid to the extent that it has been acted upon in good faith. S. 765.514(1)(e), F.S.
[5] "Procurement organization" means an organ procurement organization, eye bank, or tissue bank, s. 765.511(19), F.S.
[6] "Nontransplant anatomical donation organization" means a tissue bank or other organization that facilitates nontransplant anatomical donation, including referral, obtaining informed consent or authorization, acquisition, traceability, transport, assessing donor acceptability, preparation, packaging, labeling, storage, release, evaluating intended use, distribution, and final disposition of nontransplant anatomical donations, s. 406.49, F.S.
[7] S. 765.514(2), F.S.
[8] A gifting document or "document of gift" is any of the documents or mechanisms used in making an anatomical gift under s. 765.514, F.S. S. 765.511(8), F.S.
[9] S. 765.513(2), F.S.

Nontransplant Anatomical Donation Organizations

The American Association of Tissue Banks (AATB) is an organization that promulgates industry standards and accredits tissue banks in both the United States and Canada.[10] In 2012, the AATB also developed an accreditation standard for nontransplant anatomical donation organizations (NADO).[11] A NADO, commonly referred to as a body broker, stores human remains for the purposes of research, rather than transplant.

An accredited NADO facilitates a nontransplant anatomical donation (NTAD) by overseeing referrals, obtaining informed consent or authorization, acquisition, traceability, transport, assessing donor acceptability, preparation, packaging, labeling, storage, release, evaluating intended use, distribution, and final disposition of an NTAD.[12] Currently, the AATB has accredited seven NADOs in the U.S. and at least three of these operate in Florida.[13]

According to media reports, prices for human remains obtained through a NADO can range from $3,000 to $10,000.[14] Such prices may reflect the costs of final disposition, paid by NADOs on behalf of families. According to media reports, funeral home directors will often refer families to NADOs if they are unable to afford after-life expenses, and in some instances, will also receive monetary incentives for their referrals.[15]

Anatomical Board

Body donor programs were first created in Florida in the 1950s as medical schools were being established in the state.[16] In 1970, the University of Florida College of Medicine (UF) received authorization from the Board of Regents[17] to create an anatomical board that would oversee the donation and use of bodies for anatomical education and medical research.[18] In 1996, the Legislature created the state Anatomical Board (Board), codifying this program in statute.[19] The Board is headquartered at the UF Health Center and is comprised of representatives from the medical schools in the state.[20]

The Board is authorized to receive human remains from different sources throughout the state and is responsible for the equitable distribution of human remains among the medical and dental schools, teaching hospitals, medical institutions, and health-related teaching programs that require human remains for study.[21]

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[10] AMERICAN ASSOCIATION OF TISSUE BANKS, *About Us*, https://www.aatb.org/?q=about-us (last visited Jan. 22, 2018). The AATB has produced best practice standards for the operation of tissue banks since 1984. The association also provides an educational network for member organizations to encourage the dissemination of new practices.

[11] AMERICAN ASSOCIATION OF TISSUE BANKS, *Policies for Non-Transplant Anatomical Donation Organizations*, https://www.aatb.org/?q=content/policies-non-transplant-anatomical-donation-organizations (last visited Jan. 22, 2018).

[12] Id.

[13] AMERICAN ASSOCIATION OF TISSUE BANKS, *Accredited Bank Search,* https://www.aatb.org/?q=content/accredited-bank-search (last visited Jan. 22, 2018).

[14] Brian Grow and John Shiffman, *The Body Trade: Body Brokers,* REUTERS (Oct. 24, 2017), https://www.reuters.com/investigates/special-report/usa-bodies-brokers/ (last visited Jan. 22, 2018). Additionally, some NADOs will divide the human remains and sell parts separately for similar prices.

[15] Id.

[16] ANATOMICAL BOARD OF THE STATE OF FLORIDA, *About Us,* http://anatbd.acb.med.ufl.edu/about-us/ (last visited Jan. 17, 2018).

[17] The Florida Board of Regents governed the state university system of Florida from 1965 to 2001. These powers are now held by the Florida Board of Governors.

[18] *Supra* note 16.

[19] S. 406.49(1), F.S.; ch. 96-251, Laws of Fla. Prior to 1996, the Division of Universities of the Department of Education was responsible for these functions.

[20] *Supra* note 16. Medical schools represented include: University of Florida, University of Miami, University of South Florida, University of Central Florida, Florida State University, and Nova Southeastern University Osteopathic School of Medicine.

[21] Ss. 406.57(1); 406.56; 406.50, F.S.

The Board inspects the institutions prior to distribution of any human remains, and the human remains cannot be used for anything other than medical education or research.[22] The Board may also loan the remains to accredited colleges of mortuary science or to medical or dental examining boards for educational or research purposes.[23]

Distribution of Human Remains

The Board receives its human remains solely from anatomical gifts since unclaimed human remains are often unsuitable for distribution.[24] The number of anatomical donations made to the Board has consistently decreased in the past several years, and that trend is projected to continue.[25]

The Board first distributes human remains to the medical schools, then to other entities such as the research institutions or teaching hospitals.[26] The Board is currently unable to meet the schools' demands for human remains, and with new medical schools and programs opening in the state, the Board expects this disparity to increase.[27] Due to the prioritization in distribution and the shortage of human remains, the Board does not have enough human remains to supply research institutions or teaching hospitals.[28]

Effect of the Bill:

HB 1155 expands the list of entities that may receive anatomical gifts to include a nonprofit surgical training center for education, research, or training. Currently, human remains may only be donated to the anatomical board, a specific person for transplantation or therapy, a nontransplant anatomical donation organization or a procurement organization (i.e. a tissue bank, eye bank, organ procurement organization), or an accredited medical or dental school.

