The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 1144
INTRODUCER:	Health Policy Committee and Senator Montford
SUBJECT:	Laboratory Screening
DATE:	April 17, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Fav/CS**
2.	Loe	Williams	AHS	**Pre-meeting**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1144 amends the powers and duties of the Department of Health (DOH) pertaining to:

- Human Immunodeficiency Virus (HIV) - The bill requires providers in only nonhealth care settings to inform persons to be tested that a positive test result will be reported to the county health department (CHD) and the CHD will provide that person with locations for anonymous testing.
- Laboratory Screening for Other States - The bill authorizes the DOH to perform public health laboratory testing for other states on a fee-for-service basis.
- Lead Poison Screening - The bill revises the Lead Poisoning Prevention Screening and Educational Act to conform to federal guidelines and modifies the scope of responsibilities required of the DOH.
- Newborn Screening - The bill revises the composition of the Genetics and Newborn Screening Advisory Council (GNSAC), adds eligible individuals who may receive test results from the Newborn Screening Program (NSP), and expands the responsibility of the NSP to screen for genetic disorders even when treatment is not currently available.

The bill has no impact on state revenues or expenditures.

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

II. Present Situation:

Human Immunodeficiency Virus (HIV)

HIV is an immune system virus that can lead to acquired immunodeficiency syndrome, or AIDS. HIV affects specific cells in the immune system and, over time, the virus can destroy so many of those cells that the body cannot fight off infections 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 advances, can live nearly as long as someone who does not have HIV. If left untreated, HIV is almost always fatal.[3]

In the U.S., HIV is spread mainly through unprotected sex with someone who has HIV or by sharing needles, syringes, or other equipment used to inject drugs with someone who has HIV. HIV can also be spread from mother to baby during pregnancy, birth or breastfeeding.[4] The Centers for Disease Control and Prevention (CDC) estimated that in 2013, the most recent year for which the information is available, more than 1.2 million persons in the U.S. were living with HIV, including 13 percent (one in eight) who were unaware they were infected. However, the annual number of new HIV cases declined by 19 percent from 2005 to 2014. In 2015, approximately 39,513 persons were diagnosed with HIV; and gay and bisexual African American men were the population group most affected.[5]

HIV Testing

An HIV test is a medical test ordered to determine the presence or absence of antibodies or antigens to the human immunodeficiency virus, or the presence or absence of human immunodeficiency virus itself.[6] The CDC supports HIV testing that occurs during an individual's routine health care visit.[7] This is especially important for people who may not consider themselves at risk for HIV.[8]

The most common test for HIV is an HIV antibody test, where blood or saliva are checked for specific HIV fighting proteins known as HIV antibodies.[9] This test is considered "preliminary"

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[1] Centers for Disease Control and Prevention, *About HIV/AIDS* (updated November 30, 2016), *available at* http://www.cdc.gov/hiv/basics/whatishiv.html, (last visited March 20, 2017).
[2] *Id.*
[3] *Id.*
[4] Centers for Disease Control and Prevention, *HIV Transmission,* (updated December 21, 2016), *available at* http://www.cdc.gov/hiv/basics/transmission.html, (last visited March 20, 2017).
[5] Centers for Disease Control and Prevention, *HIV in the United States: At A Glance* (updated December 2, 2016), *available at* http://www.cdc.gov/hiv/statistics/basics/ataglance.html, (last visited March 20, 2017).
[6] Section 381.004(1)(b), F.S.
[7] Centers for Disease Control and Prevention, *State HIV Testing Laws: Consent and Counseling Requirements* (updated March 18, 2015), *available at* http://www.cdc.gov/hiv/policies/law/states/testing.html, (last visited March 20, 2017).
[8] In Florida, only 42.2 percent of adults reported having ever been tested for HIV; Florida Department of Health, *Florida Charts*, *available at* http://www.flhealthcharts.com/charts/Brfss/StateDataViewer.aspx?bid=119 (last visited March 20, 2017).
[9] The U.S. Department of Health and Human Services, *Types of HIV Tests*, (updated Mar. 7, 2017) *available at* http://aids.gov/hiv-aids-basics/prevention/hiv-testing/hiv-test-types/index.html, (last visited March 20, 2017).

because it can take between three to 12 weeks for the body to produce sufficient HIV antibodies for the test to detect the presence of the antibodies.[10] If the test result is positive, follow-up diagnostic testing is required to confirm the presence of the HIV.

