

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: SB 1144
 INTRODUCER: Senator Montford
 SUBJECT: Laboratory Screening
 DATE: March 24, 2017 REVISED: _____

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

I. Summary:

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

- Human Immunodeficiency Virus (HIV) - The bill:
 - Deletes the requirement for providers in a health care setting to inform the person to be tested that a positive test result will be reported to the county health department (CHD) and provide that person with locations for anonymous testing; and
 - Requires only providers in nonhealth care settings to inform persons to be tested of those facts.
- Laboratory Screening for other states - The bill authorizes the DOH to perform public health lab testing for other states on a fee-for-service basis.
- Lead Poison Screening - The bill:
 - Changes the DOH’s role from maintaining a program for early identification of persons at risk of having elevated blood-lead levels through systematically screening certain children under age six to establishing guidelines for early identification of these persons;
 - Amends the definition of an elevated blood-lead level (BLL);
 - Deletes the numerical description of an elevated BLL;
 - Deletes the requirement that BLL testing be performed only on whole venous blood;
 - Expands the permissive BLL tests to include a capillary draw;
 - Requires the DOH to specify by rule the BLL test result defining an elevated BLL based on national recommendations;
 - Deletes the requirement that the DOH sponsor public service announcements and develop educational pamphlets regarding lead poisoning; instead the bill authorizes a public information initiative;
 - Amends the DOH’s reporting and record keeping requirements to require the DOH to maintain only records of testees with elevated BLL;

- Deletes the DOH requirement to notify the testee, or his or her legal guardian, of the BLL test results; and requires the provider conducting or ordering the BLL test to notify the testee.
- Newborn Screening - The bill:
 - Amends the composition of the Genetics and Newborn Screening Advisory Council (GNSAC) to include a representative from four of the 10 Florida medical schools;
 - Authorizes the State Public Health Laboratory (state laboratory) to release newborn hearing or metabolic screening test results to a parent, legal guardian, personal representative, or designated person; and
 - Requires the DOH to promote detection, and the availability of genetic services, for parents, siblings and affected newborns with disorders with no known treatment.

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. 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, that 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

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 March 20, 2017).

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," and can take between 3 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 is for the detection of 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

Nucleic acid tests (NATs) are another, less common, form of HIV testing. NATs can detect an HIV infection in a blood sample one to four weeks after a person is first infected.¹² If the result is positive, additional follow-up diagnostic testing should be done to confirm the presence of HIV.

HIV in Florida

The DOH estimates that approximately 127,589 persons living in Florida are infected with HIV.¹³ 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.¹⁴

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,

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 Mar. 20, 2017).

⁸ In Florida, only 42.2 percent of adults reported having ever been tested for HIV; Florida Department of Health, *Florida Charts*, <http://www.flhealthcharts.com/charts/Brfss/StateDataViewer.aspx?bid=119> (last reviewed Mar. 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 Mar. 20, 2017).

¹⁰ *Id.*

¹¹ Centers for Disease Control and Prevention, *Testing* (updated Dec. 6, 2016), available at <http://www.cdc.gov/hiv/basics/testing.html>, (last visited Mar. 20, 2017).

¹² *Id.*

¹³ Department of Health, *HIV Data Center*, <http://www.floridahealth.gov/5C/diseases-and-conditions/aids/surveillance/index.html>, (last visited Mar. 20, 2017).

¹⁴ Department of Health, *HIV Disease: United States vs. Florida*, <http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/documents/fact-sheet/2014/2014-us-vs-fl-fact-sheet.pdf>, (last visited Mar. 20, 2017).

