Health Quality Subcommittee

Wednesday, March 15, 2017
9:00 AM – 12:00 PM
Mashburn Hall (306 HOB)

Richard Corcoran
Speaker

Cary Pigman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time:	Wednesday, March 15, 2017 09:00 am
End Date and Time:	Wednesday, March 15, 2017 12:00 pm
Location:	Mashburn Hall (306 HOB)
Duration:	3.00 hrs

Consideration of the following bill(s):

HB 249 Drug Overdoses by Rommel, Gruters
HB 723 Maintenance of Certification by Gonzalez, Massullo
HB 963 Newborn Screenings by Fitzenhagen
HB 969 Pregnancy Support Services by Toledo
HB 1037 Optometry by Diaz, M.
HB 1041 Laboratory Screening by Raschein

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, March 14, 2017.

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, March 14, 2017.

NOTICE FINALIZED on 03/13/2017 2:37PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 249 Drug Overdoses
SPONSOR(S): Rommel and others
TIED BILLS: **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

Drug overdose is now the leading cause of injury-related death in the United States. In Florida, 3,228 people died of a drug overdose in 2015.

Currently, health care providers are not required by law to report to law enforcement when they treat or attend, or are requested to treat or attend a patient who may have overdosed on a controlled substance.

HB 249 creates s. 893.22, F.S., which requires health care providers to report controlled substances overdoses. The reporting requirement applies to physicians, nurses, paramedics, emergency medical technicians, health care workers, and employees of these professionals. It also applies to any employee of a hospital, sanatorium or other institution or provider. If any of these specified individual knowingly attends, treats, or is requested to attend or treat a person who has an overdose of a controlled substance as listed in s. 893.03, F.S., they are required to make a report to law enforcement within 24 hours or face criminal penalties.

The bill requires the report to be filed with the county sheriff or chief law enforcement officer of the county within 24 hours. However, the sheriff or chief law enforcement office may designate or partner with another agency, such as the medical examiner, to receive, store, and manage these reports, which must be maintained for five years.

Additionally, the law enforcement officer who receives these reports may share the general data, other than any data about criminal charges, with health care professionals and the county health department. Each county health department must then make semi-annual reports to the Statewide Drug Policy Advisory Council that summarizes the data it receives from law enforcement. The Council may use the reports to maximize the utilization of funding programs for substance abuse treatment services.

The bill will have a significant negative fiscal impact on the Department of Health.

The bill provides an effective date of October 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Substance Abuse

Substance abuse refers to the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs.[1] Substance abuse disorders occur when the chronic use of alcohol or drugs causes significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.[2] Repeated drug use leads to changes in the brain's structure and function that can make a person more susceptible to developing a substance abuse disorder.[3] Brain imaging studies of persons with substance abuse disorders show physical changes in areas of the brain that are critical to judgment, decision making, learning and memory, and behavior control.[4]

According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, a diagnosis of substance abuse disorder is based on evidence of impaired control, social impairment, risky use, and pharmacological criteria.[5] The most common substance abuse disorders in the United States are from the use of alcohol, tobacco, cannabis, stimulants, hallucinogens, and opioids.[6]

Opioid Abuse

Opioids are commonly abused, with an estimated 15 million people worldwide suffering from opioid dependence.[7] Drug overdose is now the leading cause of injury-related death in the United States.[8] In 2015, Florida ranked fourth in the nation with 3,228 deaths from drug overdoses[9], and at least one opioid caused 2,530 of those deaths.[10] Statewide, in 2015, heroin caused 733 deaths, fentanyl caused 705, oxycodone caused 565, and hydrocodone caused 236; deaths caused by heroin and fentanyl increased more than 75% statewide when compared with 2014.[11]

Drug overdose deaths doubled in Florida from 1999 to 2012.[12] Over the same time period, drug overdose deaths occurred at a rate 13.2 deaths per 100,000 persons.[13] The crackdown on "pill mills" dispensing prescription opioid drugs, such as oxycodone and hydrocodone, reduced the rate of death

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[1] WORLD HEALTH ORGANIZATION. *Substance Abuse*, http://www.who.int/topics/substance_abuse/en/ (last visited March 13, 2017).
[2] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, *Substance Use Disorders,* available at: http://www.samhsa.gov/disorders/substance-use (last visited March 13, 2017).
[3] NATIONAL INSTITUTE ON DRUG ABUSE, *Drugs, Brains, and Behavior: The Science of Addiction*, available at: https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-abuse-addiction (last visited March 1, 2017).
[4] Id.
[5] Supra, note 2.
[6] Id.
[7] WORLD HEALTH ORGANIZATION, *Information Sheet on Opioid Overdose*, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited March 13, 2107).
[8] TRUST FOR AMERICA'S HEALTH, *The Facts Hurt: A State-by-State Injury Prevention Policy Report 2015,* available at: http://healthyamericans.org/reports/injuryprevention15/ (last visited March 11, 2017).
[9] CENTERS FOR DISEASE CONTROL AND PREVENTION, *Drug Overdose Death Data*, available at: https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited March 11, 2017).
[10] FLORIDA DEPARTMENT OF LAW ENFORCEMENT. *Drugs Identified in Deceased Persons by Florida Medical Examiners-2015 Annual Report,* available at: https://www.fdle.state.fl.us/cms/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2015-Annual-Drug-Report.aspx (last visited on March 11, 2017).
[11] Id. at pg. 3.
[12] FLORIDA DEPARTMENT OF HEALTH, *Special Emphasis Report: Drug Poisoning (Overdose) Deaths, 1999-2012*, available at: http://www.floridahealth.gov/statistics-and-data/florida-injury-surveillance-system/_documents/CDC-Special-Emphasis-Drug-poisoning-overdose-1999-2012-B-Poston-FINAL.pdf (last visited on March 11,2017).
[13] Id.

attributable to prescription drugs,[14] but may have generated a shift to heroin use, contributing to the rise in heroin addiction.[15]

Emergency Response to Overdose

Opioid overdose can occur when an individual deliberately misuses a prescription opioid or an illicit drug such as heroin.[16] It can also occur when a patient takes an opioid as directed, but the prescriber miscalculated the opioid dose, an error was made by the dispensing pharmacist, or the patient misunderstood the directions for use.[17] Opioid overdose is life threatening and requires immediate emergency attention.[18]

To treat an opioid overdose, emergency personnel or a physician may administer an opioid antagonist such as Narcan or Nalaxone. An opioid antagonist is a drug that blocks the effects of exogenously administered opioids. Opioid antagonists are used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally.[19] This occurs because opioid antagonists create a stronger bond with opioid receptors than opioids. This forces the opioids from the opioid receptors and allows the transmission of signals for respiration to resume.[20]

From 2004 through 2009, emergency department visits nationally involving the nonmedical use of pharmaceuticals increased 98.4%, from 627,291 visits to 1,244,679 visits.[21] In 2009, almost one million emergency room visits nationally involved illicit drugs, either alone or in combination with other drugs.[22] From 2008 to 2011, about half of all emergency department visits nationally for both unintentional and self-inflicted drug poisoning involved drugs in the categories of analgesics[23], antipyretics[24], and antirheumatics[25] or sedatives, hypnotics, tranquilizers, and other psychotropic agents.[26]

Opiates or related narcotics, including heroin and methadone, accounted for 14% of emergency department visits nationally for unintentional drug poisoning from 2008 to 2011.[27] In Florida, there were approximately 21,700 opioid-related emergency department visits in 2014.[28]

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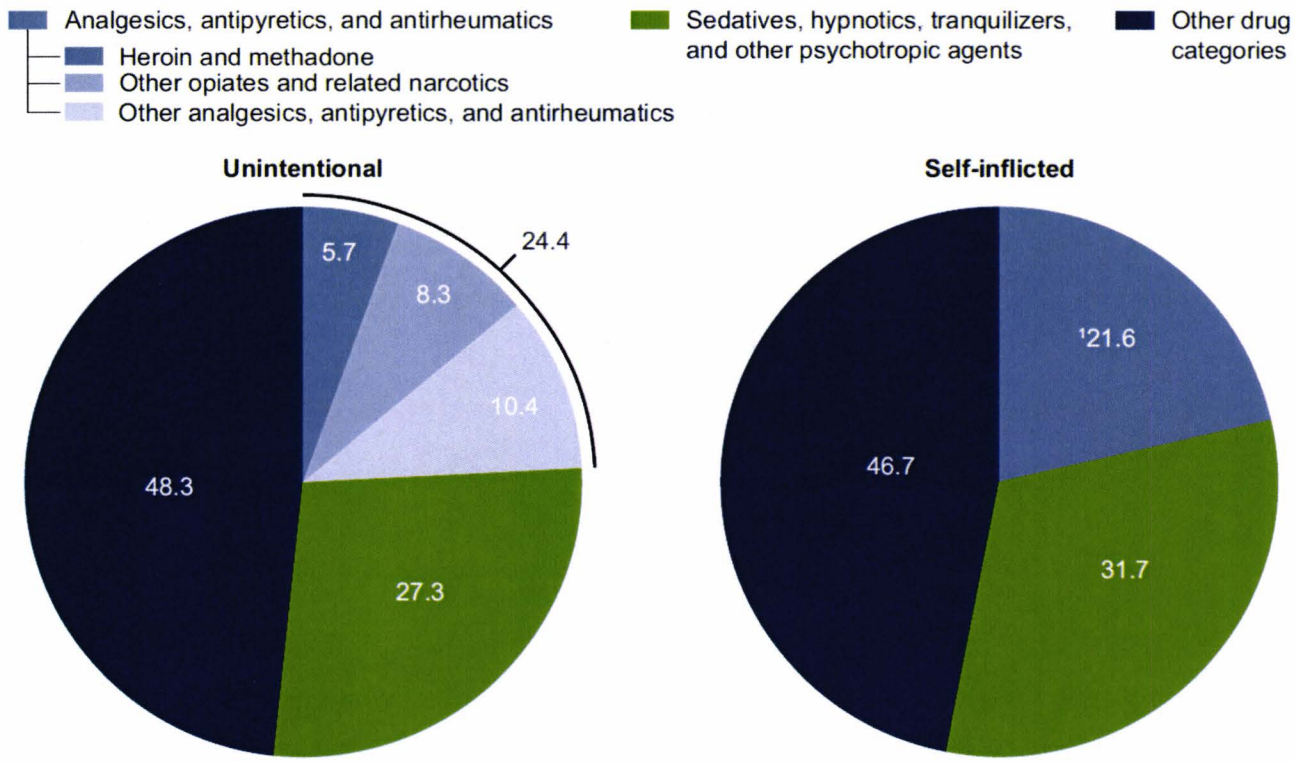
[14] *Supra*, note 10.
[15] WORLD HEALTH ORGANIZATION. *Substance Abuse*, http://www.who.int/topics/substance_abuse/en/ (last visited March 10, 2017).
[16] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, *Opioid Overdose Prevention Toolkit*, Rev. 2016, *available at*, http://store.samhsa.gov/shin/content//SMA16-4742/SMA16-4742.pdf (last visited March 13, 2017).
[17] Id.
[18] Id.
[19] HARM REDUCTION COALITION, *Understanding Naloxone,* http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/ (last visited 2/27/15).
[20] HARM REDUCTION COALITION, *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects*, Fall 2012. http://harmreduction.org/our-work/overdose-prevention/ (last visited 2/27/15).
[21] NATIONAL INSTITUTE ON DRUG ABUSE, *Drug-Related Hospital Emergency Room Visits,* available at: https://www.drugabuse.gov/publications/drugfacts/drug-related-hospital-emergency-room-visits (last visited March 9, 2017).
[22] Id.
[23] Analgesics are drugs that produce insensibility to pain.
[24] Antipyretics are drugs that reduce fever.
[25] Antirheumatics are drugs that alleviate or prevent inflammation or pain in muscles, joints, or fibrous tissue.
[26] Albert, M. et al. *Emergency Department Visits for Drug Poisoning: United States, 2008–2011*, NCHS Data Brief No. 196, April 2015, available at: https://www.cdc.gov/nchs/data/databriefs/db196.htm
[27] Id.
[28] Weiss, A.J., et al., *Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-20014*, HCUP Statistical Brief #219, January 2017, available at: https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf (last visited March 13, 2017).

Percentage of Emergency Department Visits for Drug Poisoning, By Intent and Drug Category: United States, 2008–2011[29]



SOURCE: CDC/NCHS, National Hospital Ambulatory Medical Care Survey, 2008–2011.

Privacy Rights of Individuals Receiving Substance Abuse Treatment

Florida Protections

Section 397.501, F.S., establishes statutory rights for individuals receiving substance abuse services, including the right to dignity, non-discriminatory services, quality services, confidentiality, counsel and habeas corpus. In particular, s. 397.501(7), F.S. prohibits service providers from disclosing records containing the identity, diagnosis, and prognosis of and services provided to any individual without written consent of the individual, with certain exceptions.[30] The law makes service providers who violate these rights liable for damages, unless acting in good faith, reasonably, and without negligence.

Federal Protections of Personal Health Information

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information. Privacy rules were initially issued in 2000 by the U.S. Department of Health and Human Services and later modified in 2002.[31] The rules address the use and disclosure of an individual's personal health information and create standards for information security. Only certain entities, "covered entities", are subject to HIPAA's provisions. Covered entities are obligated to meet HIPAA's

[29] Id.
[30] Disclosure is permitted to: health service providers in cases of medical emergency if the information is necessary to provide services to the individual; DCF for the purposes of scientific research; comply with state-mandated child abuse and neglect reporting; comply with a valid court order; report crimes that occur on program premises or against staff; federal, state or local governments for audit purposes; or third party payors providing financial assistance or reimbursement.
[31] UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *The Privacy Rule,* available at http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/ (last visited on March 13, 2017).

requirements to ensure privacy and confidentiality personal health information. These "covered entities" include:[32]

- Health plans;
- Health care providers;
- Health care clearinghouses; and
- Business associates of any of the above.

Additionally, federal law restricts the disclosure of alcohol and drug patient records maintained by federally assisted alcohol and drug abuse programs which identify a patient as an alcohol or drug abuser.[33] Disclosure of patient-identifying information is permitted in certain cases and patients may consent in writing to the disclosure of such information.[34]

Statewide Drug Policy Advisory Council

In 1999, the Legislature created the Office of Drug Control and the Drug Policy Advisory Council[35] in the Executive Office of the Governor, which the Legislature replaced with the Statewide Drug Policy Advisory Council (the Council)[36] under the Florida Department of Health (DOH) in 2011. Among other things, the Council submits a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives with recommendations.[37]

The Council's 2016 Annual Report concluded that a key problem in combating drug overdoses Florida is that there is "no sustainable process to compile massive amounts of data and information, perform analysis and develop an evidence-based call to action" as a.[38] To improve data collection and surveillance, the Council recommends that DOH collaborate with other agencies, organizations, and institutions to create a comprehensive statewide strategy addressing the fentanyl and heroin overdoses in the state.[39]

DOH Data Systems

Florida Injury Surveillance Data System

DOH's Injury Surveillance Data System is a passive data reporting mechanism that utilizes data resources from other agencies and systems, including:

- Vital records (death certificates);
- Hospital discharge data;
- Emergency department discharge data;
- Motor vehicle crash records;
- Behavioral Risk Factor Surveillance System;
- Youth Risk Behavior Surveillance System;
- Child Death Review;
- Uniform Crime Reporting System; and

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[32] UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *For Covered Entities and Business Associates*, available at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/ (last visited on March 13, 2017).
[33] 42 CFR Part 2.
[34] Disclosure is allowed to comply with state-mandated child abuse and neglect reporting; to report the cause of death; to comply with a valid court order; in cases of medical emergency; to report crimes that occur on program premises or against staff; to entities having administrative control; to qualified service organizations and to outside auditors, evaluators, central registries, and researchers.
[35] Section 397.332, F.S., created by s. 3, ch. 99-187, Law s of Fla.
[36] Section 397.333, F.S., created by s. 8, ch. 2011-51, Laws of Fla.
[37] Section 397.333(3), F.S.
[38] FLORIDA DEPARTMENT OF HEALTH, *Statewide Drug Policy Advisory Council 2016 Annual Report*, (Dec. 1, 2016), p. 4, *available at*, http://www.floridahealth.gov/provider-and-partner-resources/dpac/DPAC-Annual-Report-2016-FINAL.pdf (last visited March 13, 2017).
[39] Id. at 14.

- Emergency medical services.[40]

The Injury Surveillance Data System is used to monitor the frequency of fatal and non-fatal injuries, determine the risk factors for these injuries, evaluate the completeness, timeliness, and quality of data sources, provide information to Florida's injury prevention community for program planning and evaluation, and provide a foundation for injury prevention strategies.[41] One of the injury mechanisms it receives information on is poisoning, which includes drug overdoses;[42] however it is not currently set up to actively receive data regarding overdoses, or any other injury mechanism.[43]

Emergency Medical Services Tracking and Reporting System (EMSTARS)

DOH maintains[44] the Emergency Medical Services Tracking and Reporting System (EMSTARS) to ensure an optimal, uniform and standard of prehospital emergency medical care statewide.[45] This system provides for the collection and analysis of incident level data from EMS agencies for benchmarking and quality improvement initiatives.[46] Participation in the EMSTARS system, and the transmission of electronic incident level data from EMS Providers[47] to DOH, is voluntary.[48] However, the complete provision of incident level data, and full participation in the EMSTARS Program, fulfills EMS Provider prehospital reporting requirements in rule 64J-1.014(1), F.A.C. The data collected by EMSTARS includes:

- All NHTSA "national" data elements for demographic data and EMS event data;
- Other selected elements identified by participants and other stakeholders;
- Demographic elements for the provider agency, its personnel, and patients;
- Incident and unit times;
- Situation and scene information;
- Patient care information including vital signs, injury assessment, trauma score, and intervention and procedural information; and
- Outcome and disposition information.[49]

Additionally, EMSTARS collects minimal data elements for overdoses, especially if EMS administers an opioid antagonist.[50]

The electronic patient care records submitted by licensed EMS agencies to EMSTARS are confidential and exempt pursuant to s. 401.30(4), F.S.

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[40] FLORIDA DEPARTMENT OF HEALTH, *Florida Injury Surveillance Data System*, http://www.floridahealth.gov/statistics-and-data/florida-injury-surveillance-system/index.html (last visited March 13, 2017).
[41] Id.
[42] FLORIDA DEPARTMENT OF HEALTH, *External Cause of Injury Intent and Mechanism Classifications and Descriptions*, (Sept. 8, 2008), *available at*, http://www.floridahealth.gov/statistics-and-data/florida-injury-surveillance-system/_documents/icd-code-explanations.pdf (last visited March 13, 2017).
[43] Florida Department of Health, Agency Analysis of 2017 House Bill 249, p. 6, (Jan. 17, 2017) (on file with Health Quality Subcommittee staff).
[44] In 2004,DOH signed a memorandum of understanding to participate in a national project that would standardize data collection for EMS agencies nationwide. The National Emergency Medical Services Information System is the national repository used to aggregate and analyze prehospital data from all participating states.
[45] FLORIDA DEPARTMENT OF HEALTH, *The Basic Facts: Prehospital EMS Tracking and Reporting System*, p. 1, *available at*, http://www.floridaemstars.com/docs/EMSTARSFactSheet_102314.pdf (last visited March 13, 2017).
[46] Id.
[47] There are 147 participating EMS agencies. FLORIDA DEPARTMENT OF HEALTH, *Florida EMS Agencies Participating in EMSTARS, available at*, http://www.floridaemstars.com/docs/partagencies.pdf (last visited March 13, 2017).
[48] *Supra*, note 45.
[49] Id.
[50] *Supra*, note 43.

Effect of Proposed Changes

Legislative Findings, Intent, and Goals

HB 249 makes a finding that substance abuse and drug overdose is a major health problem that affects the lives of many people, and multiple service systems that leads to profoundly disturbing consequences. The bill also makes a finding that these overdoses are a crisis and stress financial, health care, and public safety resources. Additionally, it makes a finding that a central databases that could quickly help address this problem does not currently exist.

The bill also states legislative intent to require the collaboration of local, regional, and state agencies, service systems, and program offices to achieve the goals of the Florida Comprehensive Drug Abuse Prevention and Control Act, in chapter 893, F.S., and address the needs of the public. It is unclear what goals of chapter 893, F.S., such collaboration is intended to achieve, as no goals are set forth in that chapter.[51]

The bill also states a legislative intent to maximize the efficiency of financial, public education, health professional, and public safety resources and to utilize funding programs for the dissemination of available federal, state, and private funds through contractual agreements with community-based organizations or units of state or local government that deliver local substance abuse services.

The goals of the act are identified as:

- Discouraging substance abuse and overdoses by quickly identifying the type of drug involved, the age of the individual involved, and the areas where drug overdoses pose a potential risk to the public, schools, workplaces, and communities; and
- Providing a central data point in each county so that data can be shared between the health care community and municipal, county, and state agencies to quickly identify needs and provide short and long term solutions while protecting and respecting the rights of individuals.

Mandatory Overdose Reporting

Currently, health care providers are not required by law to report to law enforcement when they treat or attend or are requested to treat or attend, a patient who may have overdosed on a controlled substance. The bill creates s. 893.22, F.S., which requires mandatory reporting of controlled substances overdoses. The bill defines "overdose" as a condition which includes, but is not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death from the consumption or use of a controlled substance that requires medical attention or a condition which creates a clinical suspicion of a drug overdose such as respiratory depression, unconsciousness, or an altered mental state which is not explained by another condition.

The mandatory reporting requirement applies to physicians, nurses, paramedics, emergency medical technicians, health care workers, and employees of these professionals. It also applies to any employee of a hospital, sanatorium or other institution or provider. If any of these specified individuals knowingly attends, treats, or is requested to attend or treat a person who has an overdose of a controlled substance as listed in s. 893.03, F.S., they must make a report to law enforcement within 24 hours. The report must contain:

- The date of the overdose;
- The approximate age of the patient,
- A list of the suspected kind and quantity of the controlled substance; and

[51] Chapter 893, F.S., sets out the schedules of controlled substances, establishes laws controlling the manufacture, distribution, preparation, dispensing, or administration of such substances, and sets out criminal penalties for violations of those laws.

- The address of where the patient was picked up, where the overdose took place, or where the patient resides.

Reporting this information may be sufficient to trigger patient privacy concerns.

