

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 465 Hepatitis C Testing  
**SPONSOR(S):** Health Quality Subcommittee; Jones and others  
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 824

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Castagna	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

### SUMMARY ANALYSIS

Persons born between the years 1945 and 1965 account for approximately 75% of those infected with the Hepatitis C Virus (HCV). HCV often goes untreated due to its asymptomatic properties.<sup>1</sup> HCV is a leading cause of liver cancer and the leading cause of liver transplants.<sup>2</sup>

The bill requires that patients born between January 1, 1945, and December 31, 1965, who receive inpatient health care services or primary care services in a hospital inpatient or outpatient setting, or receive primary care services from a health care practitioner to be offered a test that screens for HCV antibodies. A health care practitioner is not required to offer the screening test if the patient:

- Is being treated for a life threatening emergency.
- Has previously been offered the test or has been tested, unless their medical condition indicates the need for testing.
- Lacks the capacity to consent.

If a person screened for HCV tests positive for the virus, the bill requires the health care practitioner to forward positive test results to a patient's primary care health care practitioner who can provide the appropriate counseling and follow-up health care. The follow-up health care must include an HCV diagnostic test.

The bill gives the Department of Health (Department) the authority to adopt rules to implement culturally and linguistically appropriate screening procedures and make available to health care practitioners a standard HCV information sheet to use when discussing and offering the screening test to patients. The bill provides that the requirements to offer screening for HCV and forward positive test results to primary care providers, do not affect the health care practitioner's scope of practice or other legal obligations or authority to offer such services.

The bill requires the State Surgeon General to submit a status report on the HCV testing program to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the chairs of the appropriate substantive committees of the Legislature.

The bill appears to have no fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2014.

### FULL ANALYSIS

<sup>1</sup> Hepatitis C Why Baby Boomers Should Get Tests, CDC, *accessible at:* <http://www.cdc.gov/hepatitis/Populations/AAC-HepC.htm> (Last accessed February 23, 2014).

<sup>2</sup>In 2012 chronic liver disease and cirrhosis was the tenth leading cause of death in Florida. Florida Death County Query System, Florida Department of Health, *accessible at:* <http://www.floridacharts.com/FLQUERY/Death/DeathCount.aspx> (Last accessed February 23, 2014).

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### **Background Information**

The Hepatitis C Virus (HCV) is a viral disease that leads to swelling of the liver. Over time, chronic HCV can cause serious health problems including liver damage, cirrhosis, liver cancer and even death.<sup>3</sup> HCV is a leading cause of liver cancer and the leading cause of liver transplants.<sup>4</sup>

HCV disproportionately affects those persons born between the years 1945 and 1965. This age group comprises an estimated 27% of the U.S. population but they account for approximately 75% of all HCV infections, 73% of HCV-associated mortality, and are at greatest risk for HCV-related liver disease.

HCV also disproportionately affects African Americans as they have a higher rate of HCV infection than Caucasians and other ethnic groups. Chronic liver disease, often HCV related, is the leading cause of death among African Americans ages 45 to 65.<sup>5</sup>

Due to the virus' asymptomatic properties, many of the 2.7 to 3.9 million persons living with HCV infection are unaware they are infected and do not receive care and treatment. As of 2012, the CDC recommends all adults born from 1945 through 1965 to be tested once for HCV even without prior detection of HCV risk factors.<sup>6</sup>

Based on national estimates, more than 310,000 Floridians are likely infected with HCV with nearly 140,000 that are not aware of their infection. This estimate does not include the homeless or incarcerated populations. Approximately 23,000 chronic cases of HCV are reported each year in Florida. However, because the initial stages of HCV infection are either asymptomatic or associated only with mild symptoms, most new infections are undiagnosed.<sup>7</sup> The Florida Department of Health's (Department) Bureau of Epidemiology provides hepatitis disease surveillance.<sup>8</sup>

#### Florida Department of Health's Hepatitis Prevention Program

The Department's County Health Departments (CHDs) offer HCV screening to those with risk factors,<sup>9</sup> including persons born between the years 1945 and 1965, through the Department's Hepatitis Prevention Program (HPP). Adult Floridians, aged 18 years and older, who test positive for HCV are offered a Hepatitis B vaccine and counseling on nutrition, exercise, and stopping drug, alcohol, and tobacco use. All of these interventions slow the progress of HCV. While CHDs generally do not charge for HCV screening and vaccination services, some CHDs charge a small administrative fee for the vaccines, usually not exceeding \$20. A CHD will waive this cost if the client cannot afford the fee.<sup>10</sup>

---

<sup>3</sup> Hepatitis C Why Baby Boomers Should Get Tests, CDC, *accessible at*: <http://www.cdc.gov/hepatitis/Populations/AAC-HepC.htm> (Last accessed February 23, 2014).

