112TH CONGRESS
1ST SESSION

S. 1809

To amend the Public Health Service Act to revise and extend the program for viral hepatitis surveillance, education, and testing in order to prevent deaths from liver cancer, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 3, 2011

Mr. KERRY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To amend the Public Health Service Act to revise and extend the program for viral hepatitis surveillance, education, and testing in order to prevent deaths from liver cancer, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Viral Hepatitis Testing Act of 2011''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Approximately 5,300,000 Americans are chronically infected with the hepatitis B virus (referred to in this section as ''HBV''), the hepatitis C virus (referred to in this section as ''HCV''), or both.

(2) In the United States, chronic HBV and HCV are the most common cause of liver cancer, one of the most lethal and fastest growing cancers in the United States. Chronic HBV and HCV are the most common cause of chronic liver disease, liver cirrhosis, and the most common indication for liver transplantation. Chronic HCV is also a leading cause of death in Americans living with HIV/AIDS, many of whom are coinfected with chronic HBV, HCV, or both. At least 15,000 deaths per year in the United States can be attributed to chronic HBV and HCV.

(3) According to the Centers for Disease Control and Prevention (referred to in this section as the ''CDC''), approximately 2 percent of the population of the United States is living with chronic HBV, HCV, or both. The CDC has recognized HCV as the Nation's most common chronic bloodborne virus infection and HBV as the deadliest vaccine-preventable disease.

(4) HBV is easily transmitted and is 100 times more infectious than HIV. According to the CDC, HBV is transmitted through percutaneous (i.e., puncture through the skin) or mucosal contact with infectious blood or body fluids. HCV is transmitted by percutaneous exposures to infectious blood.

(5) The CDC conservatively estimates that in 2008 approximately 18,000 Americans were newly infected with HCV and more than 38,000 Americans were newly infected with HBV.

(6) There were 15 outbreaks reported to CDC for investigation during 2009 and 2010 related to healthcare acquired infection of HBV and HCV, potentially exposing 30,000 people to the viruses.

(7) Chronic HBV and chronic HCV usually do not cause symptoms early in the course of the disease, but after many years of a clinically ''silent'' phase, more than 33 percent of infected individuals will develop cirrhosis, end-stage liver disease, or liver cancer. Since most individuals with chronic HBV, HCV, or both are unaware of their infection, they do not know to take precautions to prevent the spread of their infection and can unknowingly exacerbate their own disease progression.

(8) HBV and HCV disproportionately affect certain populations in the United States. Although representing only 5 percent of the population, Asian and Pacific Islanders account for over half of the 1,400,000 domestic chronic HBV cases. Baby boomers (those born between 1945 and 1965) account for more than 75 percent of domestic chronic HCV cases. In addition, African-Americans, Latinos (Latinas), and American Indian/Native Alaskans are among the groups which have disproportionately high rates of HBV infections, HCV infections, or both in the United States.

(9) For both chronic HBV and chronic HCV, behavioral changes can slow disease progression if diagnosis is made early. Early diagnosis, which is determined through simple diagnostic tests, can reduce the risk of transmission and disease progression through education and vaccination of household members and other susceptible persons at risk.

(10) Advancements have led to the development of improved diagnostic tests for viral hepatitis. These tests, including rapid, point of care testing and others in development can facilitate testing, notification of results and post-test counseling, and referral to care at the time of the testing visit. In par-

ticular, these tests are also advantageous because they can be used simultaneously with HIV rapid testing for persons at risk for both HCV and HIV infections.

(11) For those chronically infected with HBV or HCV, regular monitoring can lead to the early detection of liver cancer at a stage where a cure is still possible. Liver cancer is the second deadliest cancer in the United States; however, liver cancer has received little funding for research, prevention, or treatment.

(12) Treatment for chronic HCV can eradicate the disease in approximately 75 percent of those currently treated. The treatment of chronic HBV can effectively suppress viral replication in the overwhelming majority (over 80 percent) of those treated thereby reducing the risk of transmission and progression to liver scarring or liver cancer even though a complete cure is much less common than for HCV.

(13) To combat the viral hepatitis epidemic in the United States, in May 2011, the Department of Health and Human Services released, Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care & Treatment of Viral Hepatitis. The Institute of Medicine of the National

Academies produced a 2010 report on the Federal response to HBV and HCV titled: Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C. The recommendations and guidelines provide a framework for HBV and HCV prevention, education, control, research, and medical management programs.

