

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: CS/SB 824

INTRODUCER: Health Policy Committee and Senators Joyner and Flores

SUBJECT: Hepatitis C Testing

DATE: March 19, 2014

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Fav/CS
2.			JU	
3.			AHS	
4.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 824 creates a Hepatitis C testing program under s. 381.0044, F.S., and requires certain health care practitioners to offer a federally approved Hepatitis C screening test to individuals born between January 1, 1945, and December 31, 1965. Screening is to be offered to persons who receive services as an inpatient in a general hospital or primary care services in a hospital inpatient or outpatient setting or from a specified health care practitioner. For designated individuals, a health care provider is not required to offer the screening test.

If a person accepts a screening test offer and receives a positive result, the bill requires the health care practitioner to forward the results to the patient's primary care health care practitioner for counseling and follow-up care. Follow-up care must include a Hepatitis C diagnostic test.

The Department of Health (DOH) is required to adopt rules to provide procedures for how to offer the tests and to make available a standard information sheet. The State Surgeon General must also submit an evaluation of the effectiveness of the program by January 1, 2016. The report is due to the Governor, President of the Senate, the Speaker of the House of Representatives, and the chairs of the appropriate substantive committees.

II. Present Situation:

“Hepatitis” means inflammation of the liver and is also the name of a family of viral infections that affect the liver. The most common types are Hepatitis A, Hepatitis B, and Hepatitis C.¹ Most people infected with the Hepatitis C virus (HCV) have no symptoms and are unaware that they have the disease until liver damage is discovered years later. The HCV can either be an acute or chronic infection. The virus can last a lifetime and lead to serious liver problems.² Hepatitis C-related end-state liver disease is the most common indication for liver transplants among American adults, accounting for more than 30 percent of cases.³

The virus is passed through contact with contaminated blood. A person’s risk of an infection is increased if the individual has one of the following risk factors:

- Is a health care worker who has been exposed to infected blood, such as through an infected needle that pierced the skin;
- Injects or previously injected illicit drugs;
- Has HIV;
- Receives a piercing or tattoo in an unclean environment using unsterile equipment;
- Received a blood transfusion or organ transplant before 1992;
- Received clotting factor concentrates before 1987;
- Received hemodialysis treatments for a long period of time; or,
- Was born to a woman with a Hepatitis C infection.⁴

It is estimated that at least 3.2 million persons in the United States, including more than 310,000 Floridians, have the Hepatitis C virus infection, and most of those have chronic infections.^{5,6} Approximately 23,000 chronic cases of the HCV infection is reported each year in Florida⁷. However, because the initial stages of the HCV infection are either asymptomatic or associated only with mild symptoms, most new infections are undiagnosed.

The Centers for Disease Control and Prevention (CDC) estimates that although persons born during the 1945 - 1965 period, the “baby boomers,” comprise an estimated 27 percent of the population, they account for approximately 75 percent of all HCV infections in the United States, 73 percent of HCV-associated mortality, and are at the greatest risk for HCV-related disease.⁸ In 2012, the CDC issued new recommendations that all adults born during this time period should

¹ Centers for Disease Control and Prevention, *Hepatitis C Information for the Public*, <http://www.cdc.gov/hepatitis/C/cFAQ.htm#statistics> (last visited Mar. 14, 2014).

² *Id.*

³ United States Preventive Services Task Force, *Screening for Hepatitis C Virus Infection in Adults, U.S. Preventive Services Task Force Recommendation Statement* (June 25, 2013), <http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfinalrs.htm> (last visited Mar. 14, 2014).

⁴ Mayo Clinic, *Diseases and Conditions - Hepatitis C*, <http://www.mayoclinic.org/diseases-conditions/hepatitis-c/basics/risk-factors/con-20030618> (last visited Mar. 14, 2014).

⁵ Centers for Disease Control and Prevention, *Supra*, note 1.

⁶ Department of Health, 2014 Agency Legislative Bill Analysis - SB 824 (January 7, 2014), on file with Senate Health Policy Committee.

⁷ *Id.*

⁸ Department of Health, *Supra* note 6 at 2.

undergo one-time testing regardless of their risk status.⁹ Estimates indicate that as many as five million Floridians fall into the baby boomer cohort.

The United States Preventive Services Task Force (USPSTF) in June 2013 added, as a B-rating, a recommendation that a one-time screening for HCV infection be offered for adults born between 1945 and 1965.¹⁰ The USPSTF in its recommendation statement concluded that persons born during this time period are more likely to be diagnosed with HCV infection because they received blood transfusions before screening was introduced or have a history of other risk factors.¹¹ A one-time screening may lead to earlier detection of the infection and result in increased diagnosis and treatment.¹²

New treatments for HCV have been estimated to cost at least \$66,000 to \$84,000.¹³

Florida's Hepatitis C Programs and Coverage

Department of Health

Currently, adult Floridians, aged 18 years and older, who test positive for HCV are offered the Hepatitis B vaccine and counseling on nutrition; exercise; stopping drug, alcohol and tobacco use; and other health messages by county health departments (CHD) through the statewide Hepatitis Prevention Program. (HPP). All of these interventions slow the progress of the HCV, but there is no vaccine for HCV. While HPP testing and vaccine are provided to CHDs at no charge, some CHDs charge a small administrative fee for the vaccines, usually not more than \$20.¹⁴ A CHD will waive the cost if the client cannot afford the fee.