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.¹⁵ 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.¹⁶

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 the medical records.¹⁷ A “health care setting” is defined as a setting devoted to the diagnosis and care of persons or the provision of medical services to persons, such as:

- CHD clinics;
- Hospitals;
- Urgent care clinics;
- Substance abuse treatment clinics;
- Primary care settings;
- Community clinics;
- Blood banks;
- Mobile medical clinics; and
- Correctional health care facilities.¹⁸

In a “nonhealth care setting,” a provider is required to obtain a subject’s informed consent before performing a 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.¹⁹ 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. Nonhealth care settings include:

- Community-based organizations;
- Outreach settings;
- CHD HIV testing programs; and
- Mobile clinics.²⁰

¹⁵ Section 381.004(1), F.S.

¹⁶ 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).

¹⁷ Section 381.004(2), F.S.

¹⁸ Section 381.004(1)(a), F.S.

¹⁹ *Supra*, note 17.

²⁰ Section 381.004(1)(d), F.S.

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.²¹

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.²²

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.²³

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.²⁴

Due to costs and resource limitations, it is not feasible for all 50 states to maintain public health testing infrastructure.²⁵ Furthermore, reagents to test for rare or emerging pathogens are often only available in limited quantities from the CDC.²⁶ In response, the CDC advocates for the establishment of regional testing centers to perform specialized testing for multiple states.²⁷

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

²¹ *Id.*

²² *Id.*

²³ See s. 381.004(2)(e)14., F.S.

²⁴ Department of Health, *Bureau of Public Health Laboratories*, <http://www.floridahealth.gov/programs-and-services/public-health-laboratories/index.html>, (last visited Mar. 21, 2017).

²⁵ Department of Health, *House Bill 1041 Analysis (identical to SB 1144)*, (March 1, 2017) (on file with the Senate Committee on Health Policy).

²⁶ *Id.*

²⁷ *Id.*

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.²⁸ 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.²⁹ 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.³⁰ While the U.S. has not eradicated lead poisoning completely, it has made tremendous progress in reducing lead exposure.³¹

Adult Lead Poisoning

Lead poisoning in adults is a medical condition caused by increased BLLs in the body, which 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.³² 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 3,600,000 families with a child under 6 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 whose BLLs are high enough for the CDC to recommend public health actions be initiated. Approximately 500,000 children each year, ages 1 to 5 years, exceed the reference level, which is based on an extrapolation of the U.S. population of children, ages 1 to 5 years, who are tested for BLLs. However, there is no safe BLL for children that has been identified.³³ The median concentration of BLLs for U.S. children, 1 to 5 years of age, has declined from 15 µg/dL in

²⁸ Department of Health, *Adult Lead Poisoning*, http://www.floridahealth.gov/environmental-health/lead-poisoning/adults.html#heading_2 (last visited Mar. 21, 2017).

²⁹ 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 Mar. 21, 2017).

³⁰ Id.

³¹ See Supra note 28.

³² Id.

³³ 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://ptfeh.niehs.nih.gov/features/assets/files/key_federal_programs_to_reduce_childhood_lead_exposures_and_eliminate_associated_health_impactspresidents_508.pdf, (last visited Mar. 21, 2017).

1976-1980 to 0.7 µg/dL in 2013-2014, a decrease of 95 percent.³⁴ However, 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.³⁵

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.³⁶ Signs and symptoms of acute lead poisoning include:

- Pain;
- Muscle weakness;
- Paresthesia;³⁷
- Abdominal pain;
- Nausea;
- Vomiting;
- Diarrhea;
- Constipation;
- Poor appetite;
- Weight loss;
- Encephalitis;³⁸
- Mouth astringency and metallic taste;
- “Lead hue” or pallor;
- Hemolysis;³⁹ and
- Kidney damage.⁴⁰

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. Signs of chronic lead exposure include:

- Loss of short-term memory or concentration;
- Depression;
- Nausea;
- Abdominal pain;

³⁴ *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 Jan. 25, 2017) available at <https://www.cdc.gov/nchs/nhanes.htm>, (last visited Mar. 21, 2017); *See also* U.S. Environmental Protection Agency, *America’s Children and the Environment (ACE)* <https://www.epa.gov/ace>, (last visited Mar. 21, 2017).

