HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/HB 1041	**FINAL HOUSE FLOOR ACTION:**	
SUBJECT/SHORT TITLE	Laboratory Screening	117 **Y's**	0 **N's**
SPONSOR(S):	Health & Human Services Committee; Raschein	**GOVERNOR'S ACTION:**	Approved
COMPANION BILLS:	CS/SB 1144		

SUMMARY ANALYSIS

CS/HB 1041 passed the House on April 20, 2017, and subsequently passed the Senate on May 5, 2017.

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.

CS/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 poisoning; 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 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.

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 have a fiscal impact on state or local governments.

The bill was approved by the Governor on June 26, 2017, ch. 2017-181, L.O.F., and will become effective on July 1, 2017.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Human Immunodeficiency Virus Testing

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) recommends 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 is 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 May 8, 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 May 8, 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 May 8, 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 May 8, 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 May 8, 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 May 8, 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 – HIV Testing

CS/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 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.

Lead Screening and Education

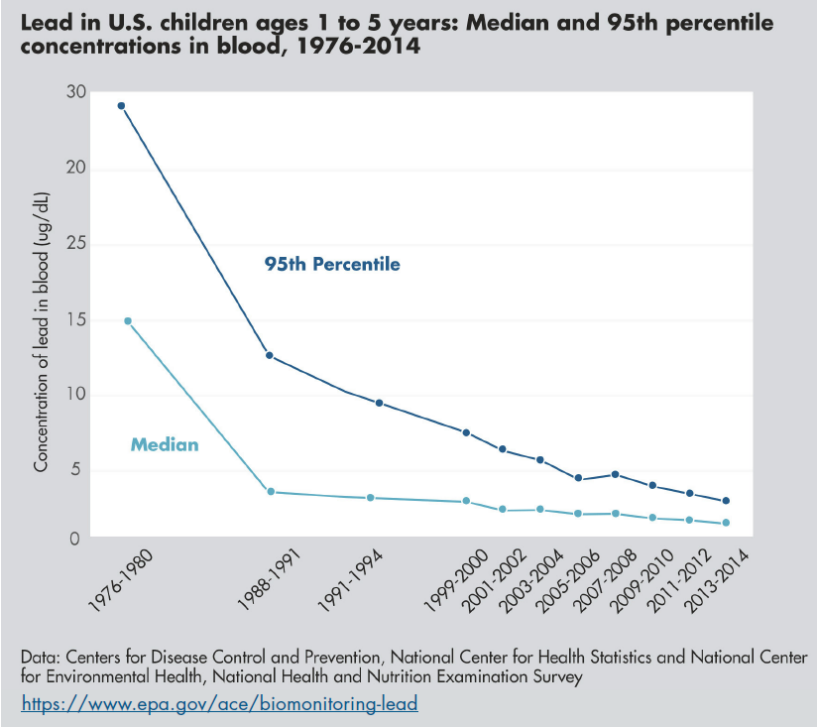
Current Situation

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

[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 May 8, 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 May 8, 2017).
[14] S. 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.
[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 May 8, 2017).

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]

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

[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 May 8, 2017).
[22] Id.
[23] Id.
[24] Centers for Disease Control and Prevention, Lead, available at: https://www.cdc.gov/nceh/lead/ (last accessed May 8, 2017).
[25] Id.

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 Changes – Lead Screening and Education

CS/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 the Governor and State Surgeon General to sponsor public service announcements on radio, television, the internet, and print media, allowing all mediums but requiring only one. The bill also removes the requirement to seek coordination and participation in the public information initiative with those involved in real estate, insurance, mortgage banking, and pediatrics, allowing all groups but requiring only one. These changes permit flexibility and cost savings in the development and 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 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.

[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.

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.

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

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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 May 8, 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 May 8, 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 May 8, 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 May 8, 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

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 – Newborn Screening

CS/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, available at: https://www.peds.ufl.edu/divisions/genetics/programs/newborn_screening/2012%20newborn%20screening%20quidelines%20FL.pdf (last accessed May 8, 2017).
[42] Florida Department of Health, Newborn Screening, http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/ (last accessed May 8, 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 May 8, 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 – Public Health Laboratory Testing for Other States

CS/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.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill's authority for DOH to perform laboratory testing for other states will have a positive but net neutral revenue impact on DOH. The per test cost varies between $40-$60 and 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.

2. Expenditures:

   The bill's authority for DOH to perform laboratory testing for other states will have a positive but net neutral expenditure impact on DOH.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

[47] Id.
[48] Id.