The bill defines nonprofit surgical training center as a nonprofit facility or department, which is owned by a licensed hospital, and offers multidisciplinary learning opportunities, including continuing medical education courses.

There are currently 308 hospitals in Florida which may have a department or facility that meets the bill's definition of a nonsurgical training center.[29] The bill allows any of these entities that qualify to solicit and receive anatomical gifts from patients or other individuals that previously could have only been donated to a transplant patient, the Board, an accredited medical or dental school, nontransplant anatomical donation organization or other tissue bank.

The bill prohibits a nonprofit surgical training center from giving an anatomical gift to another facility, meaning these entities will not be able to give or sell these human remains to any other facilities or organizations, even if the human remains are no longer of use to them.

The bill provides an effective date of July 1, 2018.

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[22] S. 406.59, F.S.
[23] S. 406.57(2), F.S.
[24] S. 406.50, F.S., authorizes the Anatomical Board to receive unclaimed human remains in certain circumstances. However, citing health concerns (unknown health conditions, risk of infectious diseases), the Board rejects most unclaimed human remains and has not accepted any unclaimed human remains in the past five or more years. Email from Dr. William Dunn, Executive Director, Anatomical Board, RE: Inquiry on Anatomical Gifts (Jan. 23, 2018)(on file with staff in the House Health and Human Services Committee).
[25] Email from Dr. William Dunn, Executive Director, Anatomical Board, RE: Inquiry on Anatomical Gifts (Jan. 23, 2018)(on file with staff in the House Health and Human Services Committee). Beginning in FY 14-15, the anatomical donations have been as follows: 393; 366; 342; 320 (projected).
[26] Id.
[27] Id. There is a projected shortage of at least 30 human remains for FY 2018-19.
[28] Id.
[29] AGENCY FOR HEALTH CARE ADMINISTRATION, *Facility/Provider Search* http://www.floridahealthfinder.gov/FacilityLocator/ListFacilities.aspx (last visited Jan. 22, 2018).

B. SECTION DIRECTORY:

Section 1: Amends s. 765.513(1), F.S., relating to donees of anatomical gifts.
Section 2: Provides an effective date.

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:

To the extent that nonsurgical training centers, as defined in the bill, currently purchase human remains through a NADO, the bill will have an indeterminate, positive impact. According to media reports, prices for human remains obtained through a NADO can range from $3,000 to $10,000.[30] The bill authorizes individuals to donate their human remains directly to a nonsurgical training center. This potentially reduces the number of human remains that a nonsurgical training center will have to purchase.

The bill may have an indeterminate, negative impact on medical and dental schools and other educational institutions that currently receive human remains from the Board. The Board charges these institutions $2,600 per body.[31] The Board is currently unable to meet the schools' demands for human remains, and with new medical schools and programs opening in the state, the Board expects this disparity to increase.[32] There are currently 308 hospitals which may own a facility or department that qualifies as a nonsurgical training center under the bill. This could potentially reduce the number of human remains that the Board receives. To the extent that this bill reduces the number of anatomical gifts the Board receives and distributes, these educational institutions may have to purchase human remains from other sources, the prices for which can range from $3,000 to $10,000 per body.[33]

D. FISCAL COMMENTS:

None.

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[30] *Supra* note 14.
[31] *Supra* note 25. *See also* ANATOMICAL BOARD OF THE STATE OF FLORIDA, *General Information,* http://anatbd.acb.med.ufl.edu/donor-packet/general-information/ (last visited Jan. 22, 2018). These costs are determined by the funeral home directors and not the Anatomical Board.
[32] Id. There is a projected shortage of at least 30 human remains for FY 2018-19.
[33] *Supra* note 14.

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

A bill to be entitled

An act relating to anatomical gifts; amending s. 765.513, F.S.; authorizing a nonprofit surgical training center to become a donee of anatomical gifts for education, research, or training purposes; defining the term "nonprofit surgical training center"; prohibiting a nonprofit surgical training center from providing an anatomical gift to another facility; providing an effective date.

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

Section 1. Subsection (1) of section 765.513, Florida Statutes, is amended, and subsection (2) is republished, to read:

765.513 Donees; purposes for which anatomical gifts may be made.—

(1) The following persons or entities may become donees of anatomical gifts of bodies or parts of them for the purposes stated:

(a) Any procurement organization or accredited medical or dental school, college, or university for education, research, therapy, or transplantation.

(b) Any individual specified by name for therapy or transplantation needed by him or her.

(c) The anatomical board or a nontransplant anatomical donation organization, as defined in s. 406.49, for donation of the whole body for medical or dental education or research.

(d) A nonprofit surgical training center for education, research, or training.

1. For purposes of this section, the term "nonprofit surgical training center" means a nonprofit facility or department, owned by a hospital licensed under chapter 395, which offers multidisciplinary learning opportunities, including continuing medical education courses.

2. A nonprofit surgical training center may not provide an anatomical gift to another facility.

(2) If multiple purposes are set forth in the document of gift but are not set forth in any priority order, the anatomical gift shall be used first for transplantation or therapy, if suitable. If the gift cannot be used for transplantation or therapy, the gift may be used for research or education.

Section 2. This act shall take effect July 1, 2018.

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 Quality Subcommittee

Representative La Rosa offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsections (15), (16), (17), (18), (19), (20), (21), (22), and (23) of section 765.511, Florida Statutes, are renumbered as subsections (16), (17), (18), (19), (20), (21), (22), (23), and (24), respectively, and subsection (15) is added to that section, to read:

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

(15) "Nonprofit surgical training center" means a nonprofit center that is owned by a statutory teaching hospital, as defined in s. 408.07(45), and that offers multidisciplinary learning opportunities, including a minimum of 100 certified

hours of continuing medical education each year which have been approved by the Board of Medicine or the appropriate regulatory board.