<sup>4</sup> In 2012, chronic liver disease and cirrhosis was the tenth leading cause of death in Florida. Florida Death County Query System, Florida Department of Health, *accessible at*: <http://www.floridacharts.com/FLQUERY/Death/DeathCount.aspx> (Last accessed February 23, 2014).

<sup>5</sup> Hepatitis C in the African American Community, *accessible at*: <http://www.cdc.gov/hepatitis/Populations/AAC-HepC.htm> (Last accessed February 24, 2014).

<sup>6</sup> Recommendations for the Identification of Chronic Hepatitis C Virus Among Persons Born During 1945-1965, *accessible at*: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6104a1.htm> (Last accessed February 24, 2014).

<sup>7</sup> DOH Analysis of HB 465, dated February 6, 2014. On file with Health Quality Subcommittee staff.

<sup>8</sup> Disease surveillance involves collecting and analyzing population level health data.

<sup>9</sup> Risk factors include: persons born between 1945-1965, current or former injection drug users, recipients of clotting factor concentrates made before 1987, recipients of blood transfusions or solid organ transplants before July 1992, persons with HIV, children born to HCV-positive mothers, and persons with known exposures to HCV.

<sup>10</sup> DOH Analysis of HB 465, dated February 6, 2014. On file with Health Quality Subcommittee staff.

Fifteen CHDs<sup>11</sup> have funding for the provision of additional hepatitis services to those at increased risk for Hepatitis A, B, and/or C. Components of these services may include:

- Enhanced surveillance;
- Education of the public and health care providers;
- Immunization against Hepatitis A and B (there is no vaccine for HCV);
- Targeted interventions;
- Screening and testing for chronic Hepatitis B and C; and
- Epidemiologic investigations.

CHDs are funded at varying levels and services may vary from county to county depending on funding.<sup>12</sup> From January 2007 through December 2012, there were 185,096 doses of Hepatitis A, B, and A/B combination vaccine given to at-risk adults through the HPP.<sup>13</sup>

In fiscal years 2012-2013 and 2013-2014, the HPP received \$1,413,745 in General Revenue funding. Other annual funding that supports the HPP includes \$121,000 from the HIV Prevention Program for viral Hepatitis testing; \$125,000 from the HIV Patient Care Program for Hepatitis A and B vaccines; and \$108,287 from the CDC for a Hepatitis Prevention Coordinator and associated expenses. The HPP also received \$212,169 from the CDC in October of 2012 for a two-year Hepatitis B vaccine project in six CHDs. This funding supports supplies and equipment to provide the vaccines and staff support for tracking and analyzing the data. This project ends on September 30, 2014.<sup>14</sup>

### HCV Treatment and Costs

HCV treatment can take from six months up to a year. Most individuals undergoing treatment suffer debilitating side effects such as fever, headaches, depression, anxiety, and more.<sup>15</sup> In late 2013, the Food and Drug Administration approved two new HCV medications, Olysio (simeprevir) and Sovaldi (sofosbuvir), which require shorter term treatment and less extreme side effects.<sup>16</sup> The state HPP does not provide treatment for HCV.

Standard treatment for chronic HCV in eligible individuals costs an average of \$30,000 per patient.<sup>17</sup> For those individuals who cannot afford treatment, there are private and nonprofit “Patient Access” programs available to provide funding for treatment purposes. Medicare has not yet decided whether the program will cover the costs of screening, testing, and treatment. Medicaid does cover screening, testing and treatment, including the current standard medications. The two new medications previously mentioned are expected to be added to the state’s Medicaid Preferred Drug List later this year.<sup>18</sup>

### **Effect of Proposed Changes**

The bill defines “health care practitioner” to mean a person licensed under chapter 458 or chapter 459, F.S., or an advanced registered nurse practitioner certified under part I of chapter 464, F.S. Physician assistants who are licensed under chapters 458 and 459, F.S., fall within that definition.