The bill does not limit the number of people who would be required to report on a single overdose; as a result, is possible, given the breadth of the individuals required to report, that there will be overlapping reports covering the same overdose. Because each individual who treats, attends, or is asked to treat or attend such a patient, must file a report, and a report must be filed each time the reporting individual treats, attends, or is asked to treat or attend such a patient, any incident is likely to result in redundant reports.

Anyone who files a report in good faith is not subject to civil or criminal liability for making the report.

Use of Report

The bill requires the report to be filed with the county sheriff or chief law enforcement officer of the county within 24 hours. However, the sheriff or chief law enforcement office may designate or partner with another agency, such as the medical examiner, to receive, store, and manage these reports. The reports must be maintained for five years. Regardless of who maintains the reports, law enforcement officers may access the records of these reports without obtaining a subpoena, search warrant, or other court order.

Additionally, the law enforcement officer who receives these reports then shares the general data, other than any data about criminal charges, with health care professionals and the county health department. Each county health department must then make semi-annual reports to the Council that summarizes the data it receives from law enforcement. The Council may use the reports to maximize the utilization of funding programs for substance abuse treatment services. It is unclear how the Council will use the data to maximize the use of funding, since it is merely advisory.

Penalties for Failure to Report

A mandatory reporter who fails to make a report is subject to criminal penalties. A person who fails by omission to make a required report within 24 hours of the treatment of a patient suffering from an overdose is guilty of a second-degree misdemeanor, which can result in a fine of up to $500 and a sentence of up to 60 days. A person who willfully fails to make a required report within 24 hours of the treatment of a patient suffering from an overdose is guilty of a second-degree misdemeanor, which can result in a fine of up to $500 and a sentence of up to 60 days.

B. SECTION DIRECTORY:

Section 1: Provides legislative findings and intent
Section 2: Creates s. 893.22, F.S., relating to mandatory reporting of controlled substance overdoses.
Section 3: Provides an effective date of October 1, 2017

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The reporting methods could require acquisition of new or additional software to collect and aggregate data.[52] In addition, county health departments may experience a recurring increase in workload associated with additional data they must collect from law enforcement and the semi-annual reports they must make to the Council.[53] The impact is indeterminate at this time; therefore, DOH cannot calculate the full fiscal impact, but notes that it could be significant.[54]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   Public EMS providers could incur additional costs related to enhanced reporting requirements.[55]

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Mandatory reporters will have to take time away from other work to comply with the reporting requirements in the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[52] *Supra*, note 43.
[53] Id.
[54] Id.
[55] Id.

A bill to be entitled

An act relating to drug overdoses; providing legislative findings and intent; creating s. 893.22, F.S.; requiring certain persons to report controlled substance overdoses; providing for a reporting agency in each county; defining the term "overdose"; providing requirements for such reports; providing immunity for persons who make such reports in good faith; requiring sharing of data with specified entities; providing for use of such data; requiring maintenance of records for a specified period; prohibiting failure to make such reports, whether by omission or willfully; providing criminal penalties; providing an effective date.

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

Section 1. (1) The Legislature finds that substance abuse and drug overdose is a major health problem that affects the lives of many people, multiple service systems, and leads to such profoundly disturbing consequences as permanent injury or death. Heroin, opiates, illegal drug, and accidental overdoses are a crisis and stress the financial, health care, and public safety resources because there exist no central databases that can quickly help address this problem. Quick data collection

will allow all agencies to focus on specific age groups, areas, criminal behavior, and needed public education and prevention with the maximum utilization of resources. Further, it is the intent of the Legislature to require the collaboration of local, regional, and state agencies, service systems, and program offices to achieve the goals of chapter 893, Florida Statutes, and address the needs of the public; to establish a comprehensive system addressing the problems associated with drug overdoses; and to reduce duplicative requirements across local, county, state, and health care agencies. This act is designed to address the crisis of drug overdoses.

(2) It is the goal of the Legislature in this act to:

(a) Discourage substance abuse and accidental or intentional overdoses by quickly identifying the type of drug involved, whether prescription or illegal, the age of the individual involved, and the areas where drug overdoses pose a potential risk to the public, schools, workplaces, and communities.

(b) Provide a central data point in each county so that data can be shared between the health care community and municipal, county, and state agencies to quickly identify needs and provide short and long term solutions while protecting and respecting the rights of individuals.

(3) It is the intent of the Legislature in this act to maximize:

(a) The efficiency of financial, public education, health professional, and public safety resources so that these resources may be concentrated on areas and groups in need on the performance of professional functions necessary to carry out the intent of chapter 893, Florida Statutes.

(b) The utilization of funding programs for the dissemination of available federal, state, and private funds through contractual agreements with community-based organizations or units of state or local government that deliver local substance abuse services in accordance with s. 397.321(4), Florida Statutes.

Section 2. Section 893.22, Florida Statutes, is created to read:

893.22 Mandatory reporting of controlled substance overdoses.—

(1)(a) A physician, nurse, paramedic, emergency medical technician, or health care worker, or employee thereof, and any employee of a hospital, sanatorium, or other institution or provider who knowingly attends or treats or who is requested to attend or treat an overdose of a controlled substance listed in s. 893.03, shall report, within 24 hours, such attention or treatment, or request therefor, to the sheriff or chief law enforcement officer in the county in which such attention or treatment is administered or request therefor received.

(b) The sheriff or chief law enforcement officer in each

county in its discretion may designate or partner with a public organization or other agency, such as the medical examiner, to receive, store, and manage the reports and other data described in this section.

(c) For purposes of this section, the term "overdose" means a condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of any substance listed in 893.03 that requires medical attention, assistance or treatment, and clinical suspicion for drug overdose, such as respiratory depression, unconsciousness, or altered mental status, without other conditions to explain the clinical condition.

(2) A person who reports an overdose of a controlled substance under this section shall include in the report:

(a) The date of overdose.

(b) The approximate age of the person receiving attention or treatment.

(c) The suspected kind and quantity of controlled substances involved in the overdose.

(d) The approximate address of where the person was picked up, where the overdose took place, or where the person resides.

(3) A person who makes a report under this section in good faith is not subject to civil or criminal liability for making the report.

(4) The sheriff or chief law enforcement officer in each county, or other organization or agency as designated by such officer pursuant to subsection (1), shall share the general data, excluding any data relating to a criminal charge, with health care professionals and the county health department. Each county health department shall make a semiannual report to the Statewide Drug Policy Advisory Council in accordance with a schedule set by the council summarizing the data for that county. The council may use the reports to maximize the utilization of funding programs for the dissemination of available federal, state, and private funds for local substance abuse services in accordance with s. 397.321(4).

(5) The sheriff or chief law enforcement officer in each county, or other organization or agency designated pursuant to subsection (1), shall maintain the records described in this section. Such records shall be kept and made available for a period of not less than 5 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. Law enforcement officers are not required to obtain a subpoena, court order, or search warrant in order to obtain access to copies of such records.

(6) A person who:

(a) Fails by omission to report the treatment of a drug overdose of a substance listed in s. 893.03 within 24 hours

after discovery as required in this section commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(b) Willfully refuses to report the treatment of a drug overdose of a substance listed in s. 893.03 within 24 hours after discovery as required in this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 3. This act shall take effect October 1, 2017.

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 Rommel offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. (1) The Legislature finds that substance abuse and drug overdose is a major health problem that affects the lives of many people, multiple service systems, and leads to such profoundly disturbing consequences as permanent injury or death. Heroin, opiates, illegal drug, and accidental overdoses are a crisis and stress the financial, health care, and public safety resources because there exist no central databases that can quickly help address this problem. Quick data collection will allow all agencies to focus on specific age groups, areas, criminal behavior, and needed public education and prevention

with the maximum utilization of resources. Further, it is the intent of the Legislature to require the collaboration of local, regional, and state agencies, service systems, and program offices to address the needs of the public; to establish a comprehensive system addressing the problems associated with drug overdoses; and to reduce duplicative requirements across local, county, state, and health care agencies.

(2) It is the goal of the Legislature in this act to:

(a) Discourage substance abuse and accidental or intentional overdoses by quickly identifying the type of drug involved, whether prescription or illegal, the age of the individual involved, and the areas where drug overdoses pose a potential risk to the public, schools, workplaces, and communities.

(b) Provide a central data point so that data can be shared between the health care community and municipal, county, and state agencies to quickly identify needs and provide short and long term solutions while protecting and respecting the rights of individuals.

(3) It is the intent of the Legislature in this act to maximize:

(a) The efficiency of financial, public education, health professional, and public safety resources so that these resources may be concentrated on areas and groups in need.

(b) The utilization of funding programs for the dissemination of available federal, state, and private funds through contractual agreements with licensed basic life support service providers, advanced life support service providers, community-based organizations, or units of state or local government that deliver local substance abuse services in accordance with the intent of this section and s. 397.321(4), Florida Statutes.

Section 2. Section 401.25, Florida Statutes, is created to read:

401.253 Mandatory reporting of controlled substance overdoses.—

(1)(a) The basic life support service or advanced life support service which treats and releases, or transports to a medical facility, in response to an emergency call for a suspected or actual overdose of a controlled substance shall report such incident within 120 hours to the department, utilizing the Emergency Medical Service Tracking and Reporting System, or other appropriate method, including, but not limited to, ESSENCE, the Washington/Baltimore High Intensity Drug Trafficking Overdose Detection Mapping Application Program, or other program identified by the department in rule.

(b) The data collected by the Department of Health shall be made available within 120 hours to law enforcement, public health, fire rescue, and EMS agencies in each county.

(c) For purposes of this section, the term "overdose" means a condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of any controlled substance that requires medical attention, assistance or treatment, and clinical suspicion for drug overdose, such as respiratory depression, unconsciousness, or altered mental status, without other conditions to explain the clinical condition.

(2) A person who reports an overdose of a controlled substance under this section shall include in the report:

(a) The date and time of overdose.

(b) The gender and approximate age of the person receiving attention or treatment.

(c) The suspected controlled substances involved in the overdose.

(d) The approximate address of where the person was picked up or where the overdose took place.

(e) Whether Narcan, naloxone, or similar anti-overdose treatment was administered.

(f) Whether the overdose was fatal or non-fatal.

(3) A person who reports information to or from the department pursuant to this section in good faith is not subject to civil or criminal liability for making the report.

(4) The Department of Health shall produce a quarterly report to the Statewide Drug Policy Advisory Council, the Department of Children and Families, and the Florida FUSION Center summarizing the raw data received pursuant to this section. Such reports shall also be made immediately available to the county-level agencies described in paragraph (1)(b). The Statewide Drug Policy Advisory Council, the Department of Children and Families, and the Department of Health may use these reports to maximize the utilization of funding programs for licensed basic life support service providers or advanced life support service providers, and for the dissemination of available federal, state, and private funds for local substance abuse services in accordance with s. 397.321(4).

Section 3. This act shall take effect October 1, 2017.

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 drug overdoses; providing legislative findings and intent; creating s. 401.253, F.S.; requiring certain persons to report controlled substance overdoses; defining the term "overdose"; providing requirements for such reports; providing immunity for persons who make such reports in good faith; requiring sharing of data with specified entities;

providing for use of such data; requiring maintenance of records for a specified period; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 723 Maintenance of Certification
SPONSOR(S): Gonzalez
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 Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners. The MQA works in conjunction with 22 boards and six councils to license and regulate seven types of health care facilities and more than 40 health care professions, including Medical Doctors (allopathic physicians) and Doctors of Osteopathic Medicine (osteopathic physicians). Chapter 458, F.S., provides for the licensure and regulation of the practice of medicine by allopathic physicians, governed by the Florida Board of Medicine (allopathic board), and chapter 459, F.S., provides for the licensure and regulation of the practice of medicine by osteopathic physicians, governed by the Florida Board of Osteopathic Medicine (osteopathic board).

DOH does not license a physician's specialty or sub-specialty based upon board certification; however, ch. 458 and ch. 459, F.S., limit which physicians may hold themselves out as board-certified specialists. An allopathic physician licensed under ch. 458, F.S., may not hold himself or herself out as a board-certified specialist unless he or she has received formal recognition as a specialist from a specialty board of the American Board of Medical Specialties (ABMS). Similarly, an osteopathic physician licensed under ch. 459, F.S., may not hold himself or herself out as a board-certified specialist unless he or she has successfully completed the requirements for certification by the American Osteopathic Association or ABMS.

HB 723 prohibits the allopathic board, osteopathic board, DOH, health care facilities, and insurers from requiring physicians to maintain board certification in a subspecialty as conditions of licensure, reimbursement, employment, or admitting privileges.

The bill specifies that this prohibition does not impact the boards' ability to require continuing medical education.

The bill does not have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Licensure and Regulation of Physicians

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 six councils to license and regulate seven types of health care facilities and more than 40 health care professions, including Medical Doctors (allopathic physicians) and Doctors of Osteopathic Medicine (osteopathic physicians).[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.

Allopathic Physician Licensure

Chapter 458, F.S., governs licensure and regulation of the practice of medicine by the Florida Board of Medicine (allopathic board) in conjunction the Department of Health (DOH). The chapter imposes requirements for licensure examination and licensure by endorsement.

Allopathic Education and Training Requirements

An individual seeking to be licensed by examination as an allopathic physician must, among other things:

- Complete 2 years of post-secondary education which includes, at a minimum, courses in fields such as anatomy, biology, and chemistry prior to entering medical school;
- Meet one of the following medical education and postgraduate training requirements:
  - Graduate from an allopathic medical school recognized and approved by an accrediting agency recognized by the U.S. Office of Education or recognized by an appropriate governmental body of a U.S. territorial jurisdiction, and have completed at least one year of approved residency training;
  - Graduate from an allopathic foreign medical school registered with the World Health Organization and certified pursuant to statute as meeting the standards required to accredit U.S. medical schools, and have completed at least one year of approved residency training; or
  - Graduate from an allopathic foreign medical school that has not been certified pursuant to statute; have an active, valid certificate issued by the Educational Commission for Foreign Medical Graduates (ECFMG),[3] have passed that commission's examination; and have completed an approved residency or fellowship of at least 2 years in one specialty area; and
- Obtain a passing score on:

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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 2014-2015*, 3, *available at* http://mqawebteam.com/annualreports/1415/#6 (last visited March 13, 2017).

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

- The United States Medical Licensing Examination (USMLE);
- A combination of the USMLE, the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or
- The Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX), if the applicant was licensed on the basis of a state board examination, is currently licensed in at least one other jurisdiction of the United States or Canada, and has practiced for a period of at least 10 years. [4]

An individual who holds an active license to practice medicine in another jurisdiction may seek licensure by endorsement to practice medicine in Florida.[5] The applicant must meet the same requirements for licensure by examination. To qualify for licensure by endorsement, the applicant must also submit evidence of the licensed active practice of medicine in another jurisdiction for at least 2 of the preceding 4 years, or evidence of successful completion of either a board-approved postgraduate training program within 2 years preceding filing of an application or a board-approved clinical competency examination within the year preceding the filing of an application for licensure.

Allopathic Continuing Medical Education (CME)

Physician licenses are renewed biennially.[6] Within each biennial licensure renewal period, a physician must complete 40 hours of continuing medical education (CME) courses approved by the allopathic board. As a part of the 40 hours of CME, a licensee must also complete the following:

- A two-hour course regarding domestic violence every third biennial;[7]
- A one-hour course addressing the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome no later than upon the first biennial licensure renewal;[8] and
- Two hours of CME relating to the prevention of medical errors.[9]

DOH may not renew a license until a licensee complies with all CME requirements.[10] The allopathic board may also take action against a license for failure to comply with CME requirements.

Osteopathic Physician Licensure

Chapter 459, F.S., provides for the licensure and regulation of the practice of medicine by the Florida Board of Osteopathic Medicine (osteopathic board) in conjunction the Department of Health (DOH). The chapter imposes requirements for licensure by examination and licensure by endorsement.

Osteopathic Education and Training Requirements

An individual seeking to be licensed as an osteopathic physician must, among other things:[11]

- Graduate from a medical college recognized and approved by the American Osteopathic Association;
- Successfully complete a resident internship of at least 12 months in a hospital approved by the Board of Trustees of the American Osteopathic Association or any other internship approved by the osteopathic board; and

[4] Section 458.311(1), F.S.
[5] Section 458.313, F.S.
[6] Rule 64B8-3.003, F.A.C. If a practitioner dispenses medicinal drugs, an additional fee of $100 must be paid at the time of renewal.
[7] Section 456.031, F.S.
[8] Section 456.033, F.S.
[9] Section 456.013(7), F.S.
[10] Section 456.031, F.S.
[11] Section 459.0055(1), F.S.

- Obtain a passing score, as established by rule of the osteopathic board, on the examination conducted by the National Board of Osteopathic Medical Examiners or other examination approved by the osteopathic board, no more than five years prior to applying for licensure.[12]

If an applicant for a license to practice osteopathic medicine is licensed in another state, the applicant must have actively practiced osteopathic medicine within the two years prior to applying for licensure in this state.

Osteopathic CME

Osteopathic physician licenses are renewed biennially. Within each biennial licensure renewal period, an osteopathic physician must complete 40 hours of continuing medical education (CME) courses approved by the osteopathic board. As a part of the 40 hours of CME, a licensee must also complete the following:

- A two-hour course regarding domestic violence every third biennial;[13]
- A one-hour course addressing the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome no later than upon the first biennial licensure renewal;[14]
- Two hours of CME relating to the prevention of medical errors;[15]
- A one-hour course on profession and medical ethics education; and
- A one-hour course on the federal and state laws related to the prescribing of controlled substances.[16]

DOH may not renew a license until a licensee complies with all CME requirements.[17] The osteopathic board may also take action against a license for failure to comply with CME requirements.

Board Certification of Physicians

Medical licensure of physicians sets the minimum competency requirements to diagnose and treat patients; it is not specialty specific.[18] Medical specialty certification is a voluntary process that gives a physician a way to develop and demonstrate expertise in a particular specialty or subspecialty.[19]

Board Certification by the Specialty Boards of the ABMS

When a physician or surgeon is board certified by an ABMS specialty board, it means he or she has met the standards[20] and requirements for certification in a specialty or subspecialty of one or more of the 24 ABMS Member Boards.[21]

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[12] However, if an applicant has been actively licensed in another state, the initial licensure in the other state must have occurred no more than five years after the applicant obtained the passing score on the licensure examination.
[13] Section 456.031, F.S.
[14] Section 456.033, F.S.
[15] Section 456.013(7), F.S.
[16] Rule 64B15-13.001, F.A.C.
[17] Section 456.031, F.S.
[18] AMERICAN BOARD OF FAMILY MEDICINE, *What does board-certified mean?*, https://www.theabfm.org/diplomate/certified.aspx (last visited March 13, 2017).
[19] Id.
[20] *See*, AMERICAN BOARD OF MEDICAL SPECIALTIES, *A Trusted Credential*, http://www.abms.org/board-certification/a-trusted-credential/ (last visited March 12, 2017).
[21] AMERICAN BOARD OF MEDICAL SPECIALTIES, *Standards for Initial certification*, 2016, *available at*, http://www.abms.org/media/119927/abms-standards-for-initial-certification.pdf (last visited March 12, 2017).

Board Certifications Offered by ABMS Member Boards:[22]

Member Board	General Certification(s)	Subspecialty Certification(s)
American Board of Allergy and Immunology	Allergy and Immunology	No Subspecialties
American Board of Anesthesiology	Anesthesiology	Critical Care Medicine Hospice and Palliative Medicine Pain Medicine Pediatric Anesthesiology Sleep Medicine
American Board of Colon and Rectal Surgery	Colon and Rectal Surgery	No Subspecialties
American Board of Dermatology	Dermatology	Dermatopathology Pediatric Dermatology
American Board of Emergency Medicine	Emergency Medicine	Anesthesiology Critical Care Medicine Emergency Medical Services Hospice and Palliative Medicine Internal Medicine-Critical Care Medicine Medical Toxicology Pain Medicine Pediatric Emergency Medicine Sports Medicine Undersea and Hyperbaric Medicine
American Board of Family Medicine	Family Medicine	Adolescent Medicine Geriatric Medicine Hospice and Palliative Medicine Pain Medicine Sleep Medicine Sports Medicine
American Board of Internal Medicine	Internal Medicine	Adolescent Medicine Adult Congenital Heart Disease Advanced Heart Failure and Transplant Cardiology Cardiovascular Disease Clinical Cardiac Electrophysiology Critical Care Medicine Endocrinology, Diabetes and Metabolism Gastroenterology Geriatric Medicine Hematology Hospice and Palliative Medicine Infectious Disease Interventional Cardiology Medical Oncology Nephrology Pulmonary Disease Rheumatology Sleep Medicine Sports Medicine Transplant Hepatology
American Board of Medical Genetics and Genomics	Clinical Biochemical Genetics Clinical Cytogenetics and Genomics Clinical Genetics and Genomics Clinical Molecular Genetics and Genomics	Medical Biochemical Genetics Molecular Genetic Pathology
American Board of Neurological Surgery	Neurological Surgery	No Subspecialties
American Board of Nuclear Medicine	Nuclear Medicine	No Subspecialties

[22] AMERICAN BOARD OF MEDICAL SPECIALTIES, *Specialty and Subspecialty Certificates*, http://www.abms.org/member-boards/specialty-subspecialty-certificates/ (last visited March 12, 2017)

Member Board	General Certification(s)	Subspecialty Certification(s)
American Board of Obstetrics and Gynecology	Obstetrics and Gynecology	Critical Care Medicine Female Pelvic Medicine and Reconstructive Surgery Gynecologic Oncology Hospice and Palliative Medicine Maternal and Fetal Medicine Reproductive Endocrinology/Infertility
American Board of Ophthalmology	Ophthalmology	No Subspecialties
American Board of Orthopaedic Surgery	Orthopaedic Surgery	Orthopaedic Sports Medicine Surgery of the Hand
American Board of Otolaryngology	Otolaryngology	Neurotology Pediatric Otolaryngology[23] Plastic Surgery Within the Head and Neck[24] Sleep Medicine
American Board of Pathology	Pathology-Anatomic/Pathology-Clinical Pathology – Anatomic Pathology - Clinical	Blood Banking/Transfusion Medicine Clinical Informatics Cytopathology Dermatopathology Hematopathology Neuropathology Pathology – Chemical Pathology – Forensic Pathology – Medical Microbiology Pathology – Molecular Genetic Pathology – Pediatric
American Board of Pediatrics	Pediatrics	Adolescent Medicine Child Abuse Pediatrics Developmental-Behavioral Pediatrics Hospice and Palliative Medicine Medical Toxicology Neonatal-Perinatal Medicine Pediatric Cardiology Pediatric Critical Care Medicine Pediatric Emergency Medicine Pediatric Endocrinology Pediatric Gastroenterology Pediatric Hematology-Oncology Pediatric Hospital Medicine[25] Pediatric Infectious Diseases Pediatric Nephrology Pediatric Pulmonology Pediatric Rheumatology Pediatric Transplant Hepatology Sleep Medicine Sports Medicine
American Board of Physical Medicine and Rehabilitation	Physical Medicine and Rehabilitation	Brain Injury Medicine Hospice and Palliative Medicine Neuromuscular Medicine Pain Medicine Pediatric Rehabilitation Medicine Spinal Cord Injury Medicine Sports Medicine
American Board of Plastic Surgery	Plastic Surgery	Plastic Surgery Within the Head and Neck[26] Surgery of the Hand
American Board of Preventive Medicine	Aerospace Medicine Occupational Medicine Public Health and General Preventive Medicine	Addiction Medicine[27] Clinical Informatics Medical Toxicology Undersea and Hyperbaric Medicine

[23] Subspecialty has been approved by the American Board of Otolaryngology but not yet issued.
[24] Id.
[25] Subspecialty has been approved by the American Board of Pediatrics, but not yet issued.
[26] Subspecialty has been approved by the American Board of Plastic Surgery, but not yet issued.
[27] Subspecialty has been approved by the American Board of Preventative Medicine, but not yet issued.