Section 2. Paragraph (d) is added to subsection (1) of section 765.513, Florida Statutes, to read:

765.513 Donees; purposes for which anatomical gifts may be made.—

(1) The following persons or entities may become donees of anatomical gifts of bodies or parts of them for the purposes stated:

(d) A nonprofit surgical training center if the center:

1. Does not provide human remains to another facility;

2. Contracts with a funeral director licensed under chapter 497 for the disposal and transportation of the human remains; and

3. Promotes its anatomical gift program only in the hospitals, nursing homes, or hospice programs that are wholly owned or controlled, directly or indirectly, by the same parent company that owns the nonprofit surgical training center.

Section 3. This act shall take effect July 1, 2018.

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

Remove everything before the enacting clause and insert:

An act relating to anatomical gifts; amending s. 765.511, F.S.; defining the term "nonprofit surgical training center"; amending s. 765.513, F.S.; authorizing a nonprofit surgical training center to become a donee of anatomical gifts for educational, research, or training purposes if it meets specified criteria; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1429 Dismemberment Abortion
SPONSOR(S): Grall and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1890

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		McElroy	McElroy
2) Judiciary Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Dilation and evacuation (D&E) abortions commonly involve the dismemberment of the fetus as part of the evacuation procedure. This dismemberment is performed on a living fetus unless the abortion provider has induced fetal demise prior to initiating the evacuation procedure. HB 1429 prohibits a physician from knowingly performing a dismemberment abortion. The bill defines a dismemberment abortion as:

> An abortion in which a person, with the purpose of causing the death of an fetus, dismembers the living fetus and extracts the fetus one piece at a time from the uterus through the use of clamps, grasping forceps, tongs, scissors, or a similar instrument that, through the convergence of two rigid levers, slices, crushes, or grasps, or performs any combination of those actions on, a piece of the fetus' body to cut or rip the piece from the body.

The bill provides an exception to this prohibition under certain circumstances if a dismemberment abortion is necessary to save the life of a mother and no other medical procedure would suffice for that purpose.

Any person who knowingly performs or actively participates in a dismemberment abortion commits a third degree felony. The bill exempts a woman upon whom a dismemberment abortion has been performed from prosecution for a conspiracy to violate this provision.

The bill does not prohibit an abortion that exclusively uses suction to dismember the body of a fetus by sucking pieces of the fetus into a collection container. The bill also does not prohibit a D&E in which fetal demise is accomplished prior to the dismemberment of the fetus.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Federal Case 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]

The Viability Standard

In *Roe v. Wade*, the U.S. Supreme Court established a rigid trimester framework dictating when, if ever, states can regulate abortion.[4] The Court held that states could not regulate abortions during the first trimester of pregnancy.[5] With respect to the second trimester, the Court held that states could only enact regulations aimed at protecting the mother's health, not the fetus's life. Therefore, no ban on abortions is permitted during the second trimester. The state's interest in the life of the fetus becomes sufficiently compelling only at the beginning of the third trimester, allowing it to prohibit abortions. Even then, the Court requires states to permit an abortion in circumstances necessary to preserve the health or life of the mother.[6]

The current viability standard is set forth in *Planned Parenthood v. Casey*.[7] Recognizing that medical advancements in neonatal care can advance viability to a point somewhat earlier than the third trimester, the U.S. Supreme Court rejected the trimester framework and, instead, limited the states' ability to regulate abortion pre-viability. Thus, while upholding the underlying holding in *Roe*, which authorizes states to "regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother[,]"[8] the Court determined that the line for this authority should be drawn at "viability," because "there may be some medical developments that affect the precise point of viability . . . but this is an imprecision within tolerable limits given that the medical community and all those who must apply its discoveries will continue to explore the matter."[9] Furthermore, the Court recognized that "[i]n some broad sense it might be said that a woman who fails to act before viability has consented to the State's intervention on behalf of the developing child."[10]

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[1] *Roe v. Wade*, 410 U.S. 113 (1973).
[2] *Id.*
[3] *Casey*, 505 U.S. 833 (1992).
[4] *Roe*, 410 U.S. 113 (1973).
[5] *Id.* at 163-64.
[6] *Id.* at 164-165.
[7] *Planned Parenthood of SE Pa. v. Casey*, 505 U.S. 833 (1992).
[8] *See Roe*, 410 U.S. at 164-65.
[9] *See Casey*, 505 U.S. at 870.
[10] *Id.*

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.[11] 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.[12] However, not every law, which makes the right to an abortion more difficult to exercise, is an infringement of that right.[13]

The Medical Emergency Exception

In *Doe v. Bolton*, the U.S. Supreme Court was faced with determining, among other things, whether a Georgia statute criminalizing abortions (pre- and post-viability), except when determined to be necessary based upon a physician's "best clinical judgment," was unconstitutionally void for vagueness for inadequately warning a physician under what circumstances an abortion could be performed.[14] In its reasoning, the Court agreed with the district court decision that the exception was not unconstitutionally vague, by recognizing that:

> [T]he medical judgment may be exercised in the light of all factors—physical, emotional, psychological, familial, and the woman's age-relevant to the well-being of the patient. All these factors may relate to health. This allows the attending physician the room he needs to make his best medical judgment.[15]

This broad interpretation of what constitutes a medical emergency was later tested in *Casey*[16], albeit in a different context. One question before the Supreme Court in *Casey* was whether the medical emergency exception to a 24-hour waiting period for an abortion was too narrow in that there were some potentially significant health risks that would not be considered "immediate."[17] The exception in question provided that a medical emergency is:

> [T]hat condition which, on the basis of the physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate abortion of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible impairment of a major bodily function.[18]