³⁵ *Id.* at p. 5.

³⁶ *Supra* note 28.

³⁷ *Id.* Paresthesia is the sensation of “pins” and “needles” in an effected area.

³⁸ *Id.* Encephalitis is an inflammation of the brain with or without seizure activity.

³⁹ *Id.* Hemolysis is the rupture of red blood cells in the body causing anemia and hemoglobin in the urine.

⁴⁰ *Supra* note 28.

- Loss of coordination;
- Numbness and tingling in the extremities;
- Fatigue;
- Problems with sleep;
- Headache;
- Stupor;
- Slurred speech;
- Anemia;
- “Lead hue” or “pallor”;
- “Burton’s Line”;⁴¹
- High blood pressure;
- Declines in mental functioning;
- Memory loss;
- Mood disorders;
- Reduced sperm count, abnormal sperm; and
- Miscarriage or premature birth in pregnant women.⁴²

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.⁴³ 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:

- Venipuncture⁴⁴ - BLL, Complete Blood Count, or EP and ZPP⁴⁵ blood levels;⁴⁶
- Capillary stick^{47,48} - for BLLs;

⁴¹ Id. “Burton’s Line” is a blue line along the gum, with bluish black edging to the teeth.

⁴² Id.

⁴³ 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 Mar. 21, 2017).

⁴⁴ 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 as a capillary stick. See Medicare Fee, Payment, Procedure code, ICD, Denial, *CPT code venipuncture - 36415 and 36416 - Billing Tips - Not separately paid*, <http://www.medicarepaymentandreimbursement.com/2010/06/cpt-venipuncture-36415-not-seperately.html>, (last visited Mar. 22, 2017).

⁴⁵ 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.

⁴⁶ 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.

⁴⁷ 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.

⁴⁸ *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.

- Radiographs -Abdominal to detect the presence of radio-dense lead foreign bodies in the gastrointestinal tract; or long bone to detect the presence of lead lines;⁴⁹and
- Hair and fingernail scrapings.⁵⁰

Federal Regulations to Address Lead Exposures in Children and Adults

The U.S. Consumer Product and Safety Commission, the EPA, the Food and Drug Administration, the Department of Housing and Urban Development, the OSHA, the Department of Labor, the Department of Transportation, the Federal Aviation Administration, and the Department Health and Human Services (HHS) all have regulations in place to address lead exposure in adults and children.⁵¹ Details of those agencies comprehensive lead exposure regulations and protection activities is beyond the scope of this analysis.

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 6 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.⁵² 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.⁵³

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.⁵⁴ 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
- Develop culturally and linguistically appropriate information pamphlets regarding lead poisoning, testing, prevention, treatment, and the purposes of the Act.⁵⁵

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 2012.⁵⁶

⁴⁹ 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.

⁵⁰ Id. to detect their lead content is an uncertain estimate of body burden and is not recommended.

⁵¹ *Supra* note 28.

⁵² Section 381.985(1), F.S.

⁵³ Section 381.983(3), F.S.

⁵⁴ Section 381.984(1), F.S.

⁵⁵ Sections 381.984(2) and (3), F.S.

⁵⁶ *Supra* note 25.

The Act also requires the DOH to maintain records of all screenings conducted, indexed geographically and by owner, to determine the location of areas of 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.⁵⁷

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.⁵⁸

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.⁵⁹ 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.⁶⁰ 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 50 of the 58 disorders listed in the federal Recommended Uniform Screening Panel (RUSP),⁶¹ including 31 core conditions and 28 secondary conditions.⁶² Currently, every disorder 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.⁶³

⁵⁷ Section 381.985(3), F.S.

⁵⁸ Department of Health, *Florida Newborn Screening Guidelines* (2012), available at https://www.peds.ufl.edu/divisions/genetics/programs/newborn_screening/2012%20newborn%20screening%20guidelines%20OFL.pdf, (last visit Mar. 21, 2017).