Follow-up HIV testing detects both antibodies and antigens. The antibody-antigen test can find a recent HIV infection earlier than tests that detect only antibodies, but antibody-antigen tests are only available for blood, not other body fluids.[11]

HIV in Florida

The DOH estimates that approximately 127,589 persons living in Florida are infected with HIV.[12] In 2016, Florida ranked first in the nation in the number of new HIV cases, with over 5,300 new cases; however, this was down from 2014, when there were more than 6,000 newly reported HIV infections in Florida.[13]

HIV Testing in Florida

Section 381.004, F.S., governs HIV testing in Florida. It creates a statewide network of confidential and anonymous HIV testing and counseling sites, and establishes procedures for HIV testing, informed consent, and reporting requirements. The DOH CHDs are the primary source for state-sponsored HIV programs and provide testing, counseling, prevention outreach, and education to the public. The CHDs, and any other person conducting an AIDS or HIV testing program, must register with the DOH and meet necessary requirements.[14] The statute was enacted to create an environment in which people would agree to seek out HIV testing because they would be sufficiently informed about the infection and assured about the privacy of a decision to be tested.[15]

Notification and Informed Consent

Section 381.004(2), F.S., differentiates between a "health care setting" and a "nonhealth care setting" when delineating the procedures required to obtain a person's consent to perform an HIV test.

In the health care setting, the person to be tested must be notified, either orally or in writing, that the test is planned and that he or she has a right to refuse. If the person consents and has a current, signed general medical consent form, no separate consent form is required for the HIV test. If the person refuses the HIV test, it must be documented in their medical records.[16] A

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[10] Id.
[11] Centers for Disease Control and Prevention, *Testing* (updated December 6, 2016), *available at* http://www.cdc.gov/hiv/basics/testing.html, (last visited March 20, 2017).
[12] Department of Health, *HIV Data Center, available at* http://www.floridahealth.gov/%5C/diseases-and-conditions/aids/surveillance/index.html, (last visited March 20, 2017).
[13] Department of Health, *HIV Disease: United States vs. Florida, available at* http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/_documents/fact-sheet/2014/2014-us-vs-fl-fact-sheet.pdf, (last visited March 20, 2017).
[14] Section 381.004(1), F.S.
[15] Florida Department of Health, "*Florida's Omnibus AIDS Act: A Brief Legal Guide for Health Care Professionals,"* Jack P. Hartog, Esq., (August 2013), *available at* http://www.floridahealth.gov/diseases-and-conditions/aids/administration/_documents/Omnibus-booklet-update-2013.pdf, (last visited March 20, 2017).
[16] Section 381.004(2), F.S.

"health care setting" is defined as a setting devoted to the diagnosis and care of persons or the provision of medical services to persons.

In a "nonhealth care setting," a provider is required to obtain a subject's informed consent before performing an HIV test. Informed consent must be preceded by an explanation of the subject's right to confidential treatment of the test results and the information identifying him or her as the test subject.[17] A "nonhealth care setting" is defined as a site that conducts HIV testing for the sole purpose of identifying HIV infection, but does not provide medical treatment.

In either the healthcare or nonhealth care setting, every person tested for HIV must first give his or her informed consent, except as specified in s. 381.004(2)(h), F.S. Informed consent for HIV testing requires:

- An explanation that the identity of the person to be tested, and the results of the test, are confidential and protected from disclosure to the extent permitted by law;
- Notice that persons with a positive HIV test will be reported to the local CHD; and
- Notice that anonymous testing is available and the locations of the anonymous testing sites.[18]

Informed consent must be in writing when it is:

- From the potential donor, or donor's legal representative, prior to donating blood, blood components, organs, skin, semen, or other human tissue or body part;
- For insurance purposes; and
- For contract purposes in a health maintenance organization.[19]