In evaluating the more objective standard under which a physician is to determine the existence of a medical emergency, the Court in *Casey* determined that the exception would not significantly threaten the life and health of a woman and imposed no undue burden on the woman's right to have an abortion.[19]

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[11] *Id.* at 878. See also *Whole Woman's Health v. Hellerstedt*, 136 S.Ct. 2292 (U.S. 2016)
[12] *Id.* at 877. See also *Whole Woman's Health v. Hellerstedt*, 136 S.Ct. 2292 (U.S. 2016)
[13] *Id.* at 873.
[14] *Doe*, 410 U.S. at 179 (1973). Other exceptions, such as in cases of rape and when, "[t]he fetus would very likely be born with a grave, permanent, and irremediable mental or physical defect." *Id.* at 183. *See also, U.S. v. Vuitich*, 402 U.S. 62, 71-72 (1971) (determining that a medical emergency exception to a criminal statute banning abortions would include consideration of the mental health of the pregnant woman).
[15] *Doe*, 410 U.S. at 192.
[16] *Casey*, 505. U.S. 833 (1992).
[17] *Id.* at 880.
[18] *Id.* at 879 (quoting 18 Pa. Cons. Stat. § 3203 (1990)).
[19] *Id.* at 880.

Partial Birth Ban

In 2003, Congress passed the Partial-Birth Abortion Ban Act (Act). The Act prohibits partial-birth abortions which it defines as an abortion in which the person performing the abortion:[20]

a. Deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and
b. Performs the overt act, other than completion of delivery, that kills the partially delivered living fetus.[21]

This prohibition applies to both pre-viability and post-viability abortions.[22]

The congressional purpose for the Act, besides maternal health, was to promote respect for human life and preserve the integrity of the medical profession. Congress expressed the prohibition was necessary to preserve the respect for the dignity of human life stating:[23]

> "Implicitly approving such a brutal and inhumane procedure by choosing not to prohibit it will further coarsen society to the humanity of not only newborns, but all vulnerable and innocent human life, making it increasingly difficult to protect such life."

Congress also expressed the prohibition was necessary to maintain the integrity of the medical profession stating:[24]

> "Partial-birth abortion ... confuses the medical, legal, and ethical duties of physicians to preserve and promote life, as the physician acts directly against the physical life of a child, whom he or she had just delivered, all but the head, out of the womb, in order to end that life."

In *Gonzales v. Carhart*, the U.S. Supreme Court was asked to determine, among other things, whether the Act created an undue burden on a woman's right to an abortion.[25] The plaintiffs argued that the Act created an undue burden because it banned second trimester abortions by prohibiting the most common second trimester method, dilation and evacuation.[26] The Court rejected this argument holding that the Act only prohibited an intended "intact" dilation and evacuation procedure on a living fetus.[27] It did not prohibit an "intact" dilation and evacuation that occurred either unintentionally or after fetal demise.[28] Additionally, it did not prohibit the standard dilation and evacuation procedure which entails dismemberment of the fetus.[29] The Court also held that the Act furthered legitimate congressional purposes of protecting the

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[20] 18 U.S. Code § 1531.
[21] The physician accomplishes fetal demise by piercing the fetal skull with scissors or crushing it with forceps. *Gonzales v. Carhart*, 127 S.Ct. 1610 (U.S. 2007).
[22] *Gonzales v. Carhart*, 127 S.Ct. 1610 (U.S. 2007).
[23] PL 108–105, November 5, 2003, 117 Stat 1201 notes to 18 U.S. Code § 1531.
[24] *Id.*
[25] Supra note 22. Plaintiffs' alleged that the Act was unconstitutional on its face and did not pursue a constitutional challenged based upon its actual impact on women or physicians.
[26] Supra note 22 at 1627.
[27] Supra note 22 at 1632.
[28] Supra note 22 at 1627.
[29] Supra note 22 at 1632.

integrity and ethics of the medical profession.[30] Thus, the Court found the Act did not create an undue burden on a woman's right to an abortion and was therefore constitutional.

Florida Law on Abortion

Right to Abortion

Florida affords greater privacy rights to its citizens than those provided under the U.S. Constitution. While the federal Constitution traditionally shields enumerated and implied individual liberties from state or federal intrusion, the Supreme Court has long held that the state constitutions may provide even greater protections.[31] In 1980, Florida amended its Constitution to include Article I, s. 23 which creates an express right to privacy:

> Every natural person has the right to be let alone and free from governmental intrusion into his 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. [32]

This amendment is an independent, freestanding constitutional provision which declares the fundamental right to privacy and provides greater privacy rights then those implied by the federal Constitution.[33]

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."[34] In *In re T.W.,* the Florida Supreme Court ruled that:

> [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 measures. [35]

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.[36]

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.[37] An abortion must be performed by a

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[30] *Supra note 22* at 1626.
[31] *In re T.W.*, 551 So.2d 1186, 1191 (Fla. 1989); citing *Pruneyard Shopping Center v. Robins*, 447 U.S. 74, 81, (U.S. 1980) ("Our reasoning ... does not ex proprio vigore limit the authority of the State to exercise its police power or its sovereign right to adopt in its own Constitution individual liberties more expansive than those conferred by the Federal Constitution."); *see also Cooper v. California*, 87 S.Ct. 788 (U.S. 1967).
[32] *Id.*
[33] *Id.* at 1191-92.
[34] *Id.* at 1192.
[35] *Id.* at 1193-94.
[36] *Id.* at 1194.
[37] Section 390.011(1), F.S.

physician[38] licensed under ch. 458, F.S., or ch. 459, F.S., or a physician practicing medicine or osteopathic medicine in the employment of the United States.[39]

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.[40] DOH and AHCA have authority to take licensure action against practitioners and clinics, respectively, which violate licensure statutes or rules.[41] Additionally, abortion providers are subject to criminal penalties for violation of certain statutes and rules.

