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113TH CONGRESS
1ST SESSION

H. R. 3723

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 chronic liver disease and liver cancer, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 12, 2013

Mr. CASSIDY (for himself, Mr. GUTHRIE, and Mr. DENT) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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 chronic liver disease and 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 2013''.

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 among the most common causes of liver cancer, one of the most lethal and fastest growing cancers in the United States. Chronic HBV and HCV are among the most common causes of chronic liver disease, liver cirrhosis, and the most common indication for liver transplantation. More than 15,000 deaths per year in the United States can be attributed to chronic HBV and HCV. Chronic HCV is also a leading cause of death in Americans living with HIV/AIDS. Many of those living with HIV/AIDS are coinfected with chronic HBV, HCV, or both.

(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.

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

(5) The CDC conservatively estimates that in 2011 approximately 16,600 Americans were newly infected with HCV and more than 18,800 Americans were newly infected with HBV. These estimates could be much higher due to many reasons, including lack of screening education and awareness, and perceived marginalization of the populations at risk.

(6) In 2012 CDC released new guidelines recommending every person born from 1945 through 1965 receive a one-time HCV test. Among the estimated 102 million (1.6 million chronically HCV-infected) eligible for screening, birth-cohort screening leads to 74,000 fewer cases of decompensated cirrhosis, 46,000 fewer cases of hepatocellular carcinoma, 15,000 fewer liver transplants and 120,000

fewer HCV-related deaths versus risk-based screening.

(7) In 2013, the United States Preventative Task Force (USPSTF) issued a Grade B rating for screening for hepatitis C virus (HCV) infection in persons at high risk for infection and adults born between 1945 and 1965. In 2009, the USPSTF issued a Grade A for screening pregnant women for the hepatitis B virus (HBV) during their first prenatal visit.

(8) There were 35 outbreaks (19 of HBV, 16 of HCV) reported to CDC for investigation from 2008–2012 related to healthcare acquired infection of HBV and HCV, 33 of which occurred in non-hospital settings. There were more than 99,975 patients potentially exposed to one of the viruses.

(9) 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, CDC estimates show 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.

(10) HBV and HCV disproportionately affect certain populations in the United States. Although representing about 6 percent of the population, Asian and Pacific Islanders account for over half of up to 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.

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

(12) 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, no-

tification of results and post-test counseling, and referral to care at the time of the testing visit. In particular, 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.

(13) 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.

(14) 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.

(15) 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.

(16) 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 current therapies—was approximately $80,000 per chronically infected person, totaling 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 pro-

gram, 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.

(17) According to the Institute of Medicine report in 2010 (described in paragraph (13)), 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 to address the scale of the health burden presented by HBV and HCV.

(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 Preven-

tion, 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.

(19) For over a decade, the Centers for Disease Control and Prevention's Viral Hepatitis Prevention Coordinator (VHPC) program has been the only national program dedicated to the prevention and control of the viral hepatitis epidemics administering the duties currently specified by Section 317N of the Public Health Service Act (42 U.S.C. 247b–15) at State and local health departments. VHPCs provide the technical expertise necessary for the management and coordination of activities to prevent viral hepatitis infection and disease with little to no Federal funding for program implementation or development. Further, these coordinators help integrate viral hepatitis prevention services into health care settings and public health programs that serve adults at risk for viral hepatitis.

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 section heading to read as follows: ''**SURVEILLANCE, EDUCATION, TESTING, AND LINKAGE TO CARE 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, in consultation with States and other public or nonprofit private entities and public-private partnerships described in subsection (d), 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 acute and 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 December 31, 2014, and to 75 percent by December 31, 2016.

''(3) To develop and disseminate public information and education programs for the detection and control of such infections.

''(4) To improve the education, training, and skills of health professionals in the detection, control, and care and treatment, of such infections.

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

''(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 or who are a part of a high-risk category as identified by the Centers for Disease Control and Prevention.

"(B) For HCV, individuals born between 1945 and 1965 or who are a part of a high-risk category as identified by the Centers for Disease Control and Prevention.

"(C) Those who have been exposed to the blood of infected individuals or of high-risk individuals or who are family members of such individuals.

"(2) PRIORITY IN PROGRAMS.—In providing for programs under this section, 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 care and 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 alleviate 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.

''(d) PUBLIC-PRIVATE PARTNERSHIPS.—

''(1) IN GENERAL.—In carrying out this section, and not later than 60 days after the date of the enactment of the Viral Hepatitis Testing Act of 2013, the Secretary shall, in consultation with the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Office of Minority Health, the Indian Health Service, other relevant agencies, and non-government stakeholder entities, establish and support public-private partnerships that facilitate the surveillance, education, screening, testing, and linkage to care programs authorized by this section.