---

<sup>11</sup> Alachua, Bay, Broward, Collier, Duval, Escambia, Lee, Miami-Dade, Monroe, Okeechobee, Orange, Palm Beach, Pinellas, Polk and Seminole have additional funds from the CDC for follow-up care under the HPP.

<sup>12</sup> Adult Vaccination and Testing Program, *accessible at*: <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/hepatitis-vaccination-testing-program.html> (Last accessed February 24, 2014).

<sup>13</sup> DOH Analysis of HB 465, dated February 6, 2014. On file with Health Quality Subcommittee staff.

<sup>14</sup> *Id.*

<sup>15</sup> Hepatitis C Treatment Side Effects Management Chart, U.S. Department of Veterans Affairs, *accessible at*: <http://www.hepatitis.va.gov/products/patient/side-effects-chart.asp> (Last accessed February 26, 2014).

<sup>16</sup> DOH Analysis of HB 465, dated February 6, 2014. On file with Health Quality Subcommittee staff.

<sup>17</sup> Funding for Hepatitis C Diagnosis, Medical Evaluation and Medical Care, The Florida Viral Hepatitis Council, dated February 2009. On file with Health Quality Subcommittee staff.

<sup>18</sup> *Id.*

The bill requires that patients born between January 1, 1945, and December 31, 1965, who receive inpatient health care services or primary care services in a hospital inpatient or outpatient setting, or receives primary care services from a health care practitioner, to be offered a test that screens for HCV antibodies. A health care practitioner is not required to offer the screening test if the patient:

- Is being treated for a life threatening emergency.
- Has previously been offered the test or has been tested, unless their medical condition indicates the need for testing.
- Lacks the capacity to consent.

If a person screened for HCV tests positive for the virus, the health care practitioner must forward the results to the patient's primary care practitioner who can provide the appropriate counseling and follow-up care. The follow-up care must include an HCV diagnostic test to confirm the presence of the virus.

The bill gives the Department the authority to adopt rules to implement culturally and linguistically appropriate screening procedures and make available to health care practitioners a standard HCV information sheet to use when discussing and offering the screening test to patients. The bill provides that the requirements to offer screening for HCV and follow-up care, or a referral for care, do not affect the health care practitioner's scope of practice or other legal obligations or authority to offer such services.

The bill requires the State Surgeon General to submit a status report on the HCV testing program to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the chairs of the appropriate substantive committees of the Legislature.

The bill provides an effective date of July 1, 2014.

**B. SECTION DIRECTORY:**

**Section 1.** Creates s. 381.0044, F.S., relating to Hepatitis C testing.

**Section 2.** Provides an effective date of July 1, 2014.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

**A. FISCAL IMPACT ON STATE GOVERNMENT:**

1. Revenues:

None.

2. Expenditures:

None.

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

2. Expenditures:

None.

**C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:**

Private insurance companies may see an increase in HCV-related claims because of this bill.

**D. FISCAL COMMENTS:**

None.

### III. COMMENTS

#### A. CONSTITUTIONAL ISSUES:

##### 1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

##### 2. Other:

None.

#### B. RULE-MAKING AUTHORITY:

The bill grants the Department specific authority to adopt rules to implement culturally and linguistically appropriate screening procedures.

#### C. DRAFTING ISSUES OR OTHER COMMENTS:

### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 18, 2014, the Health Quality Subcommittee adopted a strike-all amendment and passed HB 465 as a committee substitute (CS). The strike-all does the following:

- Revises the definition of “health care practitioner” to include physician assistants and removes registered nurses and licensed practical nurses.
- Revises the definition of “hepatitis screening test” to include multiple types of FDA approved screening tests.
- Specifies that a patient receiving primary care services from a “health care practitioner” shall be offered a Hepatitis C screening test.
- Provides that if a patient receives a positive test result, the health care practitioner shall forward the results to the patient’s primary care health care practitioner who can provide appropriate counseling and follow-up health care.
- Removes the requirement that the health care practitioner providing the testing must offer a person who tests positive follow-up health care.
- Requires the Department of Health to make available to health care practitioners a Hepatitis C information sheet to be used when discussing and offering the screening test to patients.
- Requires the State Surgeon General to submit a status report on the Hepatitis C testing program to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the chairs of the appropriate substantive committees of the Legislature.

The analysis is drafted to the committee substitute as pass by the Health Quality Subcommittee.