Florida law prohibits abortions after viability, as well as during the third trimester, unless a medical exception exists. Section 390.01112(1), F.S., prohibits an abortion from being performed if a physician determines that, in reasonable medical judgment, the fetus has achieved viability. Viability is defined as the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.[42] Section 390.0111, F.S., prohibits an abortion from being performed during the third trimester.[43] Exceptions to both of these prohibitions exist if:

- Two physicians certify in writing that, in reasonable medical judgment, the termination of the pregnancy is necessary to save the pregnant woman's life or avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition; or
- One physician certifies in writing that, in reasonable medical judgment, there is a medical necessity for legitimate emergency medical procedures for termination of the pregnancy to save the pregnant woman's life or avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition, and another physician is not available for consultation.[44]

A physician must obtain informed and voluntary consent for an abortion from a woman before an abortion is performed, unless an emergency exists. Consent is considered voluntary and informed if the physician who is to perform the procedure, or the referring physician, orally and in person, informs the woman of the nature and risks of undergoing or not undergoing the proposed procedure and the probable gestational age of the fetus at the time the termination of pregnancy is to be performed.[45] The probable gestational age must be verified by an ultrasound.[46] The woman must be offered the opportunity to view the images and hear an explanation of them.[47] If the woman refuses this right, she must acknowledge the refusal in writing.[48] The woman must acknowledge, in writing and prior to the abortion, that she has been provided with all information consistent with these requirements.[49]

Florida law prohibits a physician from knowingly performing a partial-birth abortion.[50] However, there is an exception to this prohibition if the procedure is necessary to save the life of the mother and no other procedure would suffice.[51]

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[38] Section 390.0111(2), F.S.
[39] Section 390.011(8), F.S.
[40] Section 408.802(3) provides for the applicability of the Health Care Licensing Procedures Act to abortion clinics.
[41] Section 390.018, F.S.
[42] Section 390.011(12), F.S.
[43] Section 390.011(11), F.S., defines the third trimester to mean the weeks of pregnancy after the 24th week of pregnancy.
[44] Sections 390.0111(1)(a) and (b) and 390.01112(1)(a) and (b), F.S.
[45] Section 390.0111(3)(a), F.S. This requirement applies except in the case of a medical emergency.
[46] Section 390.0111(3)(a)1.b.II, F.S.
[47] Section 390.0111(3)(a)1.b.III, F.S.
[48] Section 390.0111(3)(a)(3), F.S.
[49] *Id.*
[50] Section 390.0111(5)(a), F.S.
[51] *Id.*

Any person who violates these abortion regulations commits a second degree felony.[52] Additionally, any health care practitioner who fails to comply with such laws is subject to disciplinary action under the applicable practice act and under s. 456.072, F.S.[53]

Florida Abortion Statistics

In 2016, there were 225,018 live births in the state of Florida.[54]

For the same year, AHCA reported that there were 69,770 abortion procedures performed in the state.[55] Of those performed:

- 64,342 (slightly more than 92%) were performed in the first trimester (12 weeks and under);
- 5,192 (slightly more than 7%) were performed in the second trimester (13 to 24 weeks); and
- None were performed in the third trimester (25 weeks and over). [56]

The majority of the procedures (64,578) were listed as "elective".[57] The remainder of the abortions were performed due to:

- Emotional or psychological health of the mother (77);
- Physical health of the mother that was not life endangering (74);
- Life endangering physical condition (17);
- Rape (295);
- Serious fetal genetic defect, deformity, or abnormality (494); and
- Social or economic reasons (4,471). [58]

Second Trimester Abortion Procedures

The majority of abortions are performed during the first trimester. Nationally, in 2014,[59] 652,639 abortions were reported to the Center for Disease Control and Prevention.[60] Only 9.5% were performed during the second trimester with 7.2% performed between 14-20 weeks gestation and 1.3% after 21 weeks gestation.[61] In 2016, approximately 7.4% of the 69,770 abortions performed in Florida occurred during the second trimester.[62]

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[52] Section 390.0111(10)(a), F.S.

[53] Section 390.0111(13), F.S. The Department of Health and its professional boards regulate health care practitioners under ch. 456, F.S., and various individual practice acts. The range of disciplinary actions taken by a board includes citations, suspensions, reprimands, probations, and revocations.

[54] Ten-Year Live Birth Chart, Florida Department of Health, Bureau of Vital Statistics, available at http://www.flhealthcharts.com/charts/DataViewer/BirthViewer/TenYrsRpt.aspx?q=yNeb4i2no42x4Dcd1WE%2fkn56IlkXT75npe3ytPSLMHO6oavuZ454%2fKiGggs7ymAs (last visited January 22, 2018).

[55] Section 390.0112(1), F.S., requires the director of any medical facility in which any pregnancy is terminated to submit a monthly report to AHCA that 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 during or immediately after an attempted abortion.

[56] Reported Induced Terminations of Pregnancy (ITOP) by Reason, By Weeks of Gestation for Calendar Year 2016, AHCA, available at http://ahca.myflorida.com/MCHQ/Central_Services/Training_Support/docs/ReasonGestationYTD_2016.pdf (last visited on January 22, 2018).

[57] *Id.*

[58] *Id.*

[59] This is the most recent report for national abortion statistics.

[60] *Abortion Surveillance - United States, 2014*, Surveillance Summaries, Centers for Disease Control and Prevention, November 24, 2017 / 66(24);1–48, available at https://www.cdc.gov/mmwr/volumes/66/ss/ss6624a1.htm?s_cid=ss6624a1_w (last visited on January 22, 2018).