(14) The annual health care costs attributable to viral hepatitis in the United States are significant. For HBV, it is estimated to be approximately $2,500,000,000 ($2,000 per infected person). In 2000, the lifetime cost of HBV—before the availability of most of the current therapies—was approximately $80,000 per chronically infected person, or more than $100,000,000,000. For HCV, medical costs for patients are expected to increase from $30,000,000,000 in 2009 to over $85,000,000,000 in 2024. Avoiding these costs by screening and diagnosing individuals earlier—and connecting them to appropriate treatment and care will save lives and critical health care dollars. Currently, without a comprehensive screening, testing and diagnosis program, most patients are diagnosed too late when they need a liver transplant costing at least $314,000 for uncomplicated cases or when they have

liver cancer or end stage liver disease which costs between $30,980 to $110,576 per hospital admission. As health care costs continue to grow, it is critical that the Federal Government invests in effective mechanisms to avoid documented cost drivers.

(15) According to the Institute of Medicine report in 2010 (described in paragraph (12)), chronic HBV and HCV infections cause substantial morbidity and mortality despite being preventable and treatable. Deficiencies in the implementation of established guidelines for the prevention, diagnosis, and medical management of chronic HBV and HCV infections perpetuate personal and economic burdens. Existing grants are not sufficient for the scale of the health burden presented by HBV and HCV.

(16) Screening and testing for chronic HBV and HCV are aligned with the Healthy People 2020 goal to increase immunization rates and reduce preventable infectious diseases. Awareness of disease and access to prevention and treatment remain essential components for reducing infectious disease transmission.

(17) Federal support is necessary to increase knowledge and awareness of HBV and HCV and to assist State and local prevention and control efforts

in reducing the morbidity and mortality of these epidemics.

(18) The Secretary of Health and Human Services has the discretion to carry out this Act directly and through whichever of the agencies of the Public Health Service the Secretary determines to be appropriate, which may (in the Secretary's discretion) include the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the National Institutes of Health (including the National Institute on Minority Health and Health Disparities), and other agencies of such Service.

SEC. 3. REVISION AND EXTENSION OF HEPATITIS SURVEILLANCE, EDUCATION, AND TESTING PROGRAM.

(a) IN GENERAL.—Section 317N of the Public Health Service Act (42 U.S.C. 247b–15) is amended—

(1) by amending the heading to read as follows: ''**SURVEILLANCE, EDUCATION, AND TESTING REGARDING HEPATITIS VIRUS**'';

(2) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively; and

(3) by striking subsection (a) and inserting the following:

''(a) IN GENERAL.—The Secretary shall, in accordance with this section, carry out surveillance, education, and testing programs with respect to hepatitis B and hepatitis C virus infections (referred to in this section as 'HBV' and 'HCV', respectively). The Secretary may carry out such programs directly and through grants to public and nonprofit private entities, including States, political subdivisions of States, territories, Indian tribes, and public-private partnerships.

''(b) NATIONAL SYSTEM.—In carrying out subsection (a), the Secretary shall cooperate with States and other public or nonprofit private entities to seek to establish a national system with respect to HBV and HCV with the following goals:

''(1) To determine the incidence and prevalence of such infections, including providing for the reporting of chronic cases.

''(2) With respect to the population of individuals who have such an infection, to carry out testing programs to increase the number of individuals who are aware of their infection to 50 percent by 2014 and to 75 percent by 2016.

''(3) To develop and disseminate public information and education programs for the detection and control of such infections, with priority given to

changing behaviors that place individuals at risk of infection.

''(4) To provide appropriate referrals for counseling and medical treatment of infected individuals and to ensure, to the extent practicable, the provision of appropriate follow-up services.

''(5) To improve the education, training, and skills of health professionals in the detection, control, and treatment of such infections, with priority given to pediatricians and other primary care physicians, and obstetricians and gynecologists.

''(c) HIGH-RISK POPULATIONS; CHRONIC CASES.—

''(1) IN GENERAL.—The Secretary shall determine the populations that, for purposes of this section, are considered at high-risk for HBV or HCV. The Secretary shall include the following among those considered at high-risk:

''(A) For HBV, individuals born in countries in which 2 percent or more of the population has HBV.

''(B) For HCV, individuals born between 1945 and 1965.