Funding for specific hepatitis prevention programs is provided to 15 CHDs: Alachua, Bay, Broward, Collier, Duval, Escambia, Lee, Miami-Dade, Monroe, Okeechobee, Orange, Palm Beach, Pinellas, Polk, and Seminole. All CHDs are eligible to participate.¹⁵ In fiscal year 2013-2014, the HPP received \$1,413,745 in General Revenue funding. Other annual funding supports the HPP from the HIV Prevention Program for viral hepatitis testing; HIV Patient Care Program for Hepatitis A and B vaccines and funds from the CDC for a hepatitis prevention coordinator and associated expenses.¹⁶ The Department of Health's, Bureau of Epidemiology also funds and provides hepatitis surveillance and epidemiologic services.

⁹ United States Preventive Services Task Force, *Supra*, note 3.

¹⁰ United States Preventive Services Task Force, *Supra*, note 3. A B rating means the Task Force recommends the service and that there is a high certainty that the net benefit is moderate or that the net benefit is moderate to substantial. The practice suggestion is to offer this service. The Task Force recommends that services be offered for A and B rated services, without further qualification.

¹¹ *Id.*

¹² *Id.*

¹³ Julie Appleby, *Should Healthier Patients Be Asked to Wait to Use Costlier Hepatitis C Drugs?*, KAISER HEALTH NEWS, Mar. 11, 2014 at <http://capsules.kaiserhealthnews.org/index.php/2014/03/cost-of-new-hepatitis-c-drugs-ignites-debate-about-who-needs-them-now/>.

¹⁴ Department of Health, *Supra*, note 6 at 2.

¹⁵ Department of Health, *Supra* note 6 at 2.

¹⁶ *Id.*

The state laboratory processes all viral hepatitis tests for the HPP. In 2012, the laboratory performed 22,826 tests and of those, 9 percent were positive.¹⁷ The HPP does not provide treatment for HCV.

Medicaid

Medicaid is a joint federal and state funded program that provides health care to low income Floridians. The program is administered by the Agency for Health Care Administration (AHCA) and financed with federal and state funds. Over 3.3 million Floridians are currently enrolled in Medicaid and the program's estimated expenditures for fiscal year 2012-2013 were approximately \$21 billion.¹⁸ The statutory authority for the Medicaid program is contained in ch. 409, F.S.

Florida Medicaid covers medically necessary laboratory services for screening and diagnosis of Hepatitis C. Florida Medicaid also covers all medically necessary treatments for active Hepatitis C related illness for its recipients.

Medicaid recipients who test positive for the virus would likely have the confirming test and one or more other procedures to determine if the recipient has an active viral disease and to determine the quantity and characteristics of the virus. The estimated number of current Medicaid recipients within the "baby boomer" cohort is 301,776.¹⁹

III. Effect of Proposed Changes:

Section 1 creates s. 381.0044, F.S., relating to new Hepatitis C testing standards for certain health care practitioners and any person born between January 1, 1945, and December 31, 1965. The bill creates definitions specific to this section for:

- Health care practitioner;
- Hepatitis C diagnostic test; and,
- Hepatitis C screening test.

A person who falls within the designated age cohort and who receives health care services as an inpatient at a general hospital, primary care services in a hospital inpatient or outpatient setting, or primary care services from a physician, physician assistant or an advanced registered nurse practitioner, must be offered a Hepatitis C screening test.

A health care practitioner is not required to offer a test if the health care practitioner reasonably believes the person:

- Is being treated for a life-threatening emergency;
- Has previously been offered a Hepatitis C test or has received a screening test; however, if the person's medical condition indicates the need for additional testing, a test should be offered; or,

¹⁷ *Id.*, at 3.

¹⁸ Agency for Health Care Administration, *Florida Medicaid*, <http://ahca.myflorida.com/Medicaid/index.shtml> (last visited Mar. 14, 2014).

¹⁹ Agency for Health Care Administration, *2014 Agency Legislative Bill Analysis - SB 824* (January 2, 2014), on file with Senate Health Policy Committee.

- Lacks the capacity to consent to the test.

If a person receives a positive test result, the practitioner shall forward the results to the person's primary care health care practitioner for counseling and follow-up care. The follow-up health care must include a Hepatitis C diagnostic test.

The DOH is directed to adopt rules for linguistically and culturally appropriate procedures for offering the Hepatitis C test. The DOH must also provide health care practitioners a standard information sheet on HCV for use with patients.