[61] *Id.*

[62] Reported Induced Terminations of Pregnancy (ITOP) by Reason, By Weeks of Gestation for Calendar Year 2016, AHCA, available at http://ahca.myflorida.com/MCHQ/Central_Services/Training_Support/docs/ReasonGestationYTD_2016.pdf (last visited on January 22, 2018).

The 4 types of abortion procedures performed during the second trimester consist of dilation and evacuation, labor induction[63], hysterotomy[64] and hysterectomy[65]. Labor induction abortions represent approximately 2% of second trimester abortions.[66] Hysterotomy and hysterectomy abortions are generally only used in emergency situations[67] and combined represent less than 1% of all second trimester abortions.[68]

Dilation and Evacuation

The most common second trimester abortion procedure is an outpatient surgical procedure known as dilation and evacuation (D&E).[69] The process begins with the verification of the gestational age of the fetus through ultrasound. The next step is dilation of the cervix which is accomplished through insertion of osmotic dilators[70] into the woman's cervix.[71] Osmotic dilators expand when exposed to fluid and continue to expand and dilate the cervix until they are removed or reach their maximum size. The length of time the osmotic dilators remain in the cervix varies by patient and can be as little as a few hours or as long as 48 hours. Physicians may also utilize drugs, such as misoprostol, in conjunction with the osmotic dilators to accelerate the dilation of the cervix.[72]

The surgical component of the D&E begins once the cervix has been sufficiently dilated. The physician starts by inserting grasping forceps through the cervix and into the uterus, usually with ultrasound guidance.[73] The physician grips the fetus with the forceps and pulls until a portion of the fetus tears free and can be removed through the cervix.[74] This dismemberment process is repeated until the entire fetal body has been removed.[75] The remainder of fetal tissue and placenta are then suctioned or scraped out of the uterus.[76] The physician then examines the fetal remains to ensure the entire fetal body has been removed.[77] This procedure is generally completed in approximately 30 minutes.[78]

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[63] Labor induction abortion is the expulsion of a second or third trimester fetus from the uterus without instrumentation. Fetal demise is generally accomplished prior to labor induction through the injection of a pharmacological agent such as digoxin or potassium chloride. Medication used for inducing labor include, among others, misoprostol, mifepristone, gemeprost, ethacridine lactate and high-dose oxytocin. *Clinical Guidelines: Labor Induction Abortion in the Second Trimester*, Society of Family Planning, Contraception 84 (2011) 4–18, available at http://www.contraceptionjournal.org/article/S0010-7824(11)00057-6/fulltext#s0065 (last viewed January 22, 2018).

[64] A hysterotomy abortion is accomplished through a physician making an incision in the woman's abdomen, similar to a cesarean section, and removing the fetus from the uterine cavity. *Gonzales v. Carhart*, 127 S.Ct. 1610, 1623 (U.S. 2007).

[65] A hysterectomy is the surgical removal of the uterus. *Hysterectomy, Frequently Asked Questions*, The American College of Obstetricians and Gynecologists, available at https://www.acog.org/Patients/FAQs/Hysterectomy#what (last viewed January 22, 2018).

[66] *Clinical Guidelines: Labor Induction Abortion in the Second Trimester*, Society of Family Planning, L. Borgatta and N.Kapp, Contraception 84 (2011) 4–18, available at http://www.contraceptionjournal.org/article/S0010-7824(11)00057-6/fulltext#s0065 (last viewed January 22, 2018).

[67] Supra note 22 at 1621.

[68] Supra note 60.

[69] Dilation and evacuation procedures are used for 96% of abortions performed during the second trimester. Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care, National Abortion Federation, M. Paul, E. Lichtenberg, D. Grimes, P. Stubblefield and M. Creinin, 2009.

[70] Common osmotic dilators include laminaria (Japanese seaweed), lamicel (dry polyvinyl alcohol sponges impregnated with magnesium sulfate) and dilapan devices (synthetic, hydroscopic polyacrylonitrile rod-shaped dilators). Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care, National Abortion Federation, M. Paul, E. Lichtenberg, D. Grimes, P. Stubblefield and M. Creinin, 2009.

[71] Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care, National Abortion Federation, M. Paul, E. Lichtenberg, D. Grimes, P. Stubblefield and M. Creinin, 2009.

[72] *Id.*

[73] Supra note 22.

[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] Dilation and Evacuation (D&E), Michigan Department of Health and Human Services, available at http://www.michigan.gov/mdhhs/0,5885,7-339-73971_4909_6437_19077-46298--,00.html (last viewed on January 22, 2018).

Fetal Demise Prior to Abortion

When a D&E is performed, fetal demise is caused by exsanguination or other bodily reactions to the evacuation of the woman's uterus. However, there are methods of causing fetal demise prior to the evacuation. The three most common procedures to accomplish fetal demise are intra-fetal or intra-amniotic injection of digoxin, intra-cardiac or intra-umbilical injection of potassium chloride and transection of the umbilical cord.[79] The goal of each of these procedures is to terminate fetal cardiac activity.