Member Board	General Certification(s)	Subspecialty Certification(s)
American Board of Psychiatry and Neurology	Psychiatry Neurology Neurology with Special Qualification in Child Neurology	Addiction Psychiatry Brain Injury Medicine Child and Adolescent Psychiatry Clinical Neurophysiology Epilepsy Forensic Psychiatry Geriatric Psychiatry Hospice and Palliative Medicine Neurodevelopmental Disabilities Neuromuscular Medicine Pain Medicine Psychosomatic Medicine Sleep Medicine Vascular Neurology
American Board of Radiology	Diagnostic Radiology Interventional Radiology and Diagnostic Radiology Radiation Oncology Medical Physics	Hospice and Palliative Medicine Neuroradiology Nuclear Radiology Pain Medicine[28] Pediatric Radiology Vascular and Interventional Radiology
American Board of Surgery	Surgery Vascular Surgery	Complex General Surgical Oncology Hospice and Palliative Medicine Pediatric Surgery Surgery of the Hand Surgical Critical Care
American Board of Thoracic Surgery	Thoracic and Cardiac Surgery	Congenital Cardiac Surgery
American Board of Urology	Urology	Female Pelvic Medicine and Reconstructive Surgery Pediatric Urology

Initial certification

Initial certification occurs soon after completion of residency training.[29] To receive initial board certification in a specialty from one of the ABMS boards, the physician must first:

- Finish four years of premedical education in a college or university;
- Earn a medical degree (MD, DO or other credential approved by an ABMS Member Board) from a qualified medical school;
- Complete three to five years of full-time experience in a residency training program accredited by the ACGME;
- Provide letters of attestation from their program director and/or faculty;
- Obtain an unrestricted medical license to practice medicine in the United States or Canada; and
- Pass a written and, in some cases, an oral examination created and administered by an ABMS Member Board.[30]

The standards for initial certification consist of four general standards:

- Each ABMS Member Board's Standards for Initial certification will incorporate all six ABMS/ACGME Core Competencies:
  - Practice-Based Learning and Improvement;[31]
  - Patient Care and Procedural Skills;[32]

[28] Subspecialty has been approved by the American Board of Radiology, but not yet issued.
[29] AMERICAN BOARD OF MEDICAL SPECIALTIES, *ABMS Guide to Medical Specialties*, 2017, p. 7, *available at* http://www.abms.org/media/114634/guide-to-medicalspecialties_04_2016.pdf (last visited March 12, 2017).
[30] AMERICAN BOARD OF MEDICAL SPECIALTIES, *Steps Toward Initial certification and MOC*, http://www.abms.org/board-certification/steps-toward-initial-certification-and-moc/ (last visited March 12, 2017).
[31] *Supra*, note 21 at 3. This refers to the candidate's ability to investigate and evaluate patient care practices, appraise and assimilate scientific evidence, and improve the candidate's own practice of medicine, the collaborative practice of medicine, or both.

    - Systems-based Practice;[33]
    - Medical Knowledge;[34]
    - Interpersonal and Communication Skills;[35] and
    - Professionalism;[36]
- The Member Board and the training programs in a specialty have a shared responsibility for assessing a candidate's suitability for certification;
- Each ABMS Member Board will determine criteria for eligibility, including the expiration date for the "Board Eligible" period;[37] and
- Each ABMS Member Board will work to maintain the value of Initial certification to the Public and profession through systematic efforts to evaluate and improve the initial certification program to reflect advances in medical practice and assessment methodology.[38]

The standards for initial certification also includes standards that address professionalism;[39] education and training;[40] and assessment of knowledge, judgment, and skills.[41]

Candidates for certification must pass an exam created and administered by the relevant Member Board.[42] Candidates who have passed the exam and completed all other requirements are considered certified as a specialist and a diplomate of their specialty board.[43]

Subspecialty Board Certification

A similar eligibility process to the initial certification is followed for certified specialists seeking subspecialty certification. In order to obtain a subspecialty board certification, the physician must have an initial certification in the overarching specialty from the ABMS Member Board.[44] Subspecialty board certification involves additional training or completion of a fellowship program and passing an exam given by the ABMS Member Board.[45]

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[32] Id. This refers to the candidate's use of clinical skills and ability to provide care and promote health in an appropriate manner that incorporates evidence-based medical practice, demonstrates good clinical judgment, and fosters patient-centered decision-making.
[33] Id. This refers to the candidate's awareness of, and responsibility to, population health and systems of health care. The candidate should be able to use system resources responsibly in providing patient care (e.g., good resource stewardship, coordination of care).
[34] Id. This refers to the candidate's demonstration of knowledge about established and evolving biomedical, clinical, and cognate sciences, as well as the application of these sciences in patient care.
[35] Id. This refers to the candidate's demonstration of skills that result in effective information exchange and partnering with patients, their families, and professional associates (e.g., fostering a therapeutic relationship that is ethically sound; using effective listening skills with nonverbal and verbal communication; being mindful of health literacy; and working effectively in a team both as a team member and as a team leader).
[36] Id. This refers to the candidate's demonstration of a commitment to carrying out professional responsibilities; adhering to ethical principles; applying the skills and values to deliver compassionate, patient-centered care; demonstrating humanism; being sensitive to diverse patient populations and workforce; and practicing wellness and self-care.
[37] Id. at 4. "Board Eligibility" only applies to the period of time between a physician's completion of training and achievement of Initial certification in a specialty. The expiration date must be no fewer than three and no more than seven years following the successful completion of accredited training, and in accordance with the corresponding Member Board requirements, plus time (if any) in practice required by the Member Board for admission to the certifying examination.
[38] Id.
[39] Id. at 5. Each ABMS Member Board identifies and conveys its professionalism expectations to its candidates for Initial certification and has a process in place to consider the circumstances of an action taken against a candidate's license by a state medical board or other determination of unprofessional conduct by an appropriate authority and to respond appropriately.
[40] Id. Each ABMS Member Board establishes requirements for training and documents that candidates have met these requirements prior to awarding initial general or subspecialty certification. ABMS Member Boards' training requirements address duration and quality of education and training by specifically requiring the total training time for general certification be a minimum of three years, training for subspecialty certification be a minimum of one year, and training programs be accredited by the ACGME. Member Boards may choose to recognize alternate pathways to Initial certification for candidates who have not completed residency training programs accredited by the ACGME.
[41] Id. at 6-7. Initial certification by an ABMS Member Board is intended to provide patients, health care organizations, and the profession with a dependable mechanism for identifying specialists who have met standards for the specialty. Examination procedures should reflect accepted educational standards for test design, development, administration, reliability, validity, fidelity, scoring, and reporting.
[42] *Supra*, note 29 at p. 7.
[43] Id.
[44] Id. at 11.
[45] Id.

Maintenance of Certification (MOC)

Once Board Certified, physicians maintain their certification by participating in a professional development program called the ABMS Program for MOC.[46] The MOC program provides physicians a structured approach for enhancing patient care and improving patient outcomes through focused assessment and improvement activities. The ABMS Program for MOC involves ongoing measurement of six core competencies defined by ABMS and ACGME:

- **Practice-based Learning and Improvement:** The board certified physician must demonstrate an ability to investigate and evaluate patient care practices, appraise and assimilate scientific evidence, and improve the practice of medicine.
- **Patient Care and Procedural Skills:** The board certified physician must provide care that is compassionate, appropriate, and effective treatment.
- **Systems-based Practice:** The board certified physician must demonstrate awareness of and responsibility to the larger context and systems of health care.
- **Medical Knowledge:** The board certified physician must demonstrate knowledge about established and evolving biomedical, clinical, and cognate sciences and their application in patient care.
- **Interpersonal and Communication Skills:** The board certified physician must demonstrate skills that result in effective information exchange and teaming with patients, their families and professional associates.
- **Professionalism:** The board certified physician must demonstrate a commitment to carrying out professional responsibilities, adherence to ethical principles and sensitivity to diverse patient populations.[47]

These competencies, which are the same ones used in the ACGME's Next Accreditation System, are measured in the ABMS Program for MOC within a four-part framework:

- **Professionalism and Professional Standing.** The physician must behave in a professional manner, act in the patients' best interest, and hold a valid, unrestricted medical license.
- **Lifelong Learning and Self-Assessment.** The physician must participate in high quality, unbiased educational and self-assessment activities determined by each Member Board.
- **Assessment of Knowledge, Judgment, and Skills.** The physician must pass a written examination and other evaluations.
- **Improvement in Medical Practice.** The physician must engage in ongoing assessment and improvement activities to improve patient outcomes and demonstrate use of evidence and best practices compared to peers and national benchmarks.[48]

All Programs for MOC implemented by the Member Boards measure the same six competencies within the same four-part framework.[49] While these elements are consistent across all Member Boards, the specific activities used to measure these competencies may vary according to the specialty.[50]

Board Certification by the AOA

The AOA's Department of Certifying Board Services administers board certification for osteopathic physicians in 29 primary specialties and 77 subspecialties.[51]

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[46] *Supra*, note 30.
[47] AMERICAN BOARD OF MEDICAL SPECIALTIES, *Based on Core Competencies*, http://www.abms.org/board-certification/a-trusted-credential/based-on-core-competencies/ (last visited March 12, 2017).
[48] AMERICAN BOARD OF MEDICAL SPECIALTIES, *Assessed Through a Four-Part Framework*, http://www.abms.org/board-certification/a-trusted-credential/assessed-through-a-four-part-framework/ (last visited March 12, 2017).
[49] *Supra*, note 30.
[50] Id.
[51] AMERICAN OSTEOPATHIC ASSOCIATION, *AOA Specialty Certifying Boards and Conjoint Examination Committees*, https://www.osteopathic.org/inside-aoa/development/aoa-board-certification/Pages/aoa-specialty-boards.aspx

Board Certifications Offered by AOA Boards[52]

Specialty Board	Primary Certification(s)	Subspecialty Certification(s)
American Osteopathic Board of Anesthesiology	Anesthesiology	Critical Care Pain Management Pediatric Anesthesiology
American Osteopathic Board of Dermatology	Dermatology	Dermatopathology MOHS Micrographic Surgery Pediatric Dermatology
American Osteopathic Board of Emergency Medicine	Emergency Medicine	Emergency Medical Services Medical Toxicology Sports Medicine Undersea and Hyperbaric Medicine
American Osteopathic Board of Family Physicians[53]	Family Practice and Osteopathic Manipulative Treatment [54] Family Practice and Osteopathic Manipulative Treatment with OCC Special Emphasis in Hospital Medicine	Geriatric Medicine Hospice and Palliative Medicine Pain Medicine Sleep Medicine Sports Medicine Undersea and Hyperbaric Medicine
American Osteopathic Board of Internal Medicine	Internal Medicine Internal Medicine with OCC Special Emphasis in Hospital Medicine	Addiction Medicine Adult and Pediatric Allergy and Immunology Clinical Cardiac Electrophysiology Cardiology Correctional Medicine Critical Care Medicine[55] Endocrinology Gastroenterology Geriatric Medicine Hematology Hospice and Palliative Medicine Infectious Diseases Interventional Cardiology Nephrology Oncology Pain Medicine Pulmonary Diseases Rheumatology Sleep Medicine Sports Medicine Undersea and Hyperbaric Medicine
American Osteopathic Board of Neurology and Psychiatry	Neurology Psychiatry	Addiction Medicine Child Neurology Child Psychiatry Geriatric Psychiatry Hospice and Palliative Medicine Neurology & Psychiatry* Neurophysiology Pain Medicine Sleep Medicine

[52] AMERICAN OSTEOPATHIC ASSOCIATION, *AOA Specialties & Subspecialties,* http://www.osteopathic.org/inside-aoa/development/aoa-board-certification/Pages/specialty-subspecialty-certification.aspx (last visited March 12, 2017).

[53]) The American Osteopathic Board of Family Physicians uses the term "Certification of Added Qualifications" to describe a subspecialty certification obtained under its jurisdiction.

[54] Effective after July 1, 1999, general certification issued from AOBFP will be "Family Practice and Osteopathic Manipulative Treatment." Physicians who have general certification in family practice and whose certificates are dated before July 1, 1999 have the option of requesting reissuance of their certificates with the new nomenclature. In July 2011, the Board of Trustees of the AOA approved a change in the name of general certification in family practice from the American Osteopathic Board of Family Practice (AOBFP) to "Family Medicine and Osteopathic Manipulative Treatment."

[55] Available to diplomates of other AOA boards.

Specialty Board	Primary Certification(s)	Subspecialty Certification(s)
American Osteopathic Board of Neuromusculoskeletal Medicine	Neuromusculoskeletal Medicine and OMM	Pain Medicine Sports Medicine
American Osteopathic Board of Nuclear Medicine	No longer offered	
American Osteopathic Board of Obstetrics and Gynecology	Obstetrics and Gynecology	Female Pelvic Medicine/ Reconstructive Surgery Gynecologic Oncology Maternal and Fetal Medicine Reproductive Endocrinology
American Osteopathic Board of Ophthalmology and Otolaryngology-HNS	Ophthalmology Otolaryngology and Facial Plastic Surgery	Otolaryngic Allergy Sleep Medicine
American Osteopathic Board of Orthopedic Surgery	Orthopedic Surgery	Hand Surgery
American Osteopathic Board of Pathology	Anatomic Pathology Laboratory Medicine	Dermatopathology Forensic Pathology
American Osteopathic Board of Pediatrics	Pediatrics	Adolescent Medicine Adult and Pediatric Allergy and Immunology Neonatology Pediatric Endocrinology Pediatric Pulmonology* Sports Medicine
American Osteopathic Board of Physical Medicine and Rehabilitation	Physical Medicine and Rehabilitation	Hospice and Palliative Medicine Pain Medicine Sports Medicine
American Osteopathic Board of Preventive Medicine	Preventive Medicine-Aerospace Medicine Preventive Medicine-Occupational/Environmental Medicine Preventive Medicine-Public Health	Correctional Medicine Occupational Medicine[56] Sports Medicine* Undersea and Hyperbaric Medicine
American Osteopathic Board of Proctology	Proctology	None offered
American Osteopathic Board of Radiology	Diagnostic Radiology Radiation Oncology	Neuroradiology Pediatric Radiology Vascular and Interventional Radiology
American Osteopathic Board of Surgery	Cardiothoracic Surgery General Vascular Surgery Neurological Surgery Plastic and Reconstructive Surgery Surgery (general)	Surgical Critical Care[57]

Primary Certification

Primary certification is conferred on diplomates who meet the requirements in a specified field of medical practice under the jurisdiction of a certifying board.[58] Primary certification represents a distinct

[56] Available to diplomates of other AOA boards.
[57] Available to diplomates of other AOA boards.
[58] AMERICAN OSTEOPATHIC ASSOCIATION, *Definitions of Certifications*, http://www.osteopathic.org/inside-aoa/development/aoa-board-certification/Pages/certification-definitions.aspx (last visited March 12, 2017).

and well-defined field of osteopathic medical practice.[59]Unlike the Member Boards of the AMBS, which are all subject to the same basic criteria for board certification, each of the certifying specialty boards of the AOA have their own eligibility for board certification.

Regardless of specialty board, there are certain requirements that apply to all osteopathic physicians seeking board certification; the physician must

- Be a graduate of an AOA-accredited college of osteopathic medicine;
- Hold an unrestricted license to practice in a state or territory;
- Be a member in good standing of the AOA for a set time prior to the date of certification;
- Have satisfactorily completed residency training in the relevant specialty; and
- Pass written, oral, and clinical examinations.[60]

Subspecialty Certification

Subspecialty certification is conferred by a certifying board in a specific subspecialty area of the field to which that AOA specialty board certifies.[61] A subspecialty certification requires prior attainment of general certification; however, there are certain subspecialty certifications that are considered specialized enough to not require maintenance of the primary board certification after a physician has become subspecialty certified.[62] Such subspecialty certifications, which require longer than the standard one year of additional training, indicate the possession of knowledge, skill, training and successful examination in a subspecialty field over and above that required for primary certification.[63] For example, Cardiology is a limited area within the field of Internal Medicine for which physicians may earn a subspecialty certification that does not require them to maintain their primary certification in Internal Medicine, after they have become subspecialty certified in Cardiology.[64]

Osteopathic Continuous Certification (OCC)

Each specialty certifying board developed OCC requirements implemented as of Jan. 1, 2013.[65] A physician with a time-limited[66] board certification is required to participate in the five components of the OCC process to maintain osteopathic board certification.[67] The five components of OCC are:

- **Active Licensure**. Physicians who are board-certified by the AOA hold a valid, active license to practice medicine in one of the 50 states and must adhere to the AOA's Code of Ethics.
- **Lifelong Learning/Continuing Medical Education.** All recertifying physicians must fulfill a minimum of 120 hours of CME credit during each three-year CME cycle; a minimum of 50 credit hours must be in the specialty area of certification.
- **Cognitive Assessment.** The physician must complete one or more psychometrically valid and proctored examinations that assess a physician's specialty medical knowledge, as well as core competencies in the provision of health care.

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[59] Id.
[60] *See, e.g.*, AMERICAN OSTEOPATHIC BOARD OF ANESTHESIOLOGY, *Primary Certification in Anesthesiology,* http://www.aobanes.com/services.html (last visited March, 12, 2017); AMERICAN OSTEOPATHIC BOARD OF INTERNAL MEDICINE, *Regulations, Requirements and Procedures*, October 2016, available at http://www.aobim.org/WebPageStatic/PDF/IM_Regs_Req_Proced.pdf (last visited March 13, 2017); and American Osteopathic Board of Orthopedic Surgery, 2017 Handbook for Candidates for Board Certification, Feb. 2017, *available at*, http://www.aobos.org/mm/files/Candidate-Handbook-Master.pdf (last visited March 13, 2017).
[61] *Supra*, note 58.
[62] Id.
[63] Id.
[64] Id.
[65] AMERICAN OSTEOPATHIC ASSOCIATION, *Osteopathic Continuous Certification*, http://www.osteopathic.org/inside-aoa/development/aoa-board-certification/Pages/osteopathic-continuous-certification.aspx (last visited March 12, 2017).
[66] Certificates issued prior to 1993 are not time-limited and therefore are valid for life.
[67] *Supra*, note 65.

- **Practice Performance Assessment and Improvement.** The physician must engage in continuous quality improvement through comparison of personal practice performance measured against national standards for his or her medical specialty.
- **Continuous AOA Membership.** The physician must maintain membership in good standing through the AOA, and must participate in relevant specialty-specific educational activities.[68]

Credentialing

Credentialing is the process of collecting and verifying a provider's professional qualifications, including academic background, relevant training and experience, licensure, and certification or registration to practice in a particular health care field.[69] Health plans and insurers use credentialing to determine whether to include a provider in the plan's or insurer's network; that is, to contract with the provider to provide services to enrollees and policyholders. Credentialing is a required element for health plan accreditation by the National Commission for Quality Assurance.[70] Health plans and insurers may require board-certified physicians to maintain board certification as a condition of participating in the network.

Admitting Privileges

Health care facilities also use the credentialing process to confer admitting privileges. An admitting privilege is the right of a physician to admit patients to a particular hospital, and to provide specific services in that facility.[71] Admitting privileges are difference than clinical privileges, which are the privileges granted to a physician or other licensed health care practitioner to render patient care services in a hospital, but which do not include the privilege of admitting patients.[72]

Board Certification and Florida Licensure

DOH does not license physician by specialty or subspecialty based upon board certification; however, ch. 458 and ch. 459, F.S., limit which physicians may hold themselves out as board-certified specialists. An allopathic physician licensed under ch. 458, F.S., may not hold himself or herself out as a board-certified specialist unless he or she has received formal recognition as a specialist from a specialty board of the American Board of Medical Specialties (ABMS) or other recognizing agency[73] approved by the allopathic board.[74] Additionally, an allopathic physician may not hold himself or herself out as a board-certified specialist in dermatology unless the recognizing agency, whether authorized in statute or by rule, is triennially reviewed and reauthorized by the allopathic board.[75] Similarly, an osteopathic physician licensed under ch. 459, F.S., may not hold himself or herself out as a board-certified specialist unless he or she has successfully completed the requirements for certification by the American Osteopathic Association (AOA) or the Accreditation Council on Graduate Medical Education (ACGME) and is certified as a specialist by a certifying agency[76] approved by the board.[77] These

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[68] Id.
[69] *See, e.g.,* AETNA, *Health care professionals: Joining the Network FAQs*, https://www.aetna.com/faqs-health-insurance/health-care-professionals-join-network.html (last visited Jan. 24, 2016); FLORIDA BLUE, *Manual for Physicians and Providers*, (2015), at 14, *available at* https://www.floridablue.com/providers/tools-resources/provider-manual (last visited March 12, 2017); UNITEDHEALTHCARE, *Physician Credentialing and Recredentialing Frequently Asked Questions*, *available at* https://www.uhccommunityplan.com/content/dam/communityplan/healthcareprofessionals/providerinformation/KS-Provider-Information/KS_Credentialing_FAQ.pdf (last visited March 12, 2017).
[70] NCQA, *CR Standards & Guidelines,* http://www.ncqa.org/tabid/404/Default.aspx (last visited March 13, 2017).
[71] In order for a physician to be granted privileges, a hospital generally checks the individual's medical credentials, license and malpractice history. Many hospitals also require physicians to admit a minimum number of patients to the hospital each year before they will grant or renew privileges. Others require the doctor to live within a minimum distance of the hospital.
[72] Section 395.002(5), F.S.
[73] The allopathic board has approved the specialty boards of the ABMS as recognizing agencies. Rule 64B8-11.001(1)(f), F.A.C.
[74] Section 458.3312, F.S.
[75] Id.
[76] The osteopathic board has approved the specialty boards of the ABMS and AOA as recognizing agencies. Rule 64B15-14.001(h), F.A.C.
[77] Section 459.0152, F.S.

limitations on advertising are set out in rule 64B8-11.001, F.A.C. for allopathic physicians and rule 64B15-14.001, F.A.C., for osteopathic physicians

Effect of Proposed Changes

HB 723 creates s. 458.3113, F.S., for allopathic physicians, and s. 459.0056, F.S., for osteopathic physicians, titled "conditions of licensure, reimbursement, employment, or admitting privileges." The bill prohibits the allopathic board, osteopathic board, DOH, health care facilities licensed under chapter 395, F.S.,[78] and insurers as defined in s. 624.03, F.S.,[79] from requiring maintenance of certification or recertification as a condition of licensure, reimbursement, employment, or admitting privileges for a physician who practices medicine and has achieved initial board certification in a subspecialty. The bill does not address specialty board certifications; only subspecialty certifications.