The bill provides that its provisions do not impact the scope of practice of a health care practitioner or diminish the authority or professional obligation of a health care practitioner to offer a Hepatitis C screening or diagnostic test or to provide services or follow-up treatment.

The State Surgeon General is required to provide an evaluation on the effectiveness of the Hepatitis C testing program by January 1, 2016. The State Surgeon General must submit the report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the appropriate substantive committees of the Legislature.

Section 2 provides an effective date of the act of July 1, 2014.

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:

Currently, the CHDs charge only a small administrative fee for the test and will waive the fee if the patient is unable to pay.

B. Private Sector Impact:

Certain health care practitioners are required to offer certain individuals a Hepatitis C screening when they receive health care services in a general hospital or primary care services. The screening is voluntary, but unless the patient is being treated for an

emergency or has already been screened or tested, the health care practitioner is required to offer the screening.

CS/SB 824 requires the test to be offered; however, it does not mandate that the patient's insurance carrier provide coverage for the test or treatment. However, non-grandfathered health plans and other health insurance coverage are already required to cover any preventive services that receive an "A" or "B" grade from the USPSTF.²⁰

C. Government Sector Impact:

Hospitals or facilities owned or operated by local government that treat patients in the age cohort, are required to offer the Hepatitis C screening except in limited circumstances. The bill does not address who would incur the cost of the test should the patient not have the means to cover the fees.

The DOH reports that the bill could increase demand for its services. During the last calendar year, the CHDs saw 131,821 people born between 1945 and 1968.²¹ The DOH projects that 70 percent of these individuals had incomes below 100 percent of the federal poverty level, placing them in the "no pay" category of the CHD's fee scale. The DOH was unable to determine the total fiscal impact but stated it may exceed their current resources.²²

The DOH is also required to adopt rules, report on the effectiveness of the Hepatitis C testing program by January 1, 2016, and make available to practitioners a standard information sheet on Hepatitis C for use with patients. The DOH is responsible for the development and dissemination of this information. The DOH indicates that development of rules and a report can be accomplished within existing resources; no information is available on any fiscal impact for the standard information sheet.

The AHCA reports that the potential fiscal impact caused by the possible treatment of additional Medicaid recipients between 49 and 69 years of age is minimal and indeterminate for the following reasons:²³

- In persons without symptoms, Hepatitis C is often detected through routine blood tests to measure liver function and that treatment is already covered by Medicaid;
- The AHCA cites a World Health Organization report²⁴ that Hepatitis C does not always require treatment, so it is difficult to predict whether an increase in the number of tests will automatically result in treatment with a variety of medications; and,
- Early detection of asymptomatic patients may result in lower treatment costs in the long-term.

²⁰ See *Sec. 2713*; Pub. Law No. 111-148, H.R. 3590, 111th Cong. (Mar. 23, 2010) and 29 CFR Section 2590.715-2713.

²¹ Department of Health, *Supra*, note 6 at 5.

²² Department of Health, *Supra*, note 6 at 5.

²³ Agency for Health Care Administration, *Supra*, note 19 at 3.

²⁴ World Health Organization, *Hepatitis C - Fact Sheet*, (July 2013), <http://www.who.int/mediacentre/factsheets/fs164/en/> (last visited Mar. 14, 2014).

For year one, the AHCA estimates an overall fiscal impact of \$2,180,621, of which \$1,288,747 represents the federal share and the remaining \$891,874 the state costs. The cost impact is based on 50 percent of the eligible population receiving the test and 1.6 percent percentage of those that tested having follow-up tests.

For year two, the recurring impact estimate is \$1,090,311 (\$647,536 federal share; \$442,775 state share).

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill requires the health care practitioner to forward the results of the screening test to the person's primary care practitioner who can provide appropriate counseling and follow up care. The provision also requires that the follow-up care include a Hepatitis C diagnostic test. All activities are mandatory on the part of the health care practitioner and does not address whether the patient can afford the follow-up care or the required diagnostic test, including whether the primary care health care practitioner might later determine that the diagnostic test is not necessary.

VIII. Statutes Affected:

This bill creates the following section of the Florida Statutes: 381.0044.

IX. Additional Information:

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

CS/SB 824 by Health Policy Committee on March 19, 2014:

The CS modifies the definition of "health care practitioner" to mean a person licensed under chapter 458 or chapter 459 or an advanced registered nurse practitioner certified under part I of chapter 464. References to health care practitioner or the types of health care practitioners that may perform testing is also standardized. The definition of "Hepatitis C screening test" is narrowed to specify those with federal Food and Drug Administration approval. If a person accepts the offer of a Hepatitis C screening test and receives a positive result, the CS requires the result to be forwarded to the person's primary care practitioner for counseling and follow-up care. The CS also creates an additional responsibility for the DOH to make available to health care practitioners a standard information sheet on Hepatitis C for use when discussing the screening test.

- B. **Amendments:**

None.