''(C) Those who have been exposed to the blood of infected individuals or of high-risk in-

dividuals, are family members of such individuals, or are sexual partners of such individuals.

''(2) PRIORITY IN PROGRAMS.—In providing for programs under subsection (b), the Secretary shall give priority—

''(A) to early diagnosis of chronic cases of HBV or HCV in high-risk populations under paragraph (1); and

''(B) to education, and referrals for counseling and medical treatment, for individuals diagnosed under subparagraph (A) in order to—

''(i) reduce their risk of dying from end-stage liver disease and liver cancer, and of transmitting the infection to others;

''(ii) determine the appropriateness for treatment to reduce the risk of progression to cirrhosis and liver cancer;

''(iii) receive ongoing medical management, including regular monitoring of liver function and screenings for liver cancer;

''(iv) receive, as appropriate, drug, alcohol abuse, and mental health treatment;

''(v) in the case of women of childbearing age, receive education on how to prevent HBV perinatal infection, and to al-

leviate fears associated with pregnancy or raising a family; and

''(vi) receive such other services as the Secretary determines to be appropriate.

''(3) CULTURAL CONTEXT.—In providing for services pursuant to paragraph (2) for individuals who are diagnosed under subparagraph (A) of such paragraph, the Secretary shall seek to ensure that the services are provided in a culturally and linguistically appropriate manner.''.

(b) COORDINATION OF DEVELOPMENT OF FEDERAL SCREENING GUIDELINES.—

(1) REFERENCES.—For purposes of this subsection, the term ''CDC Director'' means the Director of the Centers for Disease Control and Prevention, and the term ''AHRQ Director'' means the Director of the Agency for Healthcare Research and Quality.

(2) HCV GUIDELINES; CENTERS FOR DISEASE CONTROL AND PREVENTION.—

(A) IN GENERAL.—Not later than March 1, 2012, the CDC Director shall complete the revision of the guidelines of the Centers for Disease Control and Prevention for screening individuals for the hepatitis C virus infection (in

this section referred to as ''HCV''), and shall transmit a copy of the guidelines to the AHRQ Director. The scope of the revised guidelines shall include testing for HCV that is carried out under section 317N of the Public Health Service Act (42 U.S.C. 247b–15), as amended by subsection (a).

(B) CERTAIN FACTORS.—In revising guidelines pursuant to subparagraph (A), the CDC Director shall take into account—

(i) the effectiveness issues that have been raised with respect to the current guidelines of the Centers for Disease Control and Prevention for screenings for HCV;

(ii) the importance of responding to the perception that receiving such screenings may be stigmatizing; and

(iii) whether age-based screenings would be effective, considering the use of that approach in breast and colon cancer screenings.

(3) AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.—

(A) HCV GUIDELINES.—The AHRQ Director shall, in developing the recommendations for screenings for HCV that the AHRQ Director will provide to the Preventive Services Task Force under section 915(a) of the Public Health Service Act (42 U.S.C. 299b–4(a)), take into account—

(i) the guidelines established pursuant to paragraph (2) by the CDC Director; and

(ii) new and improved treatments for HCV.

(B) HBV GUIDELINES.—The AHRQ Director shall, in developing the recommendations for screenings for the hepatitis B virus infection (in this section referred to as ''HBV'') that the AHRQ Director will provide to the Preventive Services Task Force referred to in subparagraph (A), take into account the guidelines for screenings for HBV that the CDC Director recommended in 2008.

(c) AUTHORIZATION OF APPROPRIATIONS.—Subsection (e) of section 317N of the Public Health Service Act (42 U.S.C. 247b–15), as redesignated by subsection (a)(2) of this section, is amended to read as follows:

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—For the purpose of testing, education, and referrals under this section, there are authorized to be appropriated $25,000,000 for fiscal year 2012, $35,000,000 for fiscal year 2013, $20,000,000 for fiscal year 2014, and $15,000,000 for each of the fiscal years 2015 and 2016.

''(2) GRANTS.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall reserve not less than 80 percent for making grants under subsection (a).''.

(d) SAVINGS PROVISION.—The amendments made by this section shall not be construed to require termination of any program or activity carried out by the Secretary of Health and Human Services under section 317N of the Public Health Service Act (42 U.S.C. 247b–15) as in effect on the day before the date of the enactment of this Act.

○