Currently, test results contained in medical records of hospitals licensed under ch. 395, F.S., can be released under s. 395.3025, F.S., if the hospital has obtained written informed consent for the HIV test. Informed consent is not required in numerous situations, including when a significant exposure has occurred.[20]

The DOH Laboratory Testing for Other States

Section 381.0202, F.S., directs the 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, safety, and welfare. The DOH operates the Bureau of Public Health Laboratories that provides diagnostic screening, monitoring, reference, research, and emergency public health laboratory services to CHDs and other official agencies, physicians, hospitals, and private laboratories.[21]

Due to costs and resource limitations, it is not feasible for all 50 states to maintain public health testing infrastructure.[22] Furthermore, reagents to test for rare or emerging pathogens are often

[17] *Supra* note 17.
[18] *Id*.
[19] *Id*.
[20] *See* s. 381.004(2)(e)14., F.S.
[21] Department of Health, B*ureau of Public Health Laboratories, available at* http://www.floridahealth.gov/programs-and-services/public-health-laboratories/index.html, (last visited Mar. 21, 2017).
[22] Department of Health, *House Bill 1041 Analysis (identical to SB 1144*), (March 1, 2017) (on file with the Senate Committee on Health Policy).

only available in limited quantities from the CDC.[23] In response, the CDC advocates for the establishment of regional testing centers to perform specialized testing for multiple states.[24]

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

Lead Poison Screening and Education

"Lead poisoning" or "lead toxicity" are both defined as high levels of lead, which is a heavy metal, typically associated with severe health effects. The amount of lead in the body and tissues, as well as the length of time of the exposure, determines the toxicity level and the signs and symptoms exhibited by a person.[25] The CDC has termed excessive absorption to lead as one of the most common pediatric health problems in the U.S. today, and it is entirely preventable.[26] Enough is known about lead poisoning to prevent lead exposure and permanently eradicate this condition. This makes the persistence of lead poisoning in the U.S. a singular and direct challenge to public health authorities, clinicians, regulatory agencies, and society.[27] While the U.S. has not eradicated lead poisoning completely, it has made tremendous progress in reducing lead exposure. [28]

Adult Lead Poisoning

Lead poisoning in adults is a medical condition caused by increased BLLs in the body that can be from, among other things, food, water, soil, home building materials including lead paint, exhaust fumes, and industrial and recycling waste. Lead interferes with a variety of biologic processes and is toxic to many organs and tissues, including the heart, bones, intestines, kidneys, and reproductive and nervous systems. The CDC states that a BLL of five micrograms per deciliter (5 µg/dL) or above for an adult is cause for concern; however, lead may impair development and have harmful health effects at even lower levels. There is no known safe level of lead exposure.[29] In 2015, the National Institute for Occupational Safety and Health also designated five micrograms per deciliter (5 µg/dL) or above from whole blood, in a venipuncture blood sample, as an elevated BLL for adults.

Childhood Lead Poisoning

In the U.S. today, there are approximately 3.6 million families with a child under six years of age who live in homes with one or more conditions that can expose a child to lead levels that the U.S. Environmental Protection Agency (EPA) considers hazardous. The CDC recognizes a reference level of five micrograms of lead per deciliter (5 µg/dL) of blood to identify children

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[23] *Id.*
[24] *Id.*
[25] Department of Health, *Adult Lead Poisoning, available at* http://www.floridahealth.gov/environmental-health/lead-poisoning/adults.html#heading_2, (last visited March 21, 2017).
[26] Centers for Disease Control and Prevention, *Preventing Lead Poisoning in Young Children, Chapter 1,* (last updated October 1991) *available at* https://www.cdc.gov/nceh/lead/publications/books/plpyc/Chapter1.htm, (last visited March 21, 2017).
[27] *Id.*
[28] *See Supra* note 28.
[29] *Id.*

whose BLLs are high enough for the CDC to recommend public health actions be initiated. Approximately 500,000 children each year ages one to five years of age exceed the reference level, which is based on an extrapolation of the U.S. population of children ages one to five who are tested for BLLs. The median concentration of BLLs for U.S. children one to five years of age has declined from 15 µg/dL in 1976-1980 to 0.7 µg/dL in 2013-2014 - a decrease of 95 percent;[30] however, there is no safe BLL for children that has been identified.[31] The largest decline occurred between 1970 and 1990 following the elimination of lead in motor vehicle gasoline, the ban on lead paint for residential use, the removal of lead from food cans, bans on the use of lead pipes and plumbing fixtures, and other limitations on lead uses.[32]