Digoxin

Digoxin is the most common pharmacological agent used to accomplish fetal demise amongst abortion providers who induce fetal demise prior to abortion.[80] Abortion providers administer the digoxin through either a transvaginal or transabdominal injection into the amniotic sac or fetal body.[81] Digoxin decreases the conduction of electrical impulses in the atrioventricular node ultimately resulting in fetal cardiac arrest.[82] The rate of fetal demise varies from a few minutes for an intra-cardiac injection[83] to over 24 hours for an intra-amniotic injection.[84] The abortion provider confirms the fetal demise through ultrasound, generally a day or two after the injection, and performs the abortion. The most common side effects are vomiting, pain from the injection and labor and delivery of the fetus prior to the scheduled abortion.[85]

Potassium Chloride

Potassium chloride is commonly used to accomplish fetal demise for multifetal pregnancy reduction or termination of an abnormal fetus.[86] A physician administers potassium chloride through a transabdominal injection into the fetal heart or umbilical cord.[87] Potassium chloride disrupts the balance of intra- and extracellular potassium ions causing the heart rate to slow until cardiac arrests occurs, generally within minutes of the injection.[88]

This procedure requires a highly skilled physician due to the technically challenging nature of the injection.[89] Errors in conducting the injection caused serious adverse outcomes in two cases. There was one case of maternal cardiac arrest after the unintentional injection of potassium chloride into the woman's bloodstream.[90] There was also one case of sepsis after an umbilical cord injection.[91] Neither case resulted in maternal fatality.[92]

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[79] *Induction of Fetal Demise Before Abortion*, Society of Family Planning, J. Diedrich and E. Drey, Contraception 81 (2010) 462-473, available at https://www.societyfp.org/_documents/resources/InductionofFetalDemise.pdf (last viewed January 22, 2018).
[80] *Id.*
[81] *Feasibility, Effectiveness and Safety of Transvaginal Digoxin Administration Prior to Dilation and Evacuation*, A. Sridhar, C. Kim, E. Forbes and A. Chen, Contraception, Vol. 90, Issue 3, September 2014, available at http://www.contraceptionjournal.org/article/S0010-7824(14)00371-0/pdf (last viewed January 22, 2018). This is commonly performed with ultrasound guidance, although an amniotic injection can be performed either without this guidance.
[82] Supra note 71.
[83] *Id.*
[84] Supra note 79. The skill level required to perform this procedure also varies with intra-amniotic injections requiring the least skill and intra-cardiac injections requiring the most.
[85] Supra note 79.
[86] Supra note 71.
[87] Supra note 79.
[88] *Id.*
[89] Supra note 71.
[90] *Potassium Chloride-Induced Fetal Demise: A Retrospective Cohort Study of Efficacy and Safety*, A. Sfakianaki, K. Davis, J. Copel, N. Stanwood and H. Lipkind, Ultrasound Med. 2014 Feb;33(2):337-41, available at http://onlinelibrary.wiley.com/doi/10.7863/ultra.33.2.337/full (last viewed January 22, 2018).
[91] *Id.*
[92] *Maternal Cardiac Arrest Associated with Attempted Fetal Injection of Potassium Chloride,* International Journal of Obstetric Anesthesia, A. Sfakianaki, K.Davis, J. Copel, N. Stanwood and H. Lipkind, 2004;Vol. 13; Issue 4; 287-290, available at http://www.obstetanesthesia.com/article/S0959-289X(04)00073-1/fulltext (last viewed on January 22, 2018)(Prompt institution of

Transection of Umbilical Cord

Transection of the umbilical cord is the least common method for inducing fetal demise prior to an abortion. The procedure consists of an abortion provider dilating the woman's cervix and then transecting the umbilical cord.[93] Fetal cardiac activity ceases shortly thereafter.

Use of Pre- D&E Fetal Demise Techniques

There is limited comparative research on the medical benefit of inducing fetal demise prior to performing abortion procedures as compared to only performing the abortion procedure. The results of the available research conflict and are primarily based upon retrospective case studies rather than randomized controlled tests.[94] Currently, practice guidelines do not recommend against fetal demise prior to abortion but instead note the lack of supporting evidence and need for additional research.[95] Thus, medical professionals induce fetal demise prior to abortion in circumstances they deem appropriate.

Fetal demise is induced prior to a second trimester abortion for a variety of reasons. Physicians may prefer fetal demise for medical reasons such as reducing the time of the abortion procedure or reducing the number of fetuses in a multiple gestation pregnancy.[96] Physicians may also prefer inducing fetal demise to ensure compliance with the federal Partial-Birth Abortion Ban Act of 2003 and any related state laws.[97] Additionally, patients may prefer fetal demise prior to abortion.[98]

Dismemberment Abortion Ban

D&Es commonly involve the dismemberment of the fetus as part of the evacuation procedure. This dismemberment is performed on a living fetus unless the abortion provider has induced fetal demise prior to initiating the evacuation procedure. Eight states[99] have enacted laws prohibiting physicians from performing a dismemberment abortion on a living fetus. Dismemberment abortions are generally defined as:

> An abortion in which a person, with the purpose of causing the death of an unborn child, dismembers the unborn child and extracts the unborn child one piece at a time from the uterus through the use of clamps, grasping forceps, tongs, scissors, or a similar instrument that, through the convergence of two rigid levers, slices, crushes, or grasps, or performs any combination of those actions on, a piece of the unborn child's body to cut or rip the piece from the body.

An abortion that exclusively uses suction to dismember the body of a fetus by sucking pieces of the fetus into a collection container is not considered a dismemberment abortion. Further, the prohibition does not extend to an abortion in which fetal demise has been induced prior to dismemberment.

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maternal cardiac life-support protocols resulted in successful maternal resuscitation); *Sepsis due to Clostridium perfringens after Pregnancy Termination with Feticide by Cordocentesis: A Case Report*, S.V. Li Kim Mui, M.C. Boulanger, L Maisonneuve, L. Choudat and P. de Bievre, Fetal Diagn. Ther. 2002;17:124–126, available at https://www.karger.com/Article/Abstract/48022 (last viewed January 22, 2018) (mother recovered under broad-spectrum antibiotherapy).

[93] Supra note 79.

[94] *Id.*

[95] *Id.* ("The Society of Family Planning 2010 Clinical Guideline reviewed these data and concluded that there was inadequate evidence to recommend inducing fetal demise to increase the safety of D&E, although they did not recommend against it; the American College of Obstetricians and Gynecologists, in its 2013 Practice Bulletin on Second-Trimester Abortion, likewise merely reiterates the absence of supporting evidence.")