The bill defines maintenance of certification as a periodic testing regimen, proprietary self-assessment requirement, peer evaluation, or other requirement imposed by a recognizing agency approved by the allopathic or osteopathic board.

The bill defines recertification as a subsequent recognition or certification of educational or scholarly achievement beyond initial board certification in a sub-specialty by a recognizing agency approved by the allopathic or osteopathic board.

These definitions would apply to MOC requirements under the ABMS and OCC requirements under the AOA for maintaining board certification. As a result, the allopathic or osteopathic board, DOH, health care facilities, or insurers cannot penalize a physician whose subspecialty board certification lapses by denying licensure, reimbursement, employment, or admitting privileges.

Because DOH does not license a physician's specialty or subspecialty based upon board certification, the bill has no impact on licensure if a physician's board certification for a specialty or subspecialty lapses. However, physicians who let their subspecialty certification lapse will no longer be able to hold themselves out as board certified in that particular subspecialty.

The bill specifically states that it does not prohibit the board from requiring CME under allopathic and osteopathic board rules. The current CME rules remain in effect for all physicians.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Creates s. 458.3113, F.S., relating to conditions of licensure, reimbursement, employment, or admitting privileges.
Section 2: Creates s. 459.0056, F.S., relating to conditions of licensure, reimbursement, employment, or admitting privileges
Section 3: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

[78] These facilities are a hospitals, ambulatory surgical centers, and mobile surgical facilities.
[79] "Insurer" includes every person engaged as indemnitor, surety, or contractor in the business of entering into contracts of insurance or of annuity. This includes insurance contracts under ch. 627, F.S., prepaid limited health service organizations and discount medical plans under ch, 636, F.S., health maintenance organizations under ch. 641, F.S., and state group health insurance under ch. 110, F.S.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

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 maintenance of certification; creating ss. 458.3113 and 459.0056, F.S.; providing definitions; providing legislative intent; prohibiting the Boards of Medicine and Osteopathic Medicine, respectively, and the Department of Health, health care facilities, and insurers from requiring certain certifications as conditions of licensure, reimbursement, employment, or admitting privileges; providing construction; providing an effective date.

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

Section 1. Section 458.3113, Florida Statutes, is created to read:

458.3113 Conditions of licensure, reimbursement, employment, or admitting privileges.—

(1) For purposes of this section, the term:

(a) "Maintenance of certification" means a periodic testing regimen, proprietary self-assessment requirement, peer evaluation, or other requirement imposed by a recognizing agency approved by the board pursuant to rule 64B8-11.001, Florida Administrative Code.

(b) "Recertification" means a subsequent recognition or certification of educational or scholarly achievement beyond

initial board certification in a subspecialty by a recognizing agency approved by the board pursuant to rule 64B8-11.001, Florida Administrative Code.

(2) It is the intent of the Legislature to further improve the efficiency of the health care market and eliminate unnecessary administrative and regulatory requirements.

(3) Notwithstanding any other provision of law, the board, the department, a health care facility licensed under chapter 395, or an insurer as defined in s. 624.03 may not require maintenance of certification or recertification as a condition of licensure, reimbursement, employment, or admitting privileges for a physician who practices medicine and has achieved initial board certification in a subspecialty pursuant to this chapter.

(4) This section may not be construed to prohibit the board from requiring continuing medical education pursuant to rule 64B8-13.001, Florida Administrative Code.

Section 2. Section 459.0056, Florida Statutes, is created to read:

459.0056 Conditions of licensure, reimbursement, employment, or admitting privileges.—

(1) For purposes of this section, the term:

(a) "Maintenance of certification" means a periodic testing regimen, proprietary self-assessment requirement, peer evaluation, or other requirement imposed by a recognizing agency approved by the board pursuant to rule 64B15-14.001, Florida

Administrative Code.

(b) "Recertification" means a subsequent recognition or certification of educational or scholarly achievement beyond initial board certification in a subspecialty by a recognizing agency approved by the board pursuant to rule 64B15-14.001, Florida Administrative Code.

(2) It is the intent of the Legislature to further improve the efficiency of the health care market and eliminate unnecessary administrative and regulatory requirements.

(3) Notwithstanding any other provision of law, the board, the department, a health care facility licensed under chapter 395, or an insurer as defined in s. 624.03 may not require maintenance of certification or recertification as a condition of licensure, reimbursement, employment, or admitting privileges for an osteopathic physician who practices medicine and has achieved initial board certification in a subspecialty pursuant to this chapter.

(4) This section may not be construed to prohibit the board from requiring continuing medical education pursuant to rule 64B15-13.001, Florida Administrative Code.

Section 3. This act shall take effect July 1, 2017.

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 Gonzalez offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 458.3113, Florida Statutes, is created to read:

458.3113 Conditions of licensure, reimbursement, employment, or admitting privileges.—

(1) For purposes of this section, the term:

(a) "Maintenance of certification" means a periodic testing regimen, proprietary self-assessment requirement, peer evaluation, or other requirement imposed by the maintenance of certification program of the American Board of Medical Specialties and its member boards, or by any recognizing agency

approved by the board pursuant to rule for any board-certified specialty or subspecialty.

(b) "Recertification" means a subsequent recognition or certification of educational or scholarly achievement beyond initial board certification imposed by the maintenance of certification program of the American Board of Medical Specialties and its member boards, or by any recognizing agency approved by the board pursuant to rule for any board-certified specialty or subspecialty.

(2) It is the intent of the Legislature to further improve the efficiency of the health care market and eliminate unnecessary administrative and regulatory requirements.

(3) Notwithstanding any other provision of law, the board, the department, a health care facility licensed under chapter 395, or an insurer as defined in s. 624.03 may not require maintenance of certification or recertification as a condition of licensure, reimbursement, or admitting privileges for a physician who practices medicine and has achieved initial board certification in a specialty or subspecialty pursuant to this chapter.

(4) This section may not be construed to prohibit the board from requiring continuing medical education.

Section 2. Section 459.0056, Florida Statutes, is created to read:

459.0056 Conditions of licensure, reimbursement, employment, or admitting privileges.—

(1) For purposes of this section, the term:

(a) "Osteopathic continuing certification" means a periodic testing regimen, proprietary self-assessment requirement, peer evaluation, or other requirement imposed by the osteopathic continuing certification program of the Bureau of Osteopathic Specialists of the American Osteopathic Association and its specialty boards, or by any recognizing agency approved by the board pursuant to rule for any board-certified specialty or subspecialty.

(b) "Recertification" means a subsequent recognition or certification of educational or scholarly achievement beyond initial board certification imposed by the Bureau of Osteopathic Specialists of the American Osteopathic Association and its specialty boards, or by any recognizing agency approved by the board pursuant to rule for any board-certified specialty or subspecialty.

(2) It is the intent of the Legislature to further improve the efficiency of the health care market and eliminate unnecessary administrative and regulatory requirements.

(3) Notwithstanding any other provision of law, the board, the department, a health care facility licensed under chapter 395, or an insurer as defined in s. 624.03 may not require osteopathic continuing certification or recertification as a

condition of licensure, reimbursement, or admitting privileges for an osteopathic physician who practices medicine and has achieved initial board certification in a specialty or subspecialty pursuant to this chapter.

(4) This section may not be construed to prohibit the board from requiring continuing medical education.

Section 3. This act shall take effect July 1, 2017.

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

Remove everything before the enacting clause and insert:

A bill to be entitled

An act relating to health care certification; creating ss. 458.3113 and 459.0056, F.S.; providing definitions; providing legislative intent; prohibiting the Boards of Medicine and Osteopathic Medicine, respectively, and the Department of Health, health care facilities, and insurers from requiring certain certifications as conditions of licensure, reimbursement, or admitting privileges; providing construction; providing an effective date.

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 Massullo offered the following:

Amendment to Amendment (186001) by Representative Gonzalez (with title amendment)

Between lines 71 and 72 of the amendment, insert:

Section 3. Section 458.3312, Florida Statutes, is amended to read:

458.3312 Specialties.—

(1) A physician licensed under this chapter may not hold himself or herself out as a board-certified specialist unless the physician has received formal recognition as a specialist from a specialty board of the American Board of Medical Specialties or other recognizing agency that has been approved by the board. However, a physician may indicate the services

offered and may state that his or her practice is limited to one or more types of services when this accurately reflects the scope of practice of the physician. A physician may not hold himself or herself out as a board-certified specialist in dermatology unless the recognizing agency, whether authorized in statute or by rule, is triennially reviewed and reauthorized by the Board of Medicine.

(2) A physician licensed under this chapter who has been certified as a specialist by an approved certifying agency in subsection (1), but whose certification has lapsed may only hold himself or herself out as an initially board-certified specialist.

Section 4. Section 459.0152, Florida Statutes, is amended to read:

459.0152 Specialties.—

(1) An osteopathic physician licensed under this chapter may not hold himself or herself out as a board-certified specialist unless the osteopathic physician has successfully completed the requirements for certification by the American Osteopathic Association or the Accreditation Council on Graduate Medical Education and is certified as a specialist by a certifying agency approved by the board. However, an osteopathic physician may indicate the services offered and may state that his or her practice is limited to one or more types of services

when this accurately reflects the scope of practice of the osteopathic physician.

(2) A physician licensed under this chapter who has been certified as a specialist by an approved certifying agency in subsection (1), but whose certification has lapsed may only hold himself or herself out as an initially board-certified specialist.

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

Remove line 86 of the amendment and insert:
providing construction; amending s. 458.3312, F.S.; providing a designation for physicians whose board certification has lapsed; amending s. 459.0152, F.S.; providing a designation for physicians whose board certification has lapsed; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 963 Newborn Screenings
SPONSOR(S): Fitzenhagen
TIED BILLS: **IDEN./SIM. BILLS:** SB 1124

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

SUMMARY ANALYSIS

Newborn screening is a preventive public health program that is provided in every state in the United States to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death. The United States Department of Health and Human Services (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) advises HHS on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards. ACHDNC establishes the heritable disorders listed on the federal Recommended Uniform Screening Panel (RUSP).

In Florida, the Department of Health (DOH) is responsible for administering the statewide Newborn Screening Program (NSP), which conducts screenings for 53 hereditary and congenital disorders. Once a disorder is added to the RUSP, it is reviewed by DOH's Genetic and Newborn Screening Advisory Council (GNSAC) to determine whether to recommend the disorder be added to the NSP panel.

The most recent disorders added to the state's panel were Severe Combined Immunodefiency (SCID) and Critical Congenital Heart Defect (CCHD). SCID was added 1 year and 10 months after recommendation by the GNSAC and CCHD was added 2 years and 6 months after the recommendation by the GNSAC.

HB 963 amends s. 383.14, F.S., to require DOH to adopt rules requiring every newborn in the state, at the appropriate age, to be tested for any condition listed on the federal RUSP that the GNSAC advises should be included in the NSP panel. DOH must adopt the rules to include any condition the GNSAC recommends within 1 year of its recommendation.

The bill also requires DOH to adopt rules requiring the GNSAC to consider addition of a condition in the NSP panel within 1 year of the condition being added to the federal RUSP.

The bill will have a significant indeterminate negative fiscal impact on DOH, and has no impact on local governments.

The bill provides for an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Federal Recommendations for Newborn Screening

Newborn screening is a preventive public health program that is provided in every state in the United States to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.

The United States Department of Health and Human Services (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), under the Public Health Service Act,[1] is established to reduce morbidity and mortality in newborns and children who have, or are at risk for, heritable disorders.[2] To that end, the ACHDNC advises the Secretary of HHS on the most appropriate application of universal newborn and child screening tests and technical information for the development of policies and priorities that will enhance the ability of state and local health agencies to provide for screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders.[3] As part of this process, ACHDNC establishes the list of heritable disorders on the federal Recommended Uniform Screening Panel (RUSP).

The RUSP currently recommends screening for 32 core conditions and 26 secondary conditions.[4]

Florida Newborn Screening Program

Section 383.14(5), F.S., establishes the Florida Genetics and Newborn Screening Advisory Council (GNSAC) to advise the Department of Health (DOH) about which disorders should be added to the Newborn Screening Program (NSP) panel of screened disorders and the procedures for collecting and transmitting specimens.[5] Florida's NSP currently screens for 50 of the 58 disorders recommended by the RUSP, including 31 core conditions and 28 secondary conditions.[6]

The intent of the NSP is to screen all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.[7] The NSP involves coordination among several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in Jacksonville (State Laboratory), DOH Children's Medical Services (CMS) Newborn Screening Follow-up Program in Tallahassee, and referral centers, birthing centers, and physicians throughout the state.[8]

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[1] 42 U.S.C. s. 300b-10; 42 U.S.C. s. 217a: Advisory councils or committees (2016).
[2] U.S. Department of Health and Human Services, *Advisory Committee on Heritable Disorders in Newborns and Children*, http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/index.html (last accessed March 11, 2017).
[3] Secretary of Health and Human Services, *Charter Discretionary Advisory Committee on Heritable Disorders in Newborns and Children*, April 24, 2013, available at: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/about/charterdachdnc.pdf (last accessed March 11, 2017).
[4] Advisory Committee on Heritable Disorders in Newborns and Children, *Recommended Uniform Screening Panel (as of November 2016), available at*: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/uniformscreeningpanel.pdf (last visited March 11, 2017).
[5] S. 383.14(5), F.S.
[6] Florida Department of Health, *Disorder List*, available at: http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/_documents/newborn-screening-disorders.pdf (last accessed March 11, 2017); this list is also maintained by DOH in Rule Rule 64C-7.002, F.A.C.
[7] Florida Department of Health, Florida Newborn Screening Guidelines, 2012, available at: https://www.peds.ufl.edu/divisions/genetics/programs/newborn_screening/2012%20newborn%20screening%20guidelines%20FL.pdf (last accessed March 11, 217).
[8] Infra, FN 9.

After a screening specimen is collected, the specimen card is sent to the State Laboratory in Jacksonville for testing.[9] The State Laboratory receives about 1,000 specimens per day from births in Florida.[10] In the event that a newborn screen has an abnormal result, the CMS program provides follow-up services for the child and his or her family.[11]

Adding Conditions to the NSP Panel

Before a disorder is added to the NSP panel, the GNSAC considers the recommendations of the ACHDNC and evaluates whether:[12]

- The disorder is known to result in significant impairment in health, intellect, or functional ability, if not treated before clinical signs appear.
- The disorder can be detected using screening methods which are accepted by current medical practice.
- The disorder can be detected prior to the infant's becoming two weeks of age, or at the appropriate age as accepted medical practice indicates.
- After screening for the disorder, reasonable cost benefits can be anticipated through a comparison of tangible program costs with those medical, institutional, and special educational costs likely to be incurred by an undetected population.

If the GNSAC recommends the inclusion of a disorder to the NSP panel, DOH assesses the availability of funding, staff, the availability of a federally approved test, and treatment options required to add the disorder to the NSP panel.[13] To prepare for the addition of a disorder to the NSP panel, DOH must:[14]

- Obtain budget authority for expenditures for reagents, equipment, data system modifications, staffing, second tier testing, and contracting with referral centers for diagnostic services; testing and validation of the screening test;
- Develop follow-up policies;
- Establish referral center contracts;
- Ensure the availability of the appropriate pediatric specialists and developing standard procedures for diagnostic services for infants with critical values; and
- Develop disorder specific educational materials for physicians and birthing facilities to include the interpretation of lab results, appropriate actions by physicians and facilities upon diagnosis, and information for families.

The most recent disorders added to the NSP panel were Severe Combined Immunodeficiency in 2012 (1 year and 10 months after recommendation by the GNSAC) and Critical Congenital Heart Defect in 2013 (2 years and 6 months after the recommendation by the GNSAC).[15]

[9] Florida Department of Health, Newborn Screening, http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/ (last accessed March 11, 2017).
[10] Id.
[11] Id.
[12] Rule 64C-7.007, F.A.C. (2014) (repealed in 2015).
[13] Florida Department of Health, *Agency Analysis of 2017 House Bill 963*, February 22, 2017 (on file with Health Quality Subcommittee).
[14] Supra, FN 13 at pg. 3.
[15] Florida Department of Health, Bureau of Public Health Laboratories Newborn Screening, *Conditions Newborn Screening Detects*, available at: http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/BPHL/_documents/nbs-screened-disorders.pdf (last accessed March 11, 2017).; Supra, FN 13 at pg. 2.

Currently, three disorders on the RUSP are not on the NSP panel:[16]

- X-linked ALD (ALD)[17]
- Glycogen Storage Disease Type II (Pompe)[18]
- Mucupolysacharidosis Type I (MPS I)[19]

The GNSAC recommended the addition of ALD to the NSP panel on February 19, 2016. DOH has requested a $1.3 million recurring appropriation in the department's FY 2017-18 Legislative Budget Request to implement screening for ALD.[20] The RUSP added Pompe and MPS I in March 2, 2015 and February 15, 2016, respectively.[21] The GNASC has not recommended either for addition to the NSP panel.

Effect Of Proposed Changes

HB 963 amends s. 383.14, F.S., to require DOH to adopt rules requiring every newborn in the state, at the appropriate age, to be tested for any condition listed on the federal RUSP which the GNSAC advises should be included in the state's screening program. The bill also requires DOH to adopt rules that expand the statewide screening of newborns to include any condition the GNSAC recommends within 1 year of that recommendation.

The bill also requires DOH to adopt rules requiring the GNSAC to consider whether to include a condition in the state's screening program within 1 year of the condition being added to the federal RUSP.

The effective date of the bill is July 1, 2017.

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[16] *See* United States Department of Health and Human Services, Advisory Committee on Heritable Disorders in Newborns and Children, *Recommended Uniform Screening Panel*, available at: https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/index.html (last accessed March 11, 2017); Florida Department of Health, Bureau of Public Health Laboratories Newborn Screening, *Conditions Newborn Screening Detects*, available at: http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/BPHL/_documents/nbs-screened-disorders.pdf (last accessed March 11, 2017).

[17] X-Linked ALD is a genetic disorder that occurs primarily in males with an incidence rate of approximately 1 in 20,000-50,000. It mainly affects the nervous system and the adrenal glands, which are small glands located on top of each kidney. In this disorder, the fatty covering (myelin) that insulates nerves in the brain and spinal cord is prone to deterioration (demyelination), which reduces the ability of the nerves to relay information to the brain. In addition, damage to the outer layer of the adrenal glands (adrenal cortex) causes a shortage of certain hormones (adrenocortical insufficiency). Adrenocortical insufficiency may cause weakness, weight loss, skin changes, vomiting, and coma. There are three distinct types of X-linked adrenoleukodystrophy: a childhood cerebral form, an adrenomyeloneuropathy type, and a form called Addison disease only; https://ghr.nlm.nih.gov/condition/x-linked-adrenoleukodystrophy (last accessed March 13, 2017).

[18] Pompe is an inherited disorder with an incidence rate of approximately 1 in 40,000. It is caused by the buildup of a complex sugar called glycogen in the body's cells. The accumulation of glycogen in certain organs and tissues, especially muscles, impairs their ability to function normally; https://ghr.nlm.nih.gov/condition/pompe-disease (last accessed March 13, 2017)>

[19] MPS I is a genetic disorder with two presentations. Severe MPS 1 has an incidence rate of approximately 1 in 100,000 and Attenuated MPS 1 – approximately 1 in 500,000. The disorder causes molecules to build up inside lysomes, which causes tissue and organ enlargement as well as interference with the function of proteins inside the lysomes; https://ghr.nlm.nih.gov/condition/mucopolysaccharidosis-type-i# (last accessed March 13, 2017).

[20] Florida Department of Health, Legislative Budget Request for FY 2017-2018, *D-3A Expenditures by Issue and Appropriation Category*, 2017, pg. 88, available at: http://floridafiscalportal.state.fl.us/Document.aspx?ID=14707&DocType=PDF (last accessed March 11, 2017).

[21] United States Department of Health and Human Services, Secretary's Final Response RE: Committee's Recommendation to add Pompe Disease to the RUSP, March 2, 2015, available at: https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/secretaryfinalresponse.pdf (last accessed March 11, 2017); United States Department of Health and Human Services, Secretary's Final Response regarding Committee's Recommendation to add MPS I to the RUSP, February 16, 2016, available at: https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/secretary-final-mpsi-rusp.pdf (last accessed March 11, 2017).

B. SECTION DIRECTORY:

Section 1: Amends s. 383.14, F.S., relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.