Signs and Symptoms of Lead Poisoning

Lead poisoning is classified acute or chronic depending upon the length of time the individual has been exposed to the source of the lead.[33] Signs and symptoms of acute lead poisoning include abdominal pain, nausea, diarrhea, and poor appetite.

Chronic lead poisoning usually presents itself with symptoms affecting multiple body systems. It is associated with three main types of symptoms: gastrointestinal, neuromuscular, and neurological. Central nervous system and neuromuscular symptoms usually result from intense exposure while gastrointestinal symptoms usually result from exposure over longer periods of time.

Lead Toxicity Testing

In 2012, the CDC adopted the BLL as its preferred method of testing children and adults for elevated levels of lead in the body, and five micrograms per deciliter (5 µg/dL) as the level where environmental or educational public health intervention is required.[34] While testing is available to detect lead in any body tissue, the primary tests used in the last 30 years to evaluate lead exposure that are readily available to practitioners to determine lead exposure levels in the human body are:

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[30] Supra note 33, at p. 6, citing Centers for Disease Control and Prevention, National Center for Health Statistics, *National Health and Nutrition Examination Survey* (updated January 25, 2017) *available at* https://www.cdc.gov/nchs/nhanes.htm, (last visited March 21, 2017); *See also* U.S. Environmental Protection Agency, *America's Children and the Environment (ACE) available at* https://www.epa.gov/ace, (last visited March 21, 2017).

[31] 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 visited March 21, 2017).

[32] *Id.* at p. 5.

[33] *Supra* note 28.

[34] U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Environmental and Health Medicine Education, *Lead Toxicity: What Tests Can Assist with Diagnosis and Treatment of Lead Toxicity? available at:* https://www.atsdr.cdc.gov/csem/csem.asp?csem=7&po=12, (last visited March 21, 2017).

- Venipuncture[35] - BLL, Complete Blood Count, or EP and ZPP[36] blood levels;[37]
- Capillary stick[38,39] - for BLLs;
- Radiographs - Abdominal radiographs to detect the presence of radio-dense lead foreign bodies in the gastrointestinal tract, or long bone radiographs to detect the presence of lead lines;[40]and
- Hair and fingernail scrapings.[41]

Lead Poisoning Prevention Screening and Education Act

In 2006, the Florida Legislature created the Lead Poisoning Prevention Screening and Education Act (Act). The Act requires the DOH to establish a program for the early identification of persons at risk for having elevated BLLs. Section 381.985(1), F.S., requires the program to systematically screen children under the age of six in certain targeted populations for the presence of elevated BLLs. The 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 six, the appropriate intervals for re-screening, and the follow-up for children found to have elevated BLLs.[42] The Act defines "elevated blood-lead level" as a quantity of lead in whole venous blood that exceeds ten micrograms per deciliter (10 µg/dL) or such other level as provided in the Act.[43]

The Act requires the 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.[44] This educational program requires the 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