''(2) DUTIES.—Public-private partnerships established or supported under paragraph (1) shall—

''(A) focus primarily on the surveillance, education, screening, testing, and linkage to care programs authorized by this section;

''(B) generate resources, in addition to the funds made available pursuant to subsection (f), to carry out the surveillance, education, screening, testing, and linkage to care programs authorized in this section by leveraging Federal funding with non-Federal funding and support;

"(C) allow for investments in such programs of financial or in-kind resources by each of the partners involved in the partnership;

"(D) include corporate and industry entities, academic institutions, public and non-profit organizations, community and faith-based organizations, foundations, and other governmental and non-governmental organizations; and

"(E) advance the core goals of each of the partners of the partnership as determined by the Secretary in development of the partnership.

"(3) ANNUAL REPORTS.—The Secretary shall provide to the Congress an annual report on the public-private partnerships established under this subsection. Each such report shall include—

"(A) the number of public-private partnerships established;

"(B) specific and quantifiable information on the surveillance, education, screening, testing, and linkage to care activities conducted as well as the outcomes achieved through each of the public-private partnerships;

''(C) the amount of Federal funding or resources dedicated to the public-private partnerships;

''(D) the amount of non-Federal funding or resources leveraged through the public-private partnerships; and

''(E) a plan for the following year that outlines future activities.

''(4) LIMITATION.—No more than 25 percent of the funds made available to carry out this section may be used for public-private partnerships established or supported under this subsection.

''(5) LINKAGE TO CARE.—For purposes of this section, the term 'linkage to care' means, with respect to an individual with a diagnosis of HBV or HCV, the referral of such individual to clinical care for a thorough evaluation of their clinical status to determine the need for treatment, vaccination for HBV, or other therapy.

''(e) AGENCY FOR HEALTHCARE RESEARCH AND QUALITY HBV AND HCV GUIDELINES.—Due to the rapidly evolving standard of care associated with diagnosing and treating viral hepatitis infection, the Director of the Agency for Healthcare Research and Quality shall convene the Preventive Services Task Force under section 915(a)

to review its recommendation for screening for HBV and HCV infection every 3 years.

''(f) FUNDING.—

''(1) IN GENERAL.—In addition to any amounts otherwise authorized by this Act, there are authorized to be appropriated to carry out this section—

''(A) $25,000,000 for fiscal year 2014;

''(B) $35,000,000 for fiscal year 2015; and

''(C) $20,000,000 for fiscal year 2016.

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

''(3) SOURCE OF FUNDS.—The funds made available to carry out this section shall be derived exclusively from the funds appropriated or otherwise made available for planning and evaluation under this Act.''.

(b) 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.

SEC. 4. HEPATITIS C SCREENING AND EVALUATION OF NEEDED CARE FOR VETERANS.

(a) IN GENERAL.—Subchapter II of chapter 17 of title 38, United States Code, is amended by adding at the end the following:

"§ 1720H. Hepatitis C screening and evaluation of needed care for veterans

''(a) IN GENERAL.—(1) The Secretary shall establish and carry out a plan to provide veterans described in paragraph (2) with—

''(A) a risk assessment for the hepatitis C virus; and

''(B) if a veteran is diagnosed with such virus—

''(i) a thorough evaluation of the clinical status of the veteran to determine the need for treatment, vaccination, or other therapy; and

''(ii) information with respect to the needs determined under clause (i).

''(2) Veterans described in this paragraph are veterans who—

''(A) are enrolled in the health care system established under section 1705(a) of this title; and

''(B) were born between 1945 and 1965.

''(b) COMPLIANCE.—(1) The Secretary shall use the plan established under subsection (a)(1) as a key measure in determining performance under the VA Handbook Per-

formance Management System, or the successor to such handbook, to ensure the compliance of such plan.

''(2) If the Secretary determines that a medical facility of the Department complies with the plan established under subsection (a)(1) at a rate less than 100 percent, the Secretary shall treat the director of such medical facility as 'less than fully successful'with respect to the performance appraisal that is used for the basis for determining performance awards under the handbook described in paragraph (1).

''(c) ANNUAL REPORT.—The Secretary shall submit annually to Congress a report on the compliance of each medical facility of the Department with the plan established under subsection (a)(1).''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 1720G the following new item:

''1720H. Hepatitis C screening and evaluation of needed care for veterans.''.

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