Section 2: Provides for an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None

2. Expenditures:

   The bill will have an indeterminate negative fiscal impact on the Department of Health. It is unknown what or how many disorders may be added by the RUSP and recommended by the GNSAC in the future. As a comparison, the most recent added test, for ALD requires a recurring appropriation of $1,331,492 (with an FDA-approved test). Without an FDA-approved test the cost would be nearly $3,000,000.[22]

   The two most recent disorders added to the state's panel, Severe Combined Immunodeficiency and Critical Congenital Heart Defect, required appropriations of $1,961,450 and $204,922, respectively. The Critical Congenital Heart Defect screen does not require a laboratory component.[23]

   Laboratory fiscal impact can range from $850,000 to $3,000,000 depending on multiple factors, including whether there is an FDA-approved test kit, whether the test will be run on existing platforms, whether the test requires additional instrumentation, and how many additional FTEs will be required.[24]

   According to the Agency for Health Care Administration, Florida Medicaid covers required screenings. AHCA will need to monitor the implementation of the bill as well as any recommendations by the GNSAC to add conditions to the NSP panel to determine the fiscal impact. Prior AHCA projections indicate there will be 131,669 newborns in the Medicaid program for Fiscal Year 2016-2017 and 133,275 newborns in in Fiscal Year 2016-2017.[25]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

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[22] Supra, FN 13 at pg. 5.
[23] Id.
[24] Id.
[25] Florida Agency for Health Care Administration, *Agency Analysis for 2015 House Bill 403*, January 22, 2015 (on file with Health Quality Subcommittee).

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There is an indeterminate negative fiscal impact to insurance carriers that cover newborn screening, depending on which screenings are added.

D. FISCAL COMMENTS:

The NSP requires legislative appropriation for implementation of screening for recommended additions to the NSP panel.[26] The process of adding a disorder to the NSP panel does not proceed prior to a legislative budget request and subsequent appropriation, which takes longer than the year required by the bill.[27]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not Applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The GNASC was presented the topic of this bill on February 3, 2017. Comments from members included that the timeframe of one year was inadequate for obtaining funding and does not allow for proper evaluation of the current status of the NSP.[28]

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[26] S. 383.14(3)(g)2., F.S.
[27] Supra, FN 13 at pg. 7.
[28] Supra, FN 13 at pg. 4; GNASC meeting minutes from this February 3, 2017 meeting have not yet been approved or published.

A bill to be entitled

An act relating to newborn screenings; amending s. 383.14, F.S.; requiring the Department of Health, upon the advice of the Genetics and Newborn Screening Advisory Council, to expand within a specified period the statewide screening of newborns to include any condition on the federal Recommended Uniform Screening Panel; requiring the council to determine whether a condition should be included in the state's screening program within a specified period after its addition to the federal panel; providing an effective date.

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

Section 1. Subsection (2) and paragraph (a) of subsection (5) of section 383.14, Florida Statutes, are amended to read:

383.14 Screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.—

(2) RULES.—

(a) After consultation with the Genetics and Newborn Screening Advisory Council, the department shall adopt and enforce rules requiring that every newborn in this state shall:

1. Before~~, prior to~~ becoming 1 week of age, be subjected to a test for phenylketonuria;

2. At the appropriate age, be tested for any condition

included on the federal Recommended Uniform Screening Panel which the council advises the department should be included under the state's screening program. The department shall expand statewide screening of newborns to include screening for such conditions within 1 year after the council renders such advice; and~~,~~

3. At the appropriate age, be tested for such other metabolic diseases and hereditary or congenital disorders as the department may deem necessary from time to time.

(b) After consultation with the Office of Early Learning, the department shall ~~also~~ adopt and enforce rules requiring every newborn in this state to be screened for environmental risk factors that place children and their families at risk for increased morbidity, mortality, and other negative outcomes.

(c) The department shall adopt such additional rules as are found necessary for the administration of this section and s. 383.145, including rules providing definitions of terms, rules relating to the methods used and time or times for testing as accepted medical practice indicates, rules relating to charging and collecting fees for the administration of the newborn screening program authorized by this section, rules for processing requests and releasing test and screening results, and rules requiring mandatory reporting of the results of tests and screenings for these conditions to the department.

(5) ADVISORY COUNCIL.—There is established a Genetics and

Newborn Screening Advisory Council made up of 15 members appointed by the State Surgeon General. The council shall be composed of two consumer members, three practicing pediatricians, at least one of whom must be a pediatric hematologist, one representative from each of the four medical schools in the state, the State Surgeon General or his or her designee, one representative from the Department of Health representing Children's Medical Services, one representative from the Florida Hospital Association, one individual with experience in newborn screening programs, one individual representing audiologists, and one representative from the Agency for Persons with Disabilities. All appointments shall be for a term of 4 years. The chairperson of the council shall be elected from the membership of the council and shall serve for a period of 2 years. The council shall meet at least semiannually or upon the call of the chairperson. The council may establish ad hoc or temporary technical advisory groups to assist the council with specific topics which come before the council. Council members shall serve without pay. Pursuant to the provisions of s. 112.061, the council members are entitled to be reimbursed for per diem and travel expenses. It is the purpose of the council to advise the department about:

(a) Conditions for which testing should be included under the screening program and the genetics program. Within 1 year after a condition is added to the federal Recommended Uniform

Screening Panel, the council shall consider whether the condition should be included under the state's screening program.

Section 2. This act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 963 (2017)

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 Fitzenhagen offered the following:

Amendment

Remove lines 25-30 and insert:

2. Be tested for any condition included on the federal Recommended Uniform Screening Panel which the council advises the department should be included under the state's screening program. The department shall expand statewide screening of newborns to include screening for such conditions within 18 months after the council renders such advice, if an FDA approved test, or an alternative vendor test, compatible with Florida lab standards is available. If an FDA approved test is not available within 18 months after the council makes its recommendation, the

Department shall implement such screening as soon as an FDA approved test or an alternative vendor test is approved.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 969 Pregnancy Support Services
SPONSOR(S): Toledo
TIED BILLS: **IDEN./SIM. BILLS:** SB 1130

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

The Florida Pregnancy Support Services Program (FPSSP), was established in 2005, to provide supportive counseling and services to pregnant women and their families that promote and encourage childbirth. Under contract with the Department of Health (DOH), Florida Pregnancy Care Network, Inc., manages a network of pregnancy help centers that offer services such as pregnancy testing, counseling, education and training, and referrals to state, community, and medical resources.

The program was created by proviso in 2005, and has received annual appropriations since 2006. The bill codifies the program and defines program requirements.

The bill requires DOH to contract with the Florida Pregnancy Care Network, Inc., (FPCN), to provide contract management services for the delivery of pregnancy support and wellness services to eligible clients. The contract must:

- Require FPCN to establish and manage subcontracts with a sufficient number of providers to ensure the availability of pregnancy support and wellness services for eligible clients;
- Limit the amount of funds that may be used for administration costs;
- Require all paid staff or volunteers of a provider to undergo a background screening if they provide direct services to minors, elderly individuals, or individuals who have a disability;
- Require FPCN to monitor its subcontractors annually, and establish sanctions for noncompliance;
- Require FPCN to only subcontract with providers that solely promote and support childbirth;
- Require informational materials provided to eligible clients be current and accurate, and the reference source of any medical statements made in such materials be made available to eligible clients; and
- Define the contract deliverables, including financial reports and other reports due DOH.

The bill requires that any services provided under FPSSP be provided in a manner that is non-coercive, and may not include any religious content.

The bill has no fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida Pregnancy Support Services Program

The Florida Pregnancy Support Services Program (FPSSP) was created in 2005, to encourage women to carry their pregnancies to term, and increase awareness of non-abortion counseling options, such as parenting or adoption.[1] The program, through a network of private pregnancy support centers, provides services to pregnant women (or women who suspect they are pregnant) and their families at no charge, which may continue for 12 months after the birth of the child. Interested women may be connected to a local participating center by accessing a free helpline via telephone, text, or email. The services provided include:

- Free pregnancy testing;
- Abortion education;
- Alternatives to abortion;
- Education and training;
- Counseling; and
- Referrals to state, community, and medical resources.[2]

Currently, the Department of Health (DOH) contracts with the Florida Pregnancy Care Network, Inc. (FPCN), to manage subcontracts with the direct service providers throughout the state that provide the services listed above, as well as an operational call center.[3] The network consists of 74 Florida pregnancy resource organizations or pregnancy centers.[4]

Under the contract with DOH, a participating provider must:

- Be an established pregnancy organization with a fully functioning pregnancy support program in existence for at least one year;
- Be recognized as tax-exempt under IRS Code 501(c)(3);
- Have a primary mission to promote life-affirming decisions among its clients;
- Provide FPSSP services in a manner that is non-coercive and does not include religious content;
- Offer pregnancy tests and counseling for women who are pregnant or suspect they are pregnant, and seek FPSSP services voluntarily;
- Have a board that hires and oversees a director who implements board policy and manages the organization's operations;
- Maintain a system of financial accountability consistent with generally accepted accounting principles;
- Have board members, directors, employees, and volunteers participate in continuing education, as necessary, in order to effectively perform their duties;
- Not discriminate on the basis of race, creed, color, national origin, age, or marital status;
- Provide services that are confidential, nonjudgmental, and free of charge;

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[1] Florida Pregnancy Care Network, Inc., *Florida Pregnancy Support Services Program (FPSSP), 2016-2017 Compliance Manual*, on file with the Health Quality Subcommittee.
[2] Florida Pregnancy Support Services, *About Us*, available at http://www.floridapregnancysupportservices.com/about-us/ (last visited March 10, 2017).
[3] *Supra* note 1.
[4] Florida Pregnancy Care Network, Inc., *About Us*, *available at* http://myfpcn.com/about.html (last visited March 10, 2017).

- Make available support information, education, and counseling to women, their partners, and their families to solely promote and support childbirth and to assist them in decisions regarding adoption or parenting; and
- Must complete FPSSP training.[5]

Under the contract, providers may only be reimbursed for the face-to-face services that they provide to eligible clients. Providers are paid $60 per hour for face-to-face services and are reimbursed $1.50 for each pregnancy test provided to a FPSSP client.[6] Payment is provided monthly through the submission of a properly completed invoice and monthly report.[7] Providers are also responsible for submitting quarterly (including financial reports) and final reports addressing operations for FPSSP during the contract period.

The FPSSP operates a 24-hour toll free number that offers referrals to local pregnancy centers, as well as a text hotline, to which an individual may text the word "choices," for assistance. Assistance is also available by e-mail.[8]

In Fiscal Year 2015-2016, the FPSSP served 24,184 clients, provided 120,929 services, and handled 5,756 phone calls to its helpline. From July 2016 through December 2016, the FPSSP has served 14,001 clients, provided 67,028 services, and handled 2,596 phone calls to its hotline.

When FPSSP was established, DOH received an initial annual appropriation of $2 million in proviso language in the General Appropriations Act to establish and operate the FPSSP.[9] DOH has annually received funding for the operation of the FPSSP in the proviso of the annual appropriations bill. In Fiscal Year 2016-2017, the FPSSP received an appropriation of $4 million and was authorized, in proviso, to provide wellness services, including but not limited to, high blood pressure screening, flu vaccines, anemia testing, thyroid screening, cholesterol screening, diabetes screening, assistance with smoking cessation, and tetanus vaccines.[10] Such wellness services may be offered through vouchers or other arrangements that allow the purchase of services from qualified providers. DOH and FPSSP executed a contract amendment in February 2017, to incorporate the new services.[11]

Effect of Proposed Changes

The bill creates s. 381.96, F.S., to codify the Florida Pregnancy Support Services Program (FPSSP) in Florida Statutes. The bill establishes eligibility for the program for pregnant women (or women who suspect they are pregnant) who voluntarily seek pregnancy support services, and their families. The family of a pregnant woman or a woman who suspects she is pregnant is also eligible to receive services. Eligibility continues for up to 12 months after the birth of the child.

The bill codifies services to be provided under the program including pregnancy support services and wellness support services. Pregnancy support services, as defined in the bill, are services that promote and encourage childbirth, including direct client services, program awareness activities, and communication activities. Wellness services, as defined by the bill, are services or activities intended to maintain and improve health or prevent illness and injury, including but not limited to flu and tetanus

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[5] *Id.*
[6] *Id.*
[7] The monthly invoice must include the total reimbursable minutes and the amount requested. In the monthly report, the provider must include the total number of client visits, the number of unduplicated clients served, the number of new clients, the total number of services provided, and how the clients learned of the services.
[8] *Supra* note
[9] Chapter 2006-25, Laws of Fla., I. 536. These funds are separate from the funds that are generated in the sale of the "Choose Life" license plate. Pursuant to s. 320.08058(29), F.S., funds generated by the license plates are distributed to nongovernmental, not-for-profit agencies within each Florida county which assist pregnant women who are making an adoption plan for their children. The funds are distributed in an amount based on the collection of annual use fees in each county. Agencies that are involved in or associated with abortion activities are specifically prohibited from receiving any fees generated by use of the license plate.
[10] Chapter 2016-66, Laws of Fla., I. 464.
[11] E-mail correspondence with DOH staff dated March 13, 2017, on file with the Health Quality Subcommittee.

vaccines, anemia testing, assistance with smoking cessation, and screenings for high blood pressure, thyroid functioning, cholesterol, and diabetes.

The bill requires DOH to contract with the Florida Pregnancy Care Network, Inc., to provide contract management services for the FPSSP. It requires the FPCN to provide a comprehensive system of care through subcontracts to meet the pregnancy support and wellness needs of eligible clients. The contract with FPCN must:

- Require that FPCN establish and manage subcontracts with a sufficient number of providers to ensure the availability pregnancy support and wellness services for eligible clients;
- Require that 90 percent of contract funds be used on pregnancy support and wellness services for eligible clients;
- Require that FPCN ensures that all paid staff and volunteers of the providers undergo background screenings if they provide direct client services to eligible clients who are minors, elderly, or have a disability;
- Require FPCN annually monitor the providers for compliance with subcontract provisions and define the actions to be taken for noncompliance;
- Limit the providers with which FPCN may contract to those that solely promote and support childbirth;
- Provide that any informational materials provided to an eligible client by a provider must be current and accurate, with reference source of any medical statement made available; and
- Define the contract deliverables, including financial reports and other reports due the DOH, timeframes for achieving contractual obligations, and any other requirements that DOH determines necessary, such as staffing and location requirements.

The bill expressly provides that the services provided under the FPSSP must be provided in a manner that is non-coercive and may not include any religious content.

The bill takes effect on July 1, 2017.

B. SECTION DIRECTORY:

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None. DOH currently incurs costs related to the oversight of the contractor, which will continue under the bill. Proviso language has limited DOH to $50,000 for agency oversight activities.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Eligible clients continue to receive pregnancy support services free of charge.

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 the pregnancy support services; creating s. 381.96, F.S.; providing definitions; requiring the Department of Health to contract with a not-for-profit statewide alliance of organizations to provide pregnancy support services through subcontractors; providing duties of the department; providing contract requirements; requiring the contractor to spend a specified percentage of funds on direct client services; requiring the contractor to annually monitor subcontractors; providing for subcontractor background screenings under certain circumstances; specifying the entities eligible for a subcontract; requiring services to be provided in a noncoercive manner and forbidding inclusion of religious content; providing an effective date.

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

Section 1. Section 381.96, Florida Statutes, is created to read:

381.96 Pregnancy support services.—

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

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

(b) "Eligible client" means a pregnant woman or a woman

who suspects she is pregnant, and the family of such woman, who voluntarily seeks pregnancy support services. The woman and her family shall continue to be eligible clients for no more than 12 months after the birth of the child.

(c) " Florida Pregnancy Care Network, Inc.," or "network" means the not-for-profit statewide alliance of pregnancy support organizations that provide pregnancy support services through a comprehensive system of care to women and their families.

(d) "Pregnancy support services" means services that promote and encourage childbirth, including, but not limited to:

1. Direct client services, such as pregnancy testing, counseling, referral, training, and education for pregnant women and their families.

2. Program awareness activities, including a promotional campaign to educate the public about the pregnancy support services offered by the network and a website that provides information on the location of providers in the user's area, as well as other available community resources.

3. Communication activities, including the operation and maintenance of a hotline or call center with a single statewide toll-free number that is available 24 hours a day for an eligible client to obtain the location and contact information for a pregnancy center located in his or her area.

(e) "Wellness services" means services or activities intended to maintain and improve health or prevent illness and

injury, including, but not limited to, high blood pressure screening, flu vaccines, anemia testing, thyroid screening, cholesterol screening, diabetes screening, assistance with smoking cessation, and tetanus vaccines.

(2) DEPARTMENT DUTIES.—The department shall contract with the network for the management and delivery of pregnancy support services to eligible clients.

(3) CONTRACT REQUIREMENTS.—The department contract shall specify the contract deliverables, including financial reports and other reports due to the department, timeframes for achieving contractual obligations, and any other requirements the department determines are necessary, such as staffing and location requirements. The contract shall require the network to:

(a) Establish, implement, and monitor a comprehensive system of care through subcontractors to meet the pregnancy support and wellness needs of eligible clients.

(b) Establish and manage subcontracts with a sufficient number of providers to ensure the availability of pregnancy support and wellness services for eligible clients, and maintain and manage the delivery of such services throughout the contract period.

(c) Spend at least 90 percent of the contract funds on pregnancy support and wellness services.

(d) Offer wellness services through vouchers or other

appropriate arrangements that allow the purchase of services from qualified health care providers.

(e) Require a background screening under s. 943.0542 for all paid staff and volunteers of a subcontractor if such staff or volunteers provide direct client services to an eligible client who is a minor or an elderly person or who has a disability.

(f) Annually monitor its subcontractors and specify the sanctions that shall be imposed for noncompliance with the terms of a subcontract.

(g) Subcontract only with providers that exclusively promote and support childbirth.

(h) Ensure that informational materials provided to an eligible client by a provider are current and accurate and cite the reference source of any medical statement included in such materials.

(4) SERVICES.—Services provided pursuant to this section must be provided in noncoercive manner and may not include any religious content.

Section 2. This act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 969 (2017)

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 Toledo offered the following:

Amendment (with title amendment)

Remove lines 32-56 and insert:

organizations that provide pregnancy support and wellness services through a comprehensive system of care to women and their families.

(d) "Pregnancy support services" means services that promote and encourage childbirth, including, but not limited to:

1. Direct client services, such as pregnancy testing, counseling, referral, training, and education for pregnant women and their families.

2. Program awareness activities, including a promotional campaign to educate the public about the pregnancy support

services offered by the network and a website that provides information on the location of providers in the user's area, as well as other available community resources.

3. Communication activities, including the operation and maintenance of a hotline or call center with a single statewide toll-free number that is available 24 hours a day for an eligible client to obtain the location and contact information for a pregnancy center located in his or her area.

(e) "Wellness services" means services or activities intended to maintain and improve health or prevent illness and injury, including, but not limited to, high blood pressure screening, flu vaccines, anemia testing, thyroid screening, cholesterol screening, diabetes screening, assistance with smoking cessation, and tetanus vaccines.

(2) DEPARTMENT DUTIES.—The department shall contract with the network for the management and delivery of pregnancy support and wellness

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

Remove line 6 and insert:

provide pregnancy support and wellness services through

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1037 Optometry
SPONSOR(S): Diaz, Jr.
TIED BILLS: **IDEN./SIM. BILLS:** SB 1168

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

SUMMARY ANALYSIS

Optometrists examine, diagnose, treat, and manage diseases and injuries of the visual system as well as identify systemic conditions which affect visual health. Optometrists are regulated under ch. 463, F.S., by the Board of Optometry within the Department of Health. Optometrists may prescribe certain ocular medications listed in law or established in a formulary by the Board of Optometry, but may not perform certain surgical procedures using an instrument, including a laser, scalpel, or needle.

Ch. 463 creates a category of licensed optometrists, "certified optometrists," that authorizes licensed optometrists who have completed board approved coursework and training to administer and prescribe certain topical medications as established by the Board of Optometry or certain oral medications listed in statute. Certified optometrists may also perform certain procedures as listed in statute that are not considered surgical procedures under ch. 463.

The bill amends ch. 463, the Optometry Practice Act, to create two categories of certification for licensed optometrists: "certified optometrists in pharmaceutical agents" and "certified optometrists in ophthalmic surgery." To be certified optometrist, the bill requires the licensed optometrist provide proof to DOH that he or she has successfully completed a board-approved course and examination.

The bill authorizes certified optometrists in pharmaceutical agents to administer and prescribe topical or oral ocular pharmaceutical agents as established by the Board of Optometry. The bill repeals the permitted oral medications listed in statute and authorizes the Board of Optometry to establish a list of permitted oral and topical medications. The bill authorizes certified optometrists in ophthalmic surgery to perform laser and non-laser ophthalmic surgeries in which human tissue is injected, cut, burned, frozen, sutured, vaporized, coagulated, or photodisrupted by the use of surgical instrumentation, including but not limited to, a scalpel, cryoprobe, laser, electric cautery, or ionizing radiation. The bill prohibits certain surgeries. Optometrists who not meet certain requirements may not administer or prescribe topical or oral medications or perform surgery.

The bill states that the Board of Optometry has the sole authority to determine the scope of practice of optometry.

The bill has an insignificant, negative fiscal impact to the Department of Health and no fiscal impact to local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Optometrists and Ophthalmologists

Optometrists examine, diagnose, treat, and manage diseases and injuries of the visual system as well as identify systemic conditions which affect visual health. Optometrists are regulated under ch. 463, F.S., by the Board of Optometry (board) within DOH.