[35] Medicare defines venipuncture, for purposes of reimbursement using CPT code 36415, as the process of puncturing a vein and withdrawing a blood sample for purposes of analysis for testing. The most common method and site of venipuncture is the insertion of a needle into the cubital vein of the anterior forearm at the elbow fold. It is fee scheduled at $3.10, the same a capillary stick. *See* Medicare Fee, Payment, Procedure code, ICD, Denial, C*PT code venipuncture - 36415 and 36416 - Billing Tips - Not separately paid*, *available at*: http://www.medicarepaymentandreimbursement.com/2010/06/cpt-venipuncture-36415-not-seperately.html, (last visited March 22, 2017).
[36] *Id.* Erythrocyte protoporphyrin (EP), commonly assayed as zinc protoporphyrin (ZPP), was previously considered the best test for screening for asymptomatic children; however, is not sufficiently sensitive at lower BLLs and therefore is not as useful a screening test for lead exposure as previously thought.
[37] *Id.* For individuals with high or chronic past exposure; however, BLLs often under-represent the total body burden because most lead is stored in the bone and may have "normal" levels in the blood.
[38] *Id.* The CDC recommends, that given the greater risk of contamination using the capillary stick method, an elevated BLL obtained through a capillary stick should always be confirmed through venipuncture.
[39] *Supra* note 43. Medicare defines a capillary stick, for purposes of reimbursement using CPT code 36416, as the collection of a blood specimen from the stick of the finger, heel, or ear. It is fee scheduled at $3.10, the same as venipuncture.
[40] *Id.* These are lines of increased density on the metaphysis growth plate of the bone, showing radiological growth retardation. This is not a routine procedure to identify lead poisoning, but a radiological finding of chronic exposure.
[41] *Id.* to detect their lead content is an uncertain estimate of body burden and is not recommended.
[42] Section 381.985(1), F.S.
[43] Section 381.983(3), F.S.
[44] Section 381.984(1), F.S.

- Develop culturally and linguistically appropriate information pamphlets regarding lead poisoning, testing, prevention, treatment, and the purposes of the Act.[45]

The DOH previously had federal funding to conduct a lead poisoning prevention program, including funding for a large media campaign; however, the federal funding for this program ended in 2012. [46]

The Act also requires the DOH to maintain records of all screenings conducted, indexed geographically and by owner, to determine the location of areas with relatively high incidence of lead poisoning and elevated BLLs. 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.[47]

Florida Newborn Screening Program

The Newborn Screening Program (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.[48]

The Florida Genetics and Newborn Screening Advisory Council (GNSAC) advises the DOH on which disorders should be added to the panel of screening for disorders, and the procedures for collecting and transmitting specimens.[49] The GNASC is made up of 15 members, including consumer members, various state agency representatives and health care providers, and one representative from each of the four medical schools in the state.[50] When the GNSAC was created, the state only had four medical schools. Currently there are ten medical schools in Florida.

The NSP currently screens for 31 core conditions and 22 secondary conditions,[51] and 50 of these conditions are included in the 58 disorders listed in the federal Recommended Uniform

[45] Sections 381.984(2) and (3), F.S.
[46] *Supra* note 25.
[47] Section 381.985(3), F.S.
[48] Department of Health, *Florida Newborn Screening Guidelines* (2012), *available at* https://www.peds.ufl.edu/divisions/genetics/programs/newborn_screening/2012%20newborn%20screening%20quidelines%20FL.pdf, (last visited March 21, 2017).
[49] Section 383.14(5), F.S.
[50] *Id.*
[51] Department of Health, *Disorder List* (December 17, 2013), *available at* http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/_documents/newborn-screening-disorders.pdf, (last visited March 21, 2017); this list is also maintained by the DOH as a Rule. *See* also Rule 64C-7.002, F.A.C.

Screening Panel (RUSP).[52] Currently, every disorder screened[53] on the NSP panel has known treatment options.

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.[54]

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.[55] Federal regulations require public health laboratories to release screening results, upon request, to the patient, the patient's parent or legal guardian, the patient's personal representative, or person designated by the patient or legal guardian.[56]

III. Effect of Proposed Changes:

Human Immunodeficiency Virus (HIV)

Section 1 amends s. 381.004(2)(a), F.S., to remove the requirement on a provider in health care settings to inform a person seeking an HIV test that a positive test result will be reported to the CHD and the CHD will provide information on the availability and locations for anonymous testing. This section requires only providers in nonhealth care settings to inform persons seeking HIV testing of those facts.

Providers in health care settings will still be required to report positive HIV test results to the DOH. This section does not remove the reporting requirement, only the requirement for providers to provide the person seeking the HIV test the information that a positive result will be reported to the CHD and the CHD will provide information on the availability and locations for anonymous testing.