[96] Supra note 90.

[97] *Id.*

[98] A study performed in 2001 determined that 91% of test subjects preferred fetal demise prior to abortion. *Digoxin to Facilitate Late Second-Trimester Abortion: A Randomized, Masked, Placebo-Controlled Trial*, R. Jackson, V. Teplin, E. Drey and P. Darney, Obstet Gynecol. 2001 Mar; 97(3):471-6, https://www.ncbi.nlm.nih.gov/pubmed/11239659 (last viewed on January 22, 2018).

[99] Alabama, Arkansas, Kansas, Louisiana, Mississippi, Oklahoma, Texas and West Virginia.

Legal challenges to these laws have been brought in six states.[100] A temporary injunction has been issued prohibiting the enforcement of these laws in each of those states. Each state has filed an appeal which are currently pending in various federal and state courts. The laws were not challenged in two states, Mississippi and West Virginia, so the prohibition remains in effect in those states.

Effect of Proposed Changes

HB 1429 prohibits a physician from knowingly performing a dismemberment abortion while performing a D&E. The bill defines a dismemberment abortion as:

> An abortion in which a person, with the purpose of causing the death of an fetus, dismembers the living fetus and extracts the fetus one piece at a time from the uterus through the use of clamps, grasping forceps, tongs, scissors, or a similar instrument that, through the convergence of two rigid levers, slices, crushes, or grasps, or performs any combination of those actions on, a piece of the fetus' body to cut or rip the piece from the body.

The bill provides an exception to this prohibition under certain conditions if a dismemberment abortion is necessary to save the life of a mother under if no other medical procedure would suffice for that purpose.

Any person who knowingly performs or actively participates in a dismemberment abortion commits a third degree felony[101]. The bill exempts a woman upon whom a dismemberment abortion has been performed from prosecution for a conspiracy to violate this provision.

The bill does not prohibit an abortion that exclusively uses suction to dismember the body of a fetus by sucking pieces of the fetus into a collection container. The bill also does not prohibit a D&E in which fetal demise is accomplished prior to the dismemberment of the fetus.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 390.011, F.S., relating to definitions.
Section 2: Amends s. 390.0111, F.S., relating to termination of pregnancies.
Section 3: Provides for an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

[100] Legal challenges have been filed in Alabama - *West Alabama Women's Center v. Miller*; Arkansas - *Hopkins, M.D., M.P.H. v. Jegley*; Kansas - *Hodes v. Schmidt*; Louisiana - *June Medical Services, LLC et al. v. Gee*; Oklahoma - *Nova Health Systems v. Pruitt*; and, Texas - *Whole Woman's Health v. Paxton.*

[101] A third degree felony is punishable by up to 5 years in prison and up to a $5,000 fine. Sections 775.082-.083, F.S.

B.

FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may have indeterminate, negative fiscal impact on women seeking abortions if the physician performs a D&E with fetal demise prior to evacuation as an alternative to the dismemberment abortion. The particular method of fetal demise selected by the abortion provider could result in the woman having to visit the abortion clinic on more than one occasion. For example, fetal demise by injection of digoxin into the amniotic sac may potentially require one visit for the injection (fetal death usually occurs within 24 hours) and a second visit for the abortion provider to evacuate the fetus from the woman's uterus. Alternatively, fetal demise by injection into the fetal heart could potentially require only a single visit (fetal death usually occurs within a few minutes of the injection). However, currently a D&E without fetal demise can require the woman to visit the abortion provider more than once (one trip to dilate and one to evacuate) so a cost increase seems unlikely.

The fetal demise procedure itself may also increase the cost of the abortion.

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:

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

A bill to be entitled

An act relating to dismemberment abortion; amending s. 390.011, F.S.; defining the term "dismemberment abortion"; amending s. 390.0111, F.S.; prohibiting dismemberment abortion; providing an exception; providing penalties; providing an effective date.

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

Section 1. Subsections (6) through (13) of section 390.011, Florida Statutes, are renumbered as subsections (7) through (14), respectively, and a new subsection (6) is added to that section to read:

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

(6) "Dismemberment abortion" means an abortion in which a person, with the purpose of causing the death of a fetus, dismembers the living fetus and extracts the fetus one piece at a time from the uterus through the use of clamps, grasping forceps, tongs, scissors, or a similar instrument that, through the convergence of two rigid levers, slices, crushes, or grasps, or performs any combination of those actions on, a piece of the fetus' body to cut or rip the piece from the body. The term does not include an abortion that uses suction to dismember the body of a fetus by sucking pieces of the fetus into a collection container.

Section 2. Subsections (6) through (15) of section 390.0111, Florida Statutes, are renumbered as subsections (7) through (16), respectively, a new subsection (6) is added to that section, and present subsection (10) of that section is amended, to read:

390.0111 Termination of pregnancies.—

(6) DISMEMBERMENT ABORTION PROHIBITED; EXCEPTION.—

(a) No physician shall knowingly perform a dismemberment abortion.

(b) A woman upon whom a dismemberment abortion is performed may not be prosecuted under this section for a conspiracy to violate the provisions of this section.

(c) This subsection does not apply to a dismemberment abortion that is necessary to save the life of a mother whose life is endangered by a physical disorder, illness, or injury, provided that no other medical procedure would suffice for that purpose.

(11) ~~(10)~~ PENALTIES FOR VIOLATION.—Except as provided in subsections (3), (8) ~~(7)~~, and (13) ~~(12)~~:

(a) Any person who willfully performs, or actively participates in, a termination of pregnancy in violation of the requirements of this section or s. 390.01112 commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) Any person who performs, or actively participates in,

a termination of pregnancy in violation of this section or s. 390.01112 which results in the death of the woman commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 3. This act shall take effect July 1, 2018.