Optometrist training involves an undergraduate degree and completion of a 4-year program at a college of optometry. Some optometrists complete residencies to gain more specialized knowledge, but residency training is not required for licensure or practice.[1]

Ophthalmologists are medical doctors who specialize in diseases of the eye. Ophthalmologists provide a full spectrum of eye care, from prescribing corrective lenses and medications to performing eye surgery. Ophthalmologists also care for patients with more advanced and complicated diseases than do optometrists. Ophthalmologists are regulated under ch. 458 and 459, F.S., by the Board of Medicine and the Board of Osteopathic Medicine within DOH. Ophthalmologist training involves an undergraduate degree, 4 years of medical school, and completion of at least 4 years of residency training in ophthalmology.[2]

Florida law requires optometrists diagnosing a patient with certain diseases to refer such patients to "physician skilled in the diseases of the eye" (ophthalmologists) for further treatment.[3] Additionally, an optometrist must promptly advise a patient to seek an evaluation by an ophthalmologist for diagnosis and possible treatment whenever the optometrist is informed by the patient of the sudden onset of spots or "floaters" with loss of all or part of the visual field.[4] Optometrists must maintain the names of at least three physicians, clinics, or hospitals to which they may refer patients who experience adverse drug reactions.[5]

Three states, Oklahoma, Kentucky, and Louisiana, allow optometrists to perform surgical procedures.[6] Oklahoma has allowed optometrists to perform surgical procedures since 1988.[7] In 1988, the Oklahoma Board of Examiners in Optometry began credentialing optometrists to perform anterior laser surgical procedures.[8] Between 1988 and 1998, 5,000 laser surgeries were performed by optometrists in Oklahoma.[9] A review by the Oklahoma Board of Examiners in Optometry of the outcomes of those surgeries found that negative outcome rates ranged between 0.5%-1.5% and were the same as those of surgeries performed by ophthalmologists in Oklahoma.[10] Since 1998, 25,000 anterior laser surgeries

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[1] American Optometric Association, *What is a Doctor of Optometry?*, *available at*: http://www.aoa.org/about-the-aoa/what-is-a-doctor-of-optometry?sso=y (last visited March 10,2017).
[2] American Academy of Ophthalmology, *What is an Ophthalmologist*, *available at:* https://www.aao.org/eye-health/tips-prevention/what-is-ophthalmologist (last visited March 10, 2017).
[3] Diagnoses which mandate a referral to an ophthalmologist include angle closure glaucoma, congenital or infantile glaucoma, and infectious corneal diseases that are unresponsive to standard treatment. Section 463.0135, F.S.
[4] Section 463.0135(4), F.S.
[5] Section 463.0135(8), F.S.
[6] American Optometric Association, In Scope. Available at: http://www.aoa.org/news/aoa-focus/novemberdecember-2014/in-scope?sso=y (last visited on March 13, 2017).
[7] Testimony of Dr. April Jasper, President of the Florida Optometric Association, on file with the Health Quality Subcommittee.
[8] Id.
[9] Id.
[10] Id.

have been performed by optometrists in Oklahoma and the Oklahoma Board of Examiners in Optometry has not received any complaints regarding those surgeries.[11]

A 2016 peer-reviewed study analyzed the outcomes for laser glaucoma surgeries between 2008 and 2013 in Oklahoma.[12] The study found that patients were nearly twice as likely to need additional treatment when the procedure was performed by an optometrist as compared to an ophthalmologist.[13] The study also found there was a 189% increased risk of needing additional treatment in the eye that had been treated when the procedure was performed by an optometrist as compared to an ophthalmologist.[14]

Optometrist Prescribing Authority in Florida

Currently, Florida law allows licensed optometrists to administer and prescribe drugs under limited circumstances. Licensed optometrists may only use topical anesthetics for glaucoma examinations, unless the licensed optometrist is also a certified optometrist.[15] Certified optometrists may administer and prescribe topical or oral ocular pharmaceutical agents for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques.[16]

To be certified by the board to administer and prescribe topical ocular pharmaceuticals, a licensed optometrist must be complete at least 110 hours of board approved coursework and training and one year of supervised experience in differential diagnosis of eye diseases or disorders.[17] Certified optometrists that also wish to administer and prescribe oral ocular pharmaceutical agents must also complete a board-approved 20-hour course and examination on general and ocular pharmaceutical agents and their side effects.[18] If a certified optometrist does not complete the course and examination, he or she may only administer or prescribe topical ocular pharmaceutical agents as established by board rule.[19]

The oral ocular pharmaceutical agents a certified optometrist may administer or prescribe are specified in a statutory formulary.[20] The agents include seven antibiotics and three antivirals:

- Amoxicillin with or without clavulanic acid;
- Azithromycin;
- Erythromycin;
- Dicloxacillin;
- Doxycycline/Tetracycline;
- Keflex; and
- Minocycline.
- Acyclovir;
- Famciclovir; and
- Valacyclovir.

Current law prohibits a certified optometrist from administering or prescribing certain drugs for more than 72 hours, including two analgesics and two anti-glaucoma agents:

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[11] Id.
[12] Stein, J.D., et. al. *Comparison of Outcomes of Laser Trabeculoplasty Performed by Optometrists vs. Ophthalmologists in Oklahoma.* JAMA Ophthalmol. 2016;134(10):1095-1101. Available at: http://jamanetwork.com/journals/jamaophthalmology/article-abstract/2535226
[13] Id.
[14] Id.
[15] Section 453.0055(1)(a), F.S.; Chapter No. 2013-26,L.O.F.
[16] Ss. 463.0055(1)(a) and 463.002(4), F.S.
[17] Rule 64B13-10.001, F.A.C.
[18] Section 463.0055, F.S.
[19] Rule 64B13-18.002, F.A.C.
[20] Section 463.0055(3), F.S.

- Tramadol hydrochloride; and
- Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.
- Acetazolamide; and
- Methazolamide.

Any oral ocular pharmaceutical agent listed in the statutory formulary which is subsequently determined by the U.S. Food and Drug Administration to be unsafe for the administration or prescription is considered to have been deleted from the statutory formulary.[21]

The statutory formulary prohibits the administration or prescription of a controlled substance listed in Schedule III[22], Schedule IV[23], or Schedule V[24] of s. 893.03, F.S., except for the oral analgesics specified in the statutory formulary for the relief of pain due to ocular conditions of the eye and its appendages, or a controlled substance for the treatment of chronic nonmalignant pain.[25]

Optometrist Scope of Practice in Florida

Optometrists may prescribe certain medications, vision therapy, and corrective lenses, but may not perform surgical procedures in Florida.[26] Florida law defines surgery as a procedure using an instrument, including a laser, scalpel, or needle, in which human tissue is cut, burned, scraped, or vaporized by incision, injection, ultrasound, laser, infusion, cryotherapy, or radiation and also includes a procedure using an instrument which requires the closure of human tissue by suture, clamp, or a similar device.[27] However, certified optometrists that are authorized to administer or prescribe certain medication, may perform the following optometric practices[28]:

- Performing an eye examination, including a dilated examination, if required or authorized under laws related to pugilistic exhibitions[29];
- Removing an eyelash by epilation;
- Probing an uninflamed tear duct in a patient 18 years of age or older;
- Blocking the puncta by plug;
- Performing a superficial scraping to remove damaged epithelial tissue or superficial foreign bodies or take a culture of the surface of the cornea or conjunctiva; and
- Using commonly accepted means or methods to immediately address incidents of anaphylaxis.

Effect of Proposed Changes

The bill amends s. 463.005, F.S. to create two separate categories of certification for licensed optometrists: "certified optometrist in pharmaceutical agents" and "certified optometrist in ophthalmic surgery."

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[21] Id.
[22] Section 893.03(3), F.S. defines a Schedule II substance as a substance that has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage.
[23] Section 893.03(4) defines a Schedule IV substance as a substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III.
[24] Section 893.03(5), F.S. defines a Schedule V substance, compound, mixture or preparation that has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.
[25] Chronic nonmalignant pain is defined in section 456.44, F.S., as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 day after surgery.
[26] Section 463.014(4), F.S.
[27] Section 463.002(6), F.S.
[28] Section 463.014(4), F.S.
[29] Ch. 548, F.S.

Optometrist Prescribing Authority in Florida

The bill allows certified optometrists in pharmaceutical agents to administer and prescribe pharmaceutical agents. The bill retains the training and examination requirements for a certified optometrist to be able to administer or prescribe oral ocular pharmaceutical agents. The bill retains the prohibition on a licensed optometrist administering or prescribing any ocular pharmaceutical agents, except for topically applied anesthetics solely for glaucoma examinations, if he or she does not complete the required board-approved course and examination.

The bill expands the range of medications a certified optometrist can administer or prescribe to include any prescription or non-prescription drug, including approved narcotics, delivered by any route of administration that is used to treat, prevent, or mitigate abnormal conditions or diseases of the eye, its appendages and visual system. The bill repeals the statutory formulary of permitted ocular pharmaceutical agents, including both oral and topical. Instead, the bill requires the board to establish by rule a formulary of permitted topical and oral ocular pharmaceutical agents.

The bill prohibits the administration and prescription of Schedule I controlled substances and repeals the current law's prohibition on the administration or prescription of Schedule III, IV, and V controlled substances and controlled substances for the treatment of chronic non-malignant pain, which allows certified optometrists to administer and prescribe these drugs.

Optometrist Scope of Practice in Florida

The bill creates a new certification category for licensed optometrists, "certified optometrists in ophthalmic surgery." To become a certified optometrist in ophthalmic surgery, the bill requires a licensed optometrist successfully complete a board-approved course and examination. The bill allows certified optometrists in ophthalmic surgery to perform laser and non-laser ophthalmic surgery. The bill defines ophthalmic surgery as any procedure performed on the human eye and its appendages and visual system in which human tissue is injected, cut, burned, frozen, sutured, vaporized, coagulated, or photodisrupted by the use of surgical instrumentation, including but not limited to, a scalpel, cryoprobe, laser, electric cautery, or ionizing radiation.

The bill also specifies certain surgical procedures that certified optometrists in ophthalmic surgery are prohibited from performing, including:

- Penetrating keratoplasty, corneal transplant, or lamellar keratoplasty.
- The administration of general anesthesia.
- Surgery done with general anesthesia.
- Laser or non-laser injection into the vitreous chamber of the eye to treat amacular or retinal disease.
- Surgery related to the removal of the eye from a living human being.
- Surgery requiring full-thickness incision or excision of the cornea or sclera, other than paracentesis in an emergency situation requiring immediate reduction of the pressure inside the eye.
- Surgery requiring incision of the iris and ciliary body, including iris diathermy or incision with cryotherapy.
- Surgery requiring incision of the vitreous.
- Surgery requiring incision of the retina.
- Surgical extraction of the crystalline lens.
- Surgical intraocular prosthetic implants.
- Incisional or excisional surgery of extraocular muscles.

- Surgery of the eyelid for suspect eyelid malignancies or for repair of, including plastic surgery for, blepharochalasis or mechanical ptosis.
- Tarsorrhaphy.
- Surgery of the boney orbit, including orbital implants.
- Incisional or excisional surgery of the lacrimal system other than lacrimal probing or related procedures.
- Surgery requiring full-thickness conjunctivoplasty with graft or flap.
- Pterygium surgery.

The bill makes the necessary conforming changes throughout Florida Statutes relating to the creation of the two new certification categories.

The bill also grants sole authority to the Board of Optometry to determine the scope of the practice of optometry which appears to prohibit any other board or entity of the state other than the Board of Optometry from determining what constitutes the practice of optometry. It is unclear what kind of impact, if any, this language will have on the authority of the board.[30]

The bill also grants the board the authority to issue advisory opinions and declaratory rulings related to Ch. 463 and the rules adopted thereunder. Typically, the Administrative Procedures Act, Ch. 120, F.S., governs the issuance of declaratory statements by agencies and boards. Ch. 120, F.S., allows any substantially affected person to seek a declaratory statement of an agency or board's opinion as to the applicability of a statutory provision or rule or order of the agency or board as it applies to the person's particular set of circumstances.

Although the bill grants the board sole authority to determine the scope of practice of optometry, the bill authorizes the State Health Officer[31] to permit a licensed optometrist to prescribe order, dispense, administer, supply, sell, or give any drug for the treatment of a systemic disease during a public health emergency.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 463.002 relating to definitions.
Section 2: Amends s. 463.005 relating to the authority of the board.
Section 3: Amends s. 463.0055 relating to the administration and prescription of ocular pharmaceutical agents.
Section 4: Creates s. 463.0056 relating to the administration and performance of laser and non-laser surgical procedures.
Section 5: Amends s. 463.014 relating to prohibited acts.
Section 6: Amends s. 463.007 relating to renewal of licenses and continuing education.
Section 7: Amends s. 463.009 relating to supportive personnel.
Section 8: Amends s. 463.013 relating to optometric services for certain public agencies.
Section 9: Amends s. 463.0135 relating to standards of practice.
Section 10: Amends s. 641.31 relating to health maintenance contracts.
Section 11: Provides an effective date of July 1, 2017.

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[30] In 1998, Oklahoma's statue regulating the profession of optometry was amended to allow optometrists to perform some laser surgeries. The statute also includes language granting sole authority to the Board to determine the scope of practice of optometry. In 2004, the Oklahoma Attorney General issued an advisory opinion that regardless of this grant of authority the board did not have the authority to authorize optometrists to perform nonlaser surgical procedures. Oklahoma subsequently amended its statute to allow performance of nonlaser surgeries by optometrists. See *OKLA. ATTY. GEN. OP. 04-009 (Apr. 6, 2004) and OKLA. STAT. ANN. Tit. 59, § 581.*

[31] The State Health Officer is the State Surgeon General and is responsible for declaring public health emergencies. Section 20.43, F.S.; Section 381.00315, F.S.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH anticipates that it will incur additional costs and workload to implement the provisions of the bill.[32] DOH anticipates the need for an additional FTE position to handle the increased workload associated with regulation, complaints, investigation and communication of the new certification category created the bill for certified optometrist in ophthalmic surgery.

   DOH reports that it will likely incur costs to modify its licensure system, but the fiscal impact is indeterminate at this time.

   DOH will incur additional costs and workload associated with developing an application for the new certification category created by the bill for certified optometrists in ophthalmic surgery, for updating its licensure, enforcement, and continuing education databases, and for rulemaking, but current resources are adequate to absorb the costs and workload.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Licensed optometrists wanting to prescribe and administer ocular pharmaceutical agents or perform ophthalmic surgery may incur costs associated with the coursework and examination required by the bill. Such optometrists will experience increased revenues for performing such services.

Patients may experience cost-savings if they can be treated immediately by an optometrist without having to be referred to an ophthalmologist for treatment.[33]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

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[32] Department of Health, *Bill Analysis for HB 1037(2017),* dated February 24, 2017, on file with committee staff.

[33] Supra, note 5.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill grants the board the authority to issue advisory opinions or declaratory rulings related to Ch. 463 and rules adopted thereunder. It is unclear whether the issuance of such advisory opinions or declaratory rulings is subject to Ch. 120, the Administrative Procedures Act. If Ch. 120 applies, this language may be unnecessary as Ch. 120 already provides procedures for such activity by the board.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to optometry; amending s. 463.002, F.S.; redefining and defining terms; amending s. 463.005, F.S.; specifying that the Board of Optometry has the sole authority to determine what constitutes the practice of optometry; authorizing the board to issue specified advisory opinions and declaratory rulings; providing construction for ch. 463, F.S.; amending s. 463.0055, F.S.; restricting what a licensed practitioner may administer or prescribe if he or she does not complete a certain board-approved course and examination; revising the date after which a formulary rule becomes effective; deleting provisions related to the creation of a statutory formulary of oral ocular pharmaceutical agents; revising the conditions under which an ocular pharmaceutical agent is deleted from the formulary; revising the controlled substances that a certified optometrist in pharmaceutical agents is prohibited from prescribing and administering; conforming provisions to changes made by the act; creating s. 463.0056, F.S.; requiring a licensed practitioner to complete a board-approved course and examination to become a certified optometrist in ophthalmic surgery; authorizing a certified optometrist in ophthalmic

surgery to perform laser and non-laser ophthalmic surgery; requiring a certified optometrist in ophthalmic surgery to provide proof of completion of a certain course and examination before he or she may perform such surgeries; providing requirements for the development and offering of such course and examination; requiring the board to review and approve the content of the initial course and examination if it determines the course and examination satisfy certain requirements; requiring an annual review thereafter; authorizing the successful completion of the course and examination to be used by a licensed practitioner to satisfy continuing education requirements; prohibiting a certified optometrist in ophthalmic surgery from performing specified surgery procedures; amending s. 463.014, F.S.; providing that specified prohibited acts may be authorized by the State Health Officer during a public emergency; deleting a provision prohibiting surgery of any kind by a certified optometrist; amending ss. 463.007, 463.009, 463.013, 463.0135, and 641.31, 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. Section 463.002, Florida Statutes, is reordered and amended to read:

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

(2)~~(1)~~ "Board" means the Board of Optometry.

(3) "Certified optometrist in ophthalmic surgery" means a licensed practitioner authorized by the board to perform ophthalmic surgery.

(6)~~(2)~~ "Department" means the Department of Health.

(9)(a)~~(3)(a)~~ "Licensed practitioner" means a person who is a primary health care provider licensed to engage in the practice of optometry under the authority of this chapter.

(b) A licensed practitioner who is not a certified optometrist in pharmaceutical agents is ~~shall be~~ required to display at her or his place of practice a sign that ~~which~~ states, "I am a Licensed Practitioner, not a Certified Optometrist in Pharmaceutical Agents, and I am not able to prescribe ocular pharmaceutical agents."

(c) All practitioners initially licensed after July 1, 1993, must be certified optometrists in pharmaceutical agents.

(d) A licensed practitioner who is not a certified optometrist in ophthalmic surgery is required to display at her or his place of practice a sign that states, "I am a Licensed Practitioner, not a Certified Optometrist in Ophthalmic Surgery, and I am not able to perform laser or non-laser ophthalmic

surgery."

(4) "Certified optometrist in pharmaceutical agents" means a licensed practitioner authorized by the board to administer and prescribe ocular pharmaceutical agents.

(10) ~~(5)~~ "Ocular pharmaceutical agent" means any prescription or nonprescription drug delivered by any route of administration, used or prescribed for the diagnosis, treatment, prevention, or mitigation of abnormal conditions and diseases of the human eye and its adnexa and visual system, or products that may be used for such purposes, and approved narcotics when used in the treatment of disorders or diseases of the eye and its adnexa and visual system. The term does not include any drug or other substance that is prohibited from use by a licensed practitioner and is listed in Schedule I of the federal Controlled Substances Act, 21 U.S.C. s. 812(c) ~~a pharmaceutical agent that is administered topically or orally for the diagnosis or treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques~~.

(11) ~~(6)~~ "Ophthalmic surgery" means a procedure performed on the human eye and its adnexa and visual system in which human tissue is injected, cut, burned, frozen, sutured, vaporized, coagulated, or photodisrupted by the use of surgical instrumentation such as, but not limited to, a scalpel, a cryoprobe, a laser, an electric cautery, or ionizing radiation

~~using an instrument, including a laser, scalpel, or needle, in which human tissue is cut, burned, scraped except as provided in s. 463.014(4), or vaporized, by incision, injection, ultrasound, laser, infusion, cryotherapy, or radiation. The term includes a procedure using an instrument which requires the closure of human tissue by suture, clamp, or other such device~~.

(12)~~(7)~~ "Optometry" means the practice in which a person:

(a) Employs primary eye care procedures, including the prescription of ocular pharmaceutical agents, medical devices, and ophthalmic surgery;

(b) Measures the power and range of vision of the human eye using subjective and objective means, including the use of lenses and prisms before the eye, autorefractors, and other automated testing devices to determine the eye's accommodative and refractive state and general scope of function;

(c) Engages in the adaption, sale, and dispensing of frames and lenses in all their forms, including plano or zero power contact lenses, to overcome errors of refraction and restore, as nearly as possible, normal human vision, or for orthotic, prosthetic, therapeutic, or cosmetic purposes with respect to contact lenses; or

(d) Examines for, diagnoses, and treats abnormal conditions and diseases of the human eye and its adnexa and visual system, including the use or prescription of vision therapy, ocular exercises, rehabilitation therapy, subnormal

vision therapy, appropriate diagnostic lab or imaging tests, and samples to initiate treatment ~~diagnosis of conditions of the human eye and its appendages; the employment of any objective or subjective means or methods, including the administration of ocular pharmaceutical agents, for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and the prescribing and employment of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or methods, including ocular pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the human eyes and their appendages~~.

(7) ~~(8)~~ "Direct supervision" means supervision to an extent that the licensee remains on the premises while all procedures are being done and gives final approval to any procedures performed by an employee.

(8) ~~(9)~~ "General supervision" means the responsible supervision of supportive personnel by a licensee who need not be present when such procedures are performed, but who assumes legal liability therefor. Except in cases of emergency, "general supervision" shall require the easy availability or physical presence of the licensee for consultation with and direction of the supportive personnel.

(1) ~~(10)~~ "Adnexa ~~Appendages~~" means the eyelids, the

eyebrows, the conjunctiva, and the lacrimal apparatus.

(13)~~(11)~~ "Transcript-quality" means a course which is in conjunction with or sponsored by a school or college of optometry or equivalent educational entity, which course is approved by the board and requires a test and passing grade.

(5)~~(12)~~ "Clock hours" means the actual time engaged in approved coursework and clinical training.

Section 2. Subsections (3) and (4) are added to section 463.005, Florida Statutes, to read:

463.005 Authority of the board.—

(3) The board has the sole authority to determine what constitutes the practice of optometry and to exercise any powers and duties conferred on it under this chapter. The board may issue advisory opinions and declaratory rulings related to this chapter and the administrative rules adopted under this chapter.

(4) This chapter may not be construed to authorize an agency or a medical board or entity of this state other than the board to determine what constitutes the practice of optometry.

Section 3. Section 463.0055, Florida Statutes, is amended to read:

463.0055 Administration and prescription of ocular pharmaceutical agents.—

(1)(a) Certified optometrists in pharmaceutical agents may administer and prescribe ocular pharmaceutical agents as provided in this section for the diagnosis and treatment of

ocular conditions of the human eye and its adnexa and visual system ~~appendages without the use of surgery or other invasive techniques~~. However, a licensed practitioner who is not a certified optometrist in pharmaceutical agents may use topically applied anesthetics solely for the purpose of glaucoma examinations, but is otherwise prohibited from administering or prescribing ocular pharmaceutical agents.

(b) Before a certified optometrist in pharmaceutical agents may administer or prescribe oral ocular pharmaceutical agents, the certified optometrist in pharmaceutical agents must provide proof to the department of successful completion of a course and subsequent examination, approved by the board, on general and ocular pharmaceutical agents and the side effects of those agents. The course must ~~shall~~ consist of 20 contact hours, all of which may be web-based. The first course and examination shall be presented by October 1, 2013, and shall be administered at least annually thereafter. The course and examination shall be developed and offered jointly by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category 1 credit and a statewide professional association of licensed practitioners which provides board-approved continuing education on an annual basis. The board shall review and approve the content of the initial course and examination if the board

determines that the course and examination adequately and reliably satisfy the criteria set forth in this section. The board shall thereafter annually review and approve the course and examination if the board determines that the content continues to adequately and reliably satisfy the criteria set forth in this section. Successful completion of the board-approved course and examination may be used by a licensed practitioner ~~certified optometrist~~ to satisfy 20 hours of the continuing education requirements in s. 463.007(3), only for the biennial period in which the board-approved course and examination are taken. If a licensed practitioner ~~certified optometrist~~ does not complete a board-approved course and examination under this section, the licensed practitioner may ~~certified optometrist is only authorized to~~ administer and prescribe only topically applied anesthetics solely for the purpose of glaucoma examinations, but is otherwise prohibited from administering or prescribing ~~topical~~ ocular pharmaceutical agents.