⁵⁹ Section 383.14(5), F.S.

⁶⁰ *Id.*

⁶¹ 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* <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/>, (last visited March 23, 2017).

⁶² Department of Health, *Disorder List* (Dec. 17, 2013), available at <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/documents/newborn-screening-disorders.pdf>, (last visit Mar. 21, 2017); this list is also maintained by the DOH as a Rule. See also Rule 64C-7.002, F.A.C.

⁶³ Department of Health, *Newborn Screening* <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/> (last visited Mar. 11, 2017).

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.⁶⁴ 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.⁶⁵

III. Effect of Proposed Changes:

Section 1: Human Immunodeficiency Virus (HIV)

The bill removes the requirement for a provider in the health care setting, to inform a person seeking an HIV test that a positive test result will be reported to the CHD and of the availability and locations for anonymous testing. The bill requires only providers in the 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. The bill 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 DOH and the information on the availability and locations for anonymous testing.

Section 2: The DOH Laboratory Testing for Other States

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

Sections 3 - 5: Lead Poison Screening and Education

The bill amends the definition of an, "elevated blood-lead level." The bill removes the requirement that, in determining a person's BLL, the blood sample tested must be only whole venous blood. The bill 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 with a second testing with a whole blood sample.⁶⁶

The bill eliminates the specific, numerical level of 10 µg/dL as the quantity of lead in the blood, which constitutes an, "elevated blood-lead level." The bill 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.

The bill changes the requirement for the DOH to sponsor public service announcements and develop educational pamphlets regarding lead based paint hazards, lead poisoning prevention and the purposes and responsibilities set out in the Lead Poisoning Prevention Screening and

⁶⁴ Section 383.14(1)(c), F.S.

⁶⁵ 42 C.F.R. s. 493.1291(l) (2016).

⁶⁶ *Supra* note 48.

Education Act.⁶⁷ The removal of these requirements creates flexibility and may result in a cost savings for the distribution of educational materials regarding lead poisoning.

The bill requires 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 6 in certain targeted populations for the presence of elevated BLLs. This change in focus, to developing guidelines for systematically screening, may have the effect of repealing the authority for the DOH to conduct screening activities, either directly or indirectly.⁶⁸

The bill reduces the DOH reporting and record keeping requirements regarding BLLs. The bill requires the DOH to maintain only records of all 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. The bill 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.

Section 6: Newborn Screening for Metabolic, Hereditary or Congenital Disorders

The bill updates 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.

The bill allows 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 amends the DOH's duties to administer, provide, and promote newborn screening, to add the duty to promote detection and the availability of genetic services to the parents, siblings and affected newborns. This will enable the screening of disorders with no known treatment to help families plan for the future care of their affected children, and avoid unnecessary costs in diagnosis. These changes update the law to reflect the advances in newborn screening and disorder detection as well as promote the availability of evidence-based services associated with genetic studies.

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

⁶⁷ Sections 381.982 - 381.985, F.S.

⁶⁸ Blood lead screening were conduct at none CHDs: Alachua, Broward, Duval, Hillsborough, Miami-Dade, Orange, Palm Beach, Pinellas, and Polk. Screenings in most CHDs were discontinued when federal funding ended in FY 2011-2012. Miami-Dade County is the only CHD where blood lead screening are still conducted on a regular basis. E-mail from DOH to Senate Health Policy staff dated March 23, 2017, on file with the Senate Health Policy Committee.

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:

Sections 3 - 5: Lead Poison Screening and Education- The use of a capillary draw sample to test for an elevated BLL might increase the cost of mandatory state testing of children under 6 years of age. According to the CDC, all elevated BLLs from a capillary stick should be confirmed with a second testing of whole venous blood sample.

The removal of the DOH's obligation to produce public service announcements and develop educational pamphlets may result in a cost savings for the distribution of educational materials regarding lead poisoning.

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

None.

- B. **Amendments:**

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