The DOH Laboratory Testing for Other States

Section 2 amends s. 381.0202, F.S., to authorize the DOH to perform laboratory testing related to public health for other states on a fee-for-service basis.

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[52] The federal Advisory Committee on Heritable Disorders in Newborns and Children (committee) advises the Secretary of the U.S. Department of Health and Human Services on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines, and standards. The committee established the Recommended Uniform Screening Panel (RUSP), and periodically updates it. *See* U.S. Department of Health and Human Services, *Advisory Committee on Heritable Disorders in Newborns and Children, available at* https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/, (last visited March 23, 2017).

[53] X-Linked Adrenoleukodystrophy (X-ALD) was recommended by the GNSAC on February 19, 2016, for inclusion to the NSP panel; however, screening for the disorder is not expected to begin until at least early 2018 when a test kit approved by the federal Food and Drug Administration is anticipated to be available.

[54] Department of Health, *Newborn Screening, available at* http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/ (last visited March 21, 2017).

[55] Section 383.14(1)(c), F.S.

[56] 42 C.F.R. s. 493.1291(l) (2016).

Lead Poison Screening and Education

Section 3 s. 381.983(3), F.S., to revise the definition of an "elevated blood-lead level." This section removes the requirement that, in determining a person's BLL, the blood sample tested must be only whole venous blood. This section broadens the permissible test samples for BLLs to include blood from a capillary draw, but does not define the term "draw". The use of a capillary sample to test for an elevated BLL might increase the cost of testing as, according to the CDC, all elevated BLLs from a capillary stick should be confirmed by secondary testing with a whole blood sample.[57]

Section 3 eliminates the specific, numerical level of 10 µg/dL as the quantity of lead in the blood which constitutes an "elevated blood-lead level." This section requires the DOH to specify by rule the test result level defining an elevated BLL based on national recommendations developed by the Council of State and Territorial Epidemiologists and the CDC. This change allows for the adjustment of reporting and screening requirements as the science relating to BLLs changes.

Section 4 amends s. 381.984(2)-(3), F.S., to revise the required media options for the DOH to use as it sponsors public service announcements regarding lead based paint hazards, lead poisoning prevention and the purposes and responsibilities set out in the Lead Poisoning Prevention Screening and Education Act.[58] This creates flexibility and may result in a cost savings for the distribution of educational materials regarding lead poisoning.

Section 5 amends s. 381.985, F.S., to require the DOH to establish guidelines for the early identification of persons at risk of having elevated BLLs and for the systematic screening of children under age six in targeted populations. This replaces the responsibility for the DOH to establish a program for the early identification of persons at risk for having elevated BLLs, which shall systematically screen children under the age of six in certain targeted populations for the presence of elevated BLLs.

Section 5 reduces the DOH reporting and record keeping requirements regarding BLLs. This section requires the DOH to only maintain records of screenings with an elevated BLL rather than all screenings, and removes the requirement to report all screening results to affected individuals and maintain geographically indexed records. This section places the requirement to notify the individual tested, or the individual's parent or legal guardian if he or she is a minor, on the provider conducting or ordering the lead level screening.

Newborn Screening for Metabolic, Hereditary or Congenital Disorders

Section 6 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.

[57] *Supra* note 48.
[58] Sections 381.982 - 381.985, F.S.

Section 6 amends s. 383.14(3)(f), F.S., to expand the DOH's duties in the newborn screening program to also promote the availability of genetic services, in addition to the availability of genetic studies and counseling, so that family members may benefit from detection and available knowledge of conditions even when no treatment is currently available.

Section 6 amends s. 383.14(5), F.S. to update the composition of the GNSAC to include a representative from four 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.

Section 7: The effective date of the bill is July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The bill has no impact on state revenues or expenditures.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.004, 381.0202, 381.983, 381.984, 381.985, and 383.14.

IX. Additional Information:

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

CS by Health Policy on March 27, 2017:
The CS reinstates the requirement for the DOH to sponsor and seek participation from the private sector for public service announcements about lead poisoning prevention but adds a choice of media for the announcements including radio, television, the internet, or in print media, rather than requiring the use of all methods.

B. Amendments:

None.