(2)(a) The board shall establish a formulary of ~~topical~~ ocular pharmaceutical agents that may be prescribed and administered by a certified optometrist in pharmaceutical agents. The formulary must ~~shall~~ consist of those ~~topical~~ ocular pharmaceutical agents that are appropriate to treat or diagnose ocular diseases and disorders and that the certified optometrist in pharmaceutical agents is qualified to use in the practice of

optometry. The board shall establish, add to, delete from, or modify the ~~topical~~ formulary by rule. Notwithstanding any provision of chapter 120 to the contrary, the ~~topical~~ formulary rule becomes effective 20 ~~60~~ days from the date it is filed with the Secretary of State.

(b) The formulary may be added to, deleted from, or modified according to the procedure described in paragraph (a). Any person who requests an addition, deletion, or modification of an authorized topical ocular pharmaceutical agent shall have the burden of proof to show cause why such addition, deletion, or modification should be made.

(c) The State Surgeon General shall have standing to challenge any rule or proposed rule of the board pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:

1. Does not protect the public from any significant and discernible harm or damages;

2. Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or

3. Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.

(d) Upon adoption of the formulary required by this section, and upon each addition, deletion, or modification to the formulary, the board shall mail a copy of the amended formulary to each certified optometrist in pharmaceutical agents and to each pharmacy licensed by the state.

~~(3) In addition to the formulary of topical ocular pharmaceutical agents established by rule of the board, there is created a statutory formulary of oral ocular pharmaceutical agents, which includes the following agents:~~

~~(a) The following analgesics or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:~~

~~1. Tramadol hydrochloride.~~

~~2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.~~

~~(b) The following antibiotics or their generic or therapeutic equivalents:~~

~~1. Amoxicillin with or without clavulanic acid.~~

~~2. Azithromycin.~~

~~3. Erythromycin.~~

~~4. Dicloxacillin.~~

~~5. Doxycycline/Tetracycline.~~

~~6. Keflex.~~

~~7. Minocycline.~~

~~(c) The following antivirals or their generic or therapeutic equivalents:~~

~~1. Acyclovir.~~

~~2. Famciclovir.~~

~~3. Valacyclovir.~~

~~(d) The following oral anti-glaucoma agents or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours:~~

~~1. Acetazolamide.~~

~~2. Methazolamide.~~

(e) Any ~~oral~~ ocular pharmaceutical agent that is in the formulary established by the board under paragraph (a) ~~listed in the statutory formulary set forth in this subsection~~ and that is subsequently determined by the United States Food and Drug Administration to be unsafe for administration or prescription shall be considered to have been deleted from the formulary of ~~oral~~ ocular pharmaceutical agents. ~~The oral ocular pharmaceutical agents on the statutory formulary set forth in this subsection may not otherwise be deleted by the board, the department, or the State Surgeon General.~~

(3) ~~(4)~~ A certified optometrist in pharmaceutical agents

shall be issued a prescriber number by the board. Any prescription written by a certified optometrist in pharmaceutical agents for an ocular pharmaceutical agent pursuant to this section must ~~shall~~ have the prescriber number printed thereon. A certified optometrist in pharmaceutical agents may not administer or prescribe~~:~~

~~(a)~~ a controlled substance listed in Schedule I of the Controlled Substances Act, 21 U.S.C. s. 812(c) ~~III, Schedule IV, or Schedule V of s. 893.03, except for an oral analgesic placed on the formulary pursuant to this section for the relief of pain due to ocular conditions of the eye and its appendages.~~

~~(b) A controlled substance for the treatment of chronic nonmalignant pain as defined in s. 456.44(1)(e)~~.

Section 4. Section 463.0056, Florida Statutes, is created to read:

463.0056 Administration and performance of laser and non-laser surgical procedures.—

(1)(a) A licensed practitioner must complete a board-approved course and examination under this section to become a certified optometrist in ophthalmic surgery.

(b) A certified optometrist in ophthalmic surgery may perform laser and non-laser ophthalmic surgery. To perform laser and non-laser ophthalmic surgery, the certified optometrist in ophthalmic surgery must provide to the department proof of the successful completion of a course and subsequent examination,

approved by the board, on laser and non-laser ophthalmic surgery.

(2) The course and examination shall be developed and offered jointly by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category 1 Credit and a statewide professional association of licensed practitioners which provides board-approved continuing education on an annual basis. The board shall review and approve the content of the initial course and examination if the board determines that the course and examination adequately and reliably satisfy the requirements for AMA PRA Category 1 Credit eligibility. The board shall thereafter annually review and approve the course and examination if the board determines that the content continues to adequately and reliably satisfy the requirements for AMA PRA Category 1 Credit eligibility. Successful completion of the board-approved course and examination may be used by a licensed practitioner to satisfy the continuing education requirements in s. 463.007(3), only for the biennial period in which the board-approved course and examination are taken.

(3) The following surgical procedures, except for the preoperative and postoperative care of these procedures, are excluded from the scope of practice of optometry by a certified optometrist in ophthalmic surgery:

(a) Penetrating keratoplasty, corneal transplant, or lamellar keratoplasty.

(b) The administration of general anesthesia.

(c) Surgery done with general anesthesia.

(d) Laser or non-laser injection into the vitreous chamber of the eye to treat a macular or retinal disease.

(e) Surgery related to the removal of the eye from a living human being.

(f) Surgery requiring full-thickness incision or excision of the cornea or sclera, other than paracentesis in an emergency situation requiring immediate reduction of the pressure inside the eye.

(g) Surgery requiring incision of the iris and ciliary body, including iris diathermy or incision with cryotherapy.

(h) Surgery requiring incision of the vitreous.

(i) Surgery requiring incision of the retina.

(j) Surgical extraction of the crystalline lens.

(k) Surgical intraocular prosthetic implants.

(l) Incisional or excisional surgery of extraocular muscles.

(m) Surgery of the eyelid for suspect eyelid malignancies or for repair of, including plastic surgery for, blepharochalasis or mechanical ptosis.

(n) Tarsorrhaphy.

(o) Surgery of the boney orbit, including orbital

implants.

(p) Incisional or excisional surgery of the lacrimal system other than lacrimal probing or related procedures.

(q) Surgery requiring full-thickness conjunctivoplasty with graft or flap.

(r) Pterygium surgery.

Section 5. Subsections (3) and (4) of section 463.014, Florida Statutes, are amended to read:

463.014 Certain acts prohibited.—

(3) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any drug for the purpose of treating a systemic disease by a licensed practitioner is prohibited, unless authorized by the State Health Officer during a public health emergency. However, a certified optometrist in pharmaceutical agents is permitted to use commonly accepted means or methods to immediately address incidents of anaphylaxis.

~~(4) Surgery of any kind is expressly prohibited. Certified optometrists may remove superficial foreign bodies. For the purposes of this subsection, the term "superficial foreign bodies" means any foreign matter that is embedded in the conjunctiva or cornea but that has not penetrated the globe. Notwithstanding the definition of surgery as provided in s. 463.002(6), a certified optometrist is not prohibited from providing any optometric care within the practice of optometry~~

~~as defined in s. 463.002(7), such as removing an eyelash by epilation, probing an uninflamed tear duct in a patient 18 years of age or older, blocking the puncta by plug, or superficial scraping for the purpose of removing damaged epithelial tissue or superficial foreign bodies or taking a culture of the surface of the cornea or conjunctiva.~~

Section 6. Subsection (3) of section 463.007, Florida Statutes, is amended to read:

463.007 Renewal of license; continuing education.—

(3) As a condition of license renewal, a licensee must demonstrate his or her professional competence by completing up to 30 hours of continuing education during the 2-year period preceding license renewal. For certified optometrists in pharmaceutical agents, the 30-hour continuing education requirement includes 6 or more hours of approved transcript-quality coursework in ocular and systemic pharmacology and the diagnosis, treatment, and management of ocular and systemic conditions and diseases during the 2-year period preceding application for license renewal.

Section 7. Section 463.009, Florida Statutes, is amended to read:

463.009 Supportive personnel.—No person other than a licensed practitioner may engage in the practice of optometry as defined in s. 463.002(12) ~~s. 463.002(7)~~. Except as provided in this section, under no circumstances shall nonlicensed

supportive personnel be delegated diagnosis or treatment duties; however, such personnel may perform data gathering, preliminary testing, prescribed visual therapy, and related duties under the direct supervision of the licensed practitioner. Nonlicensed personnel, who need not be employees of the licensed practitioner, may perform ministerial duties, tasks, and functions assigned to them by and performed under the general supervision of a licensed practitioner, including obtaining information from consumers for the purpose of making appointments for the licensed practitioner. The licensed practitioner shall be responsible for all delegated acts performed by persons under her or his direct and general supervision.

Section 8. Section 463.013, Florida Statutes, is amended to read:

463.013 Optometric services for certain public agencies.—Any agency of the state or county or any commission, clinic, or board administering relief, social security, health insurance, or health service under the laws of the state shall accept the services of licensed practitioners for the purposes of diagnosing and correcting any and all visual, muscular, neurological, and anatomic anomalies of the human eyes and their adnexa and visual systems ~~appendages~~ of any persons under the jurisdiction of said agency, clinic, commission, or board administering such relief, social security, health insurance, or

health service on the same basis and on a parity with any other person authorized by law to render similar professional service, when such services are needed, and shall pay for such services in the same way as other professionals may be paid for similar services.

Section 9. Subsections (3) and (10) of section 463.0135, Florida Statutes, are amended to read:

463.0135 Standards of practice.—

(3) When an infectious corneal disease condition has not responded to standard methods of treatment within the scope of optometric practice, the licensed practitioner or certified optometrist in pharmaceutical agents shall consult with a physician skilled in diseases of the eye and licensed under chapter 458 or chapter 459.

(10) A certified optometrist in pharmaceutical agents is authorized to perform any eye examination, including a dilated examination, required or authorized by chapter 548 or by rules adopted to implement that chapter.

Section 10. Subsection (19) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(19) Notwithstanding any other ~~provision of~~ law, health maintenance policies or contracts that ~~which~~ provide coverage, benefits, or services as described in s. 463.002(12) ~~s. 463.002(7)~~, shall offer to the subscriber the services of an

optometrist licensed pursuant to chapter 463.

Section 11. This act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 1037 (2017)

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 Diaz, M. offered the following:

Amendment

Remove line 389 and insert:

a public health emergency pursuant to s. 381.00315. However, a certified optometrist in

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1041 Laboratory Screening
SPONSOR(S): Raschein
TIED BILLS: **IDEN./SIM. BILLS:** SB 1144

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

SUMMARY ANALYSIS

The Department of Health (DOH) provides numerous public health education and screening programs including:

- The Newborn Screening Program which screens all newborns to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.
- The Lead Poisoning Prevention Screening and Education program that screens children under 6 years of age who are determined to be at-risk of having elevated blood-lead levels.
- A statewide network of county health departments and other sites that provide confidential and anonymous HIV testing, counseling, prevention outreach, and education to the public.

HB 1041 amends the Lead Poisoning Prevention Screening and Education Act to:

- Update the definition of "elevated blood-lead level" allowing DOH to update the blood-lead cutoff level to align with national guidance as the science determining acceptable blood-lead level changes;
- Require DOH to adopt rules to follow established national guidelines related to reporting elevated blood-levels;
- Remove certain requirements and provide flexibility for DOH to develop and distribute educational information on lead poisioning; and
- Reduce DOH's reporting and record maintenance requirements.

The bill amends the Newborn Screening Program to:

- Allow the State Laboratory to release metabolic tests to the parent or legal guardian, personal representative, or a person designated by the newborn's parent or legal guardian;
- Recognize that disorders with no known treatment may be added to the Newborn Screening Panel (NSP) and that detection of these disorders, even without treatment, helps families plan for the care of their children and avoid unnecessary costs in diagnosis; and
- Update the composition of the Genetics and Newborn Screening Advisory Council (GNSAC).

The bill removes the requirement for providers in healthcare settings to inform a person seeking an HIV test that a positive test result will be reported to the County Health Departments and of the availability and location of anonymous testing sites.

The bill also authorizes DOH to perform laboratory testing related to public health for other states on a fee-for-service basis.

The bill does not appear to have a fiscal impact on state or local governments.

The bill has an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Human Immunodeficiency Virus

Current Situation

Human Immunodeficiency Virus (HIV) is an immune system debilitating virus that can lead to fatal acquired immunodeficiency syndrome (AIDS). HIV affects specific cells of the immune system and over time the virus can destroy enough of these cells that the body can no longer fight off infection and disease.[1] There is no cure for HIV but it can be controlled with proper medical care, including antiretroviral therapy (ART). If taken properly, ART can dramatically prolong the lives of people infected with HIV, keep them healthy, and greatly lower the chance of infecting others.[2] A person diagnosed with HIV and treated before the disease is able to advance can live nearly as long as someone who does not have HIV. However, untreated HIV is almost always fatal.[3]

HIV Testing

In the United States, approximately 1.2 million people are living with HIV, 12.5 % of which are unaware of their infection.[4] HIV testing is essential for improving the health of people living with HIV and reducing new HIV infections. The Centers for Disease Control and Prevention (CDC) recommend that testing occur as part of a routine healthcare visit.[5] This is especially important for people who may not consider themselves at risk for HIV.[6]

The most common type of HIV test is an HIV antibody test, where blood or saliva are checked for specific HIV fighting proteins known as HIV antibodies.[7] It can take 3 to 12 weeks for the body to produce enough HIV antibodies for the test to detect.[8] Nucleic acid tests (NATS) are another, less common, form of testing that can diagnose an HIV infection in a blood sample 1 to 4 weeks after a person is first infected.[9] Legal and programmatic advances have streamlined testing services to provide confidentiality, and, in some cases, anonymity to test subjects, to encourage widespread testing. To increase HIV screening, the CDC does not recommend prevention counseling with HIV diagnostic testing or as part of HIV screening programs in healthcare settings.[10] The CDC strongly encourages prevention counseling in settings in which routine assessment of risk behaviors occurs, but indicates it should not be required for HIV testing.[11]

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[1] Centers for Disease Control and Prevention, *About HIV/AIDS*, accessible at: http://www.cdc.gov/hiv/basics/whatishiv.html#panel0 (last accessed March 12, 2017).
[2] Id.
[3] Id.
[4] Centers for Disease Control and Prevention, *HIV in the United States: At a Glance*, accessible at: http://www.cdc.gov/hiv/statistics/basics/ataglance.html#ref1 (last accessed March 11, 2017).
[5] Centers for Disease Control and Prevention, *State HIV Testing Laws: Consent and Counseling Requirements*, July 11, 2013, accessible at http://www.cdc.gov/hiv/policies/law/states/testing.html (last accessed March 11, 2017).
[6] In Florida, only 42.2% of adults reported having ever been tested for HIV; Florida Department of Health, *Florida Charts*, accessible at: http://www.flhealthcharts.com/charts/Brfss/StateDataViewer.aspx?bid=119 (last accessed March 11, 2017).
[7] U.S. Department of Health and Human Services, *Types of HIV Tests*, accessible at: http://aids.gov/hiv-aids-basics/prevention/hiv-testing/hiv-test-types/index.html (last accessed March 11, 2017).
[8] Id.
[9] Id.
[10] Centers for Disease Control, MMWR, *Revised Recommendations for HIV testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, 2006, available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm (last accessed March 12, 2017).
[11] Id.

HIV Testing in Florida

HIV testing in Florida is governed by s. 381.004, F.S., which creates a statewide network of confidential and anonymous HIV testing and counseling sites, procedures for HIV testing, informed consent requirements, and reporting requirements. The Department of Health (DOH) county health departments (CHDs) are the primary sources for state-sponsored HIV programs and provide testing, counseling, prevention outreach, and education to the public.[12] The statute was enacted to create an environment in Florida in which people will agree to or seek out HIV testing because they are sufficiently informed about HIV infection and assured about the privacy of a decision to be tested.[13]

To promote an environment of informed patient decision-making, providers are prohibited from performing an HIV test without a person's knowledge and informed consent, except under certain defined circumstances.[14] The statute gives the patient special rights to control who learns of the HIV test results and requires providers in both "**health care**"[15] and "**nonhealth care**"[16] settings to inform the person seeking an HIV test that a positive result will be reported to the CHD with sufficient information to identify the test subject and of the availability and location of sites that provide anonymous testing.[17]

Effect of Proposed Changes

HB 1041 amends s. 381.004(2)(a), F.S., to remove the requirement for providers in healthcare settings to inform a person seeking an HIV test that a positive test result will be reported to the CHD and of the availability and location of anonymous testing sites. Providers in nonhealth care settings will still be required to inform persons seeking HIV testing of those facts.

Pursuant to ss. 381.0031 and 384.25, F.S., providers in health care settings will still be required to report positive HIV test results to DOH.[18] The bill does not remove the reporting requirement, only the requirement to provide the person seeking an HIV test with the information that a positive result will be reported.

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[12] County health departments are the local sector of the Florida Department of Health, providing public health services in all 67 Florida counties. Their core functions are infectious disease prevention and control, basic family health services, and environmental health services. Florida Department of Health, *County Health Departments*, accessible at: http://www.floridahealth.gov/public-health-in-your-life/county-health-departments/index.html (last accessed March 11, 2017).

[13] Hartog, Jack, *Florida's Omnibus AIDS Act: A Brief Legal Guide for Health Care Professionals,* Florida Dep't of Health, accessible at: http://www.floridahealth.gov/diseases-and-conditions/aids/administration/_documents/Omnibus-booklet-update-2013.pdf (last accessed March 12, 2017).

[14] Section 381.004(2)(h), F.S., lists the exceptions to the requirement to obtain informed consent, including: when a person is tested for sexually transmitted diseases; when blood, plasma, or other human fluids or tissues are donated; when a determination for appropriate emergency medical care or treatment is required; during an autopsy; when testing pregnant women; when a defendant is charged with sexual battery and is consented to by the defendant, pursuant to court order; or for certain research purposes.

[15] S. 381.004(1)(a), F.S.; "**Health care setting**" means a setting devoted to the diagnosis and care of persons or the provision of medical services to persons, such as county health department clinics, hospitals, urgent care clinics, substance abuse treatment clinics, primary care settings, community clinics, blood banks, mobile medical clinics, and correctional health care facilities.

[16] S. 381.004(1)(d), F.S.; "Nonhealth care setting" means a site that conducts HIV testing for the sole purpose of identifying HIV infection. Such setting does not provide medical treatment but may include community-based organizations, outreach settings, county health department HIV testing programs, and mobile vans.

[17] S. 381.004(2)(a), F.S.

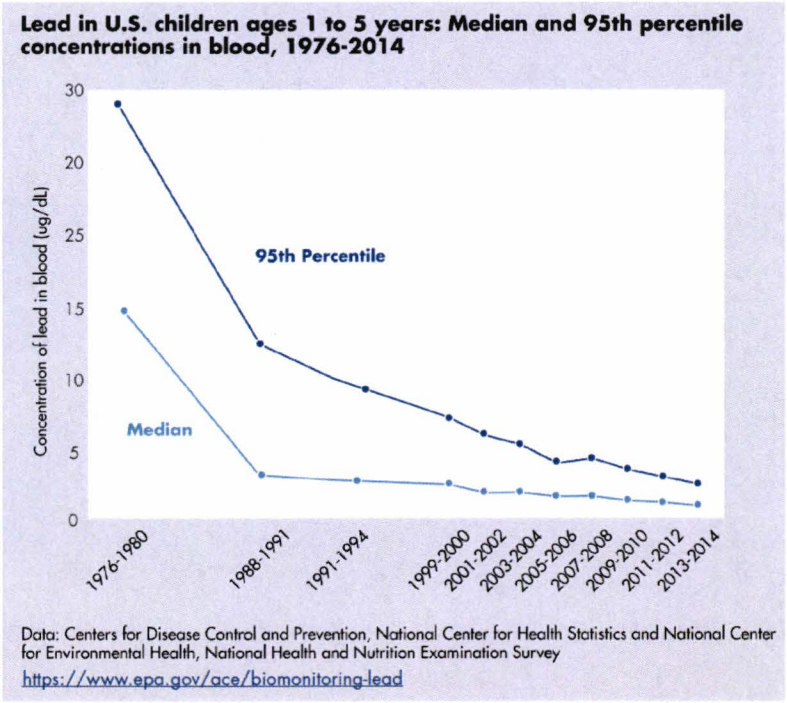
[18] Rule 64D-3.029, F.A.C.

Lead Screening and Education

Current Situation

Childhood Lead Poisoning

The CDC has termed excessive absorption of lead as "one of the most common pediatric health problems in the United States today, and it is entirely preventable."[19] Enough is known about the prevention of lead exposure to eradicate permanently this disease, making the persistence of lead poisoning in the U.S. a singular and direct challenge to public health authorities, clinicians, regulatory agencies, and society.[20] While the U.S. has not eradicated lead poisoning, tremendous progress in reducing lead exposure has been made.[21] Median blood lead levels of children in the U.S. have declined from 15 µg/dL from 1976-1980 to 0.7 µg/dL in 2013-214, a decrease of 95%.[22] The largest decline occurred from the 1970s to the 1990s following the elimination of lead in motor-vehicle gasoline, the ban on lead paint for residential use, removal of lead from solder in food cans, bans on the use of lead pipes and plumbing fixtures and other limitations on the uses of lead.[23]



The CDC reports that currently at least 4 million households have children living in them that are being exposed to high levels of lead.[24] While no safe blood level in children exists, there are approximately half a million children in the U.S. between the ages of 1 to 5 years old with blood levels above 5 micrograms per deciliter (µg/dL), the level at which the CDC recommends the initiation of public health action.[25]

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[19] Centers for Disease Control and Prevention, Preventing Lead Poisoning in Young Children, A Statement by the Centers for Disease Control, October 1991, available at: https://www.cdc.gov/nceh/lead/publications/books/plpyc/Chapter1.htm (last accessed March 12, 2017).
[20] Id.
[21] President's Task Force on Environmental Health Risks and Safety Risks to Children, *Key Federal Program to Reduce Childhood Lead Exposures and Eliminate Associated Health Impacts*, November 2016, available at: https://ptfceh.niehs.nih.gov/features/assets/files/key_federal_programs_to_reduce_childhood_lead_exposures_and_eliminate_associated_health_impactspresidents_508.pdf (last accessed March 12, 2017).
[22] Id.
[23] Id.
[24] Centers for Disease Control and Prevention, Lead, available at: https://www.cdc.gov/nceh/lead/ (last accessed March 13, 2017).
[25] Id.

Lead Poisoning Prevention Screening and Education Act

In 2006, the Legislature created the Lead Poisoning Prevention Screening and Education Act (Act). The Act requires DOH to establish a program for the early identification of persons at risk of having elevated blood-lead levels. Section 381.985(1), F.S., requires the program to systematically screen children under 6 years of age in certain target populations for the presence of elevated blood-lead levels. DOH is required to consult with professional medical groups and other sources and adopt rules that establish procedural guidelines for the screening of children under 6 years of age, appropriate intervals for screening, and follow-up for children found to have elevated blood-lead levels.[26] The Act defines "elevated blood-lead level" as a quantity of lead in whole venous blood that exceeds 10 µg/dL or such other level as provided in the Act.[27]

The Act requires DOH to establish a statewide, multifaceted, ongoing educational program designed to meet the needs of tenants, property owners, health care providers, early childhood educators, care providers, and realtors concerning lead poisoning prevention.[28] This educational program requires DOH to:

- Sponsor public service announcements on radio, television, print media, and the internet about the nature of lead-based paint hazards, the importance of standards for lead poisoning prevention, and the purposes and responsibilities of the Act; and
- Develop culturally and linguistically appropriate information pamphlets regarding lead poisoning, testing, prevention, treatment, and the purposes of the Act.[29]

DOH previously had federal funding to conduct a lead poisoning prevention program, including funding for a large media campaign.[30] However, the federal funding for this program ended in 2012.

The Act also requires DOH to maintain records of all screenings conducted pursuant to the Act indexed geographically and by owner to determine the location of areas of relatively high incidence of lead poisoning and other elevated blood-lead levels. All confirmed and probable cases of lead poisoning found in the course of screening must be reported to the affected individual, his or her parent or legal guardian if he or she is a minor, and the State Surgeon General.[31]

Effect of Proposed Chages

HB 1041 amends s. 381.985(1), F.S., to require DOH to adopt rules to follow established national guidelines or recommendations such as those issued by the Council of State and Territorial Epidemiologists and the CDC related to reporting elevated blood-levels. The bill amends the definition of "elevated blood-lead level" by removing the 10 µg/dL cutoff and requires the cutoff level to be specified by DOH rule. The rule must be based on national recommendations developed by the council of State and Territorial Epidemiologists and the CDC. This change allows DOH to change reporting and screening requirements as the science relating to blood-lead levels changes.

The bill amends s. 381.984, F.S. to remove the requirement for DOH to sponsor public service announcements and develop educational pamphlets. The change permits flexibility and cost savings in the distribution of information and educational materials regarding childhood lead poisoning.

The bill amends s. 381.985(3), F.S., to reduce the reporting and record maintenance requirements on DOH. The new language requires DOH to maintain comprehensive records of all screenings indicating an elevated blood-lead level and removes the requirement for DOH to report screening results to individuals. This change removes the requirement to maintain geographically indexed records and

[26] S. 381.985(1), F.S.
[27] S. 381.983(3), F.S.
[28] S. 381.984(1), F.S.
[29] Ss. 381.984(2) and (3), F.S.
[30] Department of Health, Agency Analysis of 2017 House Bill 1041, (March 1, 2017).
[31] S. 381.985(3), F.S.

creates s. 381.985(4), F.S., to require the health care provider who ordered or conducted the blood-lead level screen to report the results to the screened individual who, or the screened individual's parent or legal guardian if he or she is a minor.

Newborn Screening Program

Current Situation

Federal Recommendations for Newborn Screening

The United States Department of Health and Human Services (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC),[32] was established to reduce morbidity and mortality in newborns and children who have, or are at risk for, heritable disorders.[33] The ACHDNC advises the Secretary of HHS on the most appropriate application of universal newborn and child screening tests and technical information for the development of policies and priorities that will enhance the ability of state and local health agencies to provide for screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders.[34] As part of this process, ACHDNC establishes the list of heritable disorders on the federal Recommended Uniform Screening Panel (RUSP). The RUSP currently recommends screening for 32 core conditions and 26 secondary conditions.[35]

Florida Newborn Screening Program

Section 383.14(5), F.S., establishes the Florida Genetics and Newborn Screening Advisory Council (GNSAC) to advise the Department of Health (DOH) about which disorders should be added to the Newborn Screening Program (NSP) panel of screened disorders and the procedures for collecting and transmitting specimens.[36] Florida's NSP currently screens for 50 of the 58 disorders recommended by the RUSP, including 31 core conditions and 28 secondary conditions.[37] Currently, every disorder on the NSP panel has known treatment options. However, the GNSAC recommended the addition of X-linked ALD (ALD)[38] on February 19, 2016. One of ALD's presentations has no known treatment at this time.[39]

The GNASC is made up of 15 members, including consumer members, various state agency representatives and healthcare providers, and one representative from each of the four medical schools in the state.[40] When the GNSAC was created, the state only had 4 medical schools. Currently there are 10 medical schools in Florida.

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[32] 42 U.S.C. s. 300b-10; 42 U.S.C. s. 217a: Advisory councils or committees (2016).
[33] U.S. Department of Health and Human Services, *Advisory Committee on Heritable Disorders in Newborns and Children*, http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/index.html (last accessed March 11, 2017).
[34] Secretary of Health and Human Services, *Charter Discretionary Advisory Committee on Heritable Disorders in Newborns and Children*, April 24, 2013, available at: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/about/charterdachdnc.pdf (last accessed March 11, 2017).
[35] Advisory Committee on Heritable Disorders in Newborns and Children, *Recommended Uniform Screening Panel (as of November 2016), available at*: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/uniformscreeningpanel.pdf (last visited March 11, 2017).
[36] S. 383.14(5), F.S.
[37] Florida Department of Health, *Disorder List*, available at: http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/_documents/newborn-screening-disorders.pdf (last accessed March 11, 2017); this list is also maintained by DOH in Rule Rule 64C-7.002, F.A.C.
[38] X-Linked ALD is a genetic disorder that occurs primarily in males with an incidence rate of approximately 1 in 20,000-50,000. It mainly affects the nervous system and the adrenal glands, which are small glands located on top of each kidney. In this disorder, the fatty covering (myelin) that insulates nerves in the brain and spinal cord is prone to deterioration (demyelination), which reduces the ability of the nerves to relay information to the brain. In addition, damage to the outer layer of the adrenal glands (adrenal cortex) causes a shortage of certain hormones (adrenocortical insufficiency). Adrenocortical insufficiency may cause weakness, weight loss, skin changes, vomiting, and coma. There are three distinct types of X-linked adrenoleukodystrophy: a childhood cerebral form, an adrenomyeloneuropathy type, and a form called Addison disease only.
[39] Infra, FN 46 at pg. 3.
[40] Supra, FN 36

The NSP screens all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.[41] The NSP involves coordination among several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in Jacksonville (State Laboratory), Children's Medical Services (CMS) Newborn Screening Follow-up Program, and referral centers, birthing centers, and physicians throughout the state.[42]

Currently, the State Laboratory is only authorized to release the results of a newborn's metabolic tests or screenings to the newborn's health care practitioner.[43] Federal regulations require public health laboratories to release screening results, upon request, to the patient, the patent's parent or legal guardian, the patient's personal representative, or person designated by the patient or legal guardian.[44]

Effect of Proposed Changes

HB 1041 amends s. 383.14(5), F.S., to update the composition of the GNSAC to include a representative from 4 of the 10 medical schools in the state. The number of medical school representatives remains the same, but this change allows representatives from all medical schools in the state the potential to be appointed to the GNSAC, not just those medical schools in existence when the GNSAC was created.

The bill amends s. 383.14(1)(c), F.S, to allow the State Laboratory to release metabolic tests or screenings to a newborn's parent or legal guardian, the newborn's personal representative, or a person designated by the newborn's parent or legal guardian. This change aligns state law with federal regulations relating to public health laboratories.

The bill also amends s. 383.14(3)(f), F.S., to recognize that disorders with no known treatment may be added to the NSP panel and that detection of these disorders, even without treatment, helps families plan for the care of their children and avoid unnecessary costs in diagnosis. The bill also adds language to this paragraph to recognize that DOH's duty to promote genetic studies includes the promotion of the services associated with those studies. These changes update the duties of DOH to reflect the advances of newborn screening and disorder detection as well as promote the availability of evidence-based services associated with genetic studies.

Public Health Laboratory Testing for Other States

Current Situation

Section 381.0202, F.S., directs DOH to establish and maintain laboratories in the state for microbiological and chemical analysis and any other purpose it determines necessary for the protection of public health. DOH operates the Bureau of Public Health Laboratories that provide diagnostic screening, monitoring, reference, research and emergency public health laboratory services to county health departments and other official agencies, physicians, hospitals and private laboratories.[45]

Due to costs and resource limitations, it is not feasible for all 50 states to maintain public health testing infrastructure.[46] Furthermore, reagents to test for rare or emerging pathogens are often only available in

[41] Florida Department of Health, Florida Newborn Screening Guidelines, 2012, avaialable at: https://www.peds.ufl.edu/divisions/genetics/programs/newborn_screening/2012%20newborn%20screening%20quidelines%20FL.pdf (last accessed March 11, 217).
[42] Florida Department of Health, Newborn Screening, http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/ (last accessed March 11, 2017).
[43] S. 383.14(1)(c), F.S.
[44] 42 C.F.R. § 493.1291(l)
[45] Florida Department of Health, Bureau of Public Health Laboratories, available at: http://www.floridahealth.gov/programs-and-services/public-health-laboratories/index.html (last accessed March 13, 2017).
[46] Department of Health, Agency Analysis of 2017 House Bill 1041, (March 1, 2017).

limited quantities from the CDC.[47] In response, the CDC advocates for the establishment of regional testing centers to perform specialized testing for multiple states.[48]

Current statutory language does not give DOH authority to perform public health laboratory testing for samples from other states.

Effect of Proposed Changes

HB 1041 amends s. 381.0202, F.S. to authorize DOH to perform laboratory testing related to public health for other states on a fee-for-service basis. DOH would charge other states the actual cost per test, to include the cost of reagents, controls, labor, and overhead required to produce the result. DOH anticipates performing fewer than 10 tests per month.

The bill provides for an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.004, F.S., relating to HIV testing.
Section 2: Amends s. 381.0202, F.S., relating to laboratory services.
Section 3: Amends s. 381.983, F.S., relating to definitions.
Section 4: Amends s. 381.984, F.S., relating to educational programs.
Section 5: Amends s. 381.985, F.S., relating to screening program.
Section 6: Amends s. 383.14, F.S., relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.
Section 7: Provides for an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Any revenue for lab testing services performed by DOH for other states would be cost neutral. The per test cost varies between $40-$60 and DOH would charge other states the actual cost per test.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

[47] Id.
[48] Id.

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:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to laboratory screening; amending s. 381.004, F.S.; clarifying that certain requirements related to the reporting of positive HIV test results to county health departments apply only to testing performed in a nonhealth care setting; amending s. 381.0202, F.S.; authorizing the Department of Health to perform laboratory testing for other states; amending s. 381.983, F.S.; redefining the term "elevated blood-lead levels"; amending s. 381.984, F.S.; authorizing, rather than requiring, that the Governor, in conjunction with the State Surgeon General, sponsor a public information initiative on lead-based paint hazards; amending s. 381.985, F.S.; revising requirements for the State Surgeon General's program for early identification of persons at risk of having elevated blood-lead levels; requiring the department to maintain records showing elevated blood-lead levels; requiring that health care providers report to the individual who was screened the results that indicate elevated blood-lead levels; amending s. 383.14, F.S.; authorizing the State Public Health Laboratory to release the results of a newborn's hearing and metabolic tests to certain individuals; requiring the department to promote the availability

of services to promote detection of genetic conditions; clarifying that the membership of the Genetics and Newborn Screening Advisory Council must include one member representing each of four medical schools in this state; providing an effective date.

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

Section 1. Paragraph (a) of subsection (2) of section 381.004, Florida Statutes, is amended to read:

381.004 HIV testing.—

(2) HUMAN IMMUNODEFICIENCY VIRUS TESTING; INFORMED CONSENT; RESULTS; COUNSELING; CONFIDENTIALITY.—

(a) Before performing an HIV test:

1. In a health care setting, the person to be tested shall be notified orally or in writing that the test is planned and that he or she has the right to decline the test. If the person to be tested declines the test, such decision shall be documented in the medical record. A person who has signed a general consent form for medical care is not required to sign or otherwise provide a separate consent for an HIV test during the period in which the general consent form is in effect.

2. In a nonhealth care setting, a provider shall obtain the informed consent of the person upon whom the test is to be performed. Informed consent shall be preceded by an explanation

of the right to confidential treatment of information identifying the subject of the test and the results of the test as provided by law. The provider shall also inform the test subject that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and provide him or her with information on the availability and location of sites where anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites where anonymous testing is performed which includes site locations, telephone numbers, and hours of operation.

~~The test subject shall also be informed that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and of the availability and location of sites at which anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, telephone numbers, and hours of operation of the sites.~~

Section 2. Section 381.0202, Florida Statutes, is amended to read:

381.0202 Laboratory services.—

(1) The department shall establish and maintain, in suitable and convenient places in the state, laboratories for

microbiological and chemical analyses and any other purposes it determines necessary for the protection of the public health.

(2) The department may contract or agree with any person or public or private agency to provide laboratory services relating to or having potential impact on the public health or relating to the health of clients directly under the care of the state.

(3) The department is authorized to establish and collect reasonable fees and charges for laboratory services provided. Such fees and charges shall be deposited in a trust fund administered by the department and shall be used solely for this purpose.

(4) The department may perform laboratory testing related to public health for other states on a fee-for-service basis.

Section 3. Subsection (3) of section 381.983, Florida Statutes, is amended to read:

381.983 Definitions.—As used in this act, the term:

(3) "Elevated blood-lead level" means a quantity of lead in the ~~whole venous~~ blood, measured from a venous or capillary draw ~~expressed in micrograms per deciliter (ug/dL)~~, which exceeds the cutpoint specified in department rule. The determination of elevated blood-lead level must be based on national recommendations developed by the Council of State and Territorial Epidemiologists and the Centers for Disease Control and Prevention. ~~10 ug/dL or such other level as specifically~~

~~provided in this act.~~

Section 4. Subsections (2) and (3) of section 381.984, Florida Statutes, are amended to read:

381.984 Educational programs.—

(2) PUBLIC INFORMATION INITIATIVE.—The Governor, in conjunction with the State Surgeon General and his or her designee, may ~~shall~~ sponsor a series of public service announcements on radio, television, and the Internet~~,~~ and in print media about the nature of lead-based-paint hazards, the importance of standards for lead poisoning prevention in properties, and the purposes and responsibilities set forth in this act. In developing and coordinating this public information initiative, the sponsors may ~~shall~~ seek the participation and involvement of private industry organizations, including those involved in real estate, insurance, mortgage banking, and pediatrics.

(3) DISTRIBUTION OF INFORMATION ~~LITERATURE~~ ABOUT CHILDHOOD LEAD POISONING. ~~By January 1, 2007,~~ The State Surgeon General or his or her designee shall develop culturally and linguistically appropriate information and distribution methods ~~pamphlets~~ regarding childhood lead poisoning, the importance of testing for elevated blood-lead levels, prevention of childhood lead poisoning, treatment of childhood lead poisoning, and, as ~~where~~ appropriate, the requirements of this act. This ~~These~~ information ~~pamphlets~~ shall be distributed to parents or ~~the~~

~~other~~ legal guardians of children 6 years of age or younger on the following occasions:

(a) By a health care provider at the time of a child's birth and at the time of any childhood immunization or vaccination unless it is established that such information ~~pamphlet~~ has been provided ~~previously~~ to the parent or legal guardian by the health care provider within the prior 12 months.

(b) By the owner or operator of any child care facility or preschool or kindergarten class on or before each October 15 ~~of the calendar year~~.

Section 5. Section 381.985, Florida Statutes, is amended to read:

381.985 Screening program.—

(1) The State Surgeon General shall establish guidelines ~~a program~~ for early identification of persons at risk of having elevated blood-lead levels and for the systematic screening of ~~. Such program shall systematically screen~~ children under 6 years of age in the target populations identified in subsection (2) for the presence of elevated blood-lead levels. Children within the specified target populations shall be screened with a blood-lead test at age 12 months and age 24 months, or between the ages of 36 months and 72 months if they have not previously been screened. The State Surgeon General shall, after consultation with recognized professional medical groups and such other sources as the State Surgeon General deems appropriate, adopt

rules to follow established national guidelines or recommendations such as those issued by the Council of State and Territorial Epidemiologists and the Centers for Disease Control and Prevention related to reporting elevated blood-lead levels and screening results to the department pursuant to this section. ~~promulgate rules establishing:~~

~~(a) The means by which and the intervals at which such children under 6 years of age shall be screened for lead poisoning and elevated blood-lead levels.~~

~~(b) Guidelines for the medical followup on children found to have elevated blood-lead levels.~~

(2) In developing screening programs to identify persons at risk with elevated blood-lead levels, priority shall be given to persons within the following categories:

(a) All children enrolled in the Medicaid program at ages 12 months and 24 months, or between the ages of 36 months and 72 months if they have not previously been screened.

(b) Children under the age of 6 years exhibiting delayed cognitive development or other symptoms of childhood lead poisoning.

(c) Persons at risk residing in the same household, or recently residing in the same household, as another person at risk with an elevated ~~a~~ blood-lead level ~~of 10 ug/dL or greater~~.

(d) Persons at risk residing, or who have recently resided, in buildings or geographical areas in which significant

numbers of cases of lead poisoning or elevated blood-lead levels have recently been reported.

(e) Persons at risk residing, or who have recently resided, in an affected property contained in a building that during the preceding 3 years has been subject to enforcement for violations of lead-poisoning-prevention statutes, ordinances, rules, or regulations ~~as specified by the State Surgeon General~~.

(f) Persons at risk residing, or who have recently resided, in a room or group of rooms contained in a building whose owner also owns a building containing affected properties which, during the preceding 3 years, has been subject to an enforcement action for a violation of lead-poisoning-prevention statutes, ordinances, rules, or regulations.

(g) Persons at risk residing in other buildings or geographical areas in which the State Surgeon General reasonably determines there is ~~to be~~ a significant risk of affected individuals having an elevated blood-lead level. ~~a blood-lead level of 10 ug/dL or greater.~~

(3) The department ~~State Surgeon General~~ shall maintain comprehensive records of all screenings indicating an elevated blood-lead level. ~~conducted pursuant to this section. Such records shall be indexed geographically and by owner in order to determine the location of areas of relatively high incidence of lead poisoning and other elevated blood-lead levels.~~

~~All cases or probable cases of lead poisoning found in the course of screenings conducted pursuant to this section shall be reported to the affected individual, to his or her parent or legal guardian if he or she is a minor, and to the State Surgeon General.~~

(4) The results of screenings conducted pursuant to this section shall be reported by the health care provider who conducted or ordered the screening to the individual who was screened, or to the individual's parent or legal guardian if he or she is a minor.

Section 6. Paragraph (c) of subsection (1), paragraph (f) of subsection (3), and subsection (5) of section 383.14, Florida Statutes, are amended to read:

383.14 Screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.—

(1) SCREENING REQUIREMENTS.—To help ensure access to the maternal and child health care system, the Department of Health shall promote the screening of all newborns born in Florida for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, as screening programs accepted by current medical practice become available and practical in the judgment of the department. The department shall also promote the identification and screening of all newborns in this state and their families for environmental risk factors such as low income, poor education, maternal and family

stress, emotional instability, substance abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services, including, but not limited to, parent support and training programs, home visitation, and case management. Identification, perinatal screening, and intervention efforts shall begin prior to and immediately following the birth of the child by the attending health care provider. Such efforts shall be conducted in hospitals, perinatal centers, county health departments, school health programs that provide prenatal care, and birthing centers, and reported to the Office of Vital Statistics.

(c) *Release of screening results.*—Notwithstanding any law to the contrary, the State Public Health Laboratory may release, directly or through the Children's Medical Services program, the results of a newborn's hearing and metabolic tests or screenings to the newborn's health care practitioner, the newborn's parent or legal guardian, the newborn's personal representative, or a person designated by the newborn's parent or legal guardian. As used in this paragraph, the term "health care practitioner" means a physician or physician assistant licensed under chapter 458; an osteopathic physician or physician assistant licensed under chapter 459; an advanced registered nurse practitioner, registered nurse, or licensed practical nurse licensed under part I of chapter 464; a midwife licensed under chapter 467; a

speech-language pathologist or audiologist licensed under part I of chapter 468; or a dietician or nutritionist licensed under part X of chapter 468.

(3) DEPARTMENT OF HEALTH; POWERS AND DUTIES.—The department shall administer and provide certain services to implement the provisions of this section and shall:

(f) Promote the availability of genetic studies, services, and counseling in order that the parents, siblings, and affected newborns may benefit from detection and available knowledge of the condition.

All provisions of this subsection must be coordinated with the provisions and plans established under this chapter, chapter 411, and Pub. L. No. 99-457.

(5) ADVISORY COUNCIL.—There is established a Genetics and Newborn Screening Advisory Council made up of 15 members appointed by the State Surgeon General. The council shall be composed of two consumer members, three practicing pediatricians, at least one of whom must be a pediatric hematologist, a ~~one~~ representative from each of ~~the~~ four medical schools in this ~~the~~ state, the State Surgeon General or his or her designee, one representative from the Department of Health representing Children's Medical Services, one representative from the Florida Hospital Association, one individual with experience in newborn screening programs, one individual

representing audiologists, and one representative from the Agency for Persons with Disabilities. All appointments shall be for a term of 4 years. The chairperson of the council shall be elected from the membership of the council and shall serve for a period of 2 years. The council shall meet at least semiannually or upon the call of the chairperson. The council may establish ad hoc or temporary technical advisory groups to assist the council with specific topics which come before the council. Council members shall serve without pay. Pursuant to the provisions of s. 112.061, the council members are entitled to be reimbursed for per diem and travel expenses. It is the purpose of the council to advise the department about:

(a) Conditions for which testing should be included under the screening program and the genetics program.

(b) Procedures for collection and transmission of specimens and recording of results.

(c) Methods whereby screening programs and genetics services for children now provided or proposed to be offered in the state may be more effectively evaluated, coordinated, and consolidated.

Section 7. This act shall take effect July 1, 2017.