

114TH CONGRESS
1ST SESSION

S. 1287

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 SENATE OF THE UNITED STATES

MAY 12, 2015

Mr. KIRK (for himself, Ms. HIRONO, Mr. CASSIDY, Mr. SCHUMER, and Mr. MERKLEY) 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 chronic liver disease and liver cancer, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Viral Hepatitis Testing
5 Act of 2015”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Approximately 5,300,000 Americans are
2 chronically infected with the hepatitis B virus (re-
3 ferred to in this section as “HBV”), the hepatitis C
4 virus (referred to in this section as “HCV”), or
5 both.

6 (2) In the United States, chronic HBV and
7 HCV are among the most common causes of liver
8 cancer, one of the most lethal and fastest growing
9 cancers in the United States. Chronic HBV and
10 HCV are among the most common causes of chronic
11 liver disease, liver cirrhosis, and the most common
12 indication for liver transplantation. More than
13 15,000 deaths per year in the United States can be
14 attributed to chronic HBV and HCV. Current infor-
15 mation indicates these represent a fraction of deaths
16 attributable in whole or in part to chronic hepatitis
17 C. From 2007 through 2011, mortality rates of per-
18 sons with hepatitis C increased 39 percent among
19 persons aged 55–64 years to a rate of 21.9 deaths
20 per 100,000 population in 2011. In 2011, the high-
21 est mortality rates of persons with hepatitis C by
22 race/ethnicity and sex were observed among Amer-
23 ican Indians and Alaska Natives (10.6 deaths per
24 100,000 population) and males (7.1 deaths per
25 100,000 population) respectively. Mortality data

1 from 2011, the latest year for which these data were
2 available, reveal the serious health consequences as-
3 sociated with viral hepatitis: chronic liver disease, in-
4 cluding cirrhosis, was the 12th leading cause of
5 death in the United States in 2011. Chronic HCV
6 is also a leading cause of death in Americans living
7 with HIV/AIDS. Many of those living with HIV/
8 AIDS are coinfectd with chronic HBV, HCV, or
9 both.

10 (3) According to the Centers for Disease Con-
11 trol and Prevention (referred to in this section as
12 the “CDC”), approximately 2 percent of the popu-
13 lation of the United States is living with chronic
14 HBV, HCV, or both. The CDC has recognized HCV
15 as the Nation’s most common chronic bloodborne
16 virus infection.

17 (4) HBV is easily transmitted and is 100 times
18 more infectious than HIV. According to the CDC,
19 HBV is transmitted through contact with infectious
20 blood, semen, or other body fluids. HCV is trans-
21 mitted by contact with infectious blood, particularly
22 through percutaneous exposures (i.e. puncture
23 through the skin).

24 (5) The CDC conservatively estimates that in
25 2011 approximately 16,500 Americans were newly

1 infected with HCV and more than 18,800 Americans
2 were newly infected with HBV. These estimates
3 could be much higher due to many reasons, includ-
4 ing lack of screening education and awareness, and
5 perceived marginalization of the populations at risk.
6 According to the CDC, from 2010 to 2011 there was
7 a 45 percent increase in the number of reported
8 acute hepatitis C cases (from 850 to 1,229 cases)
9 and another 45 percent increase from 2011 to 2012
10 (from 1,229 to 1,778 cases), representing a 75 per-
11 cent increase from 2010–2012. In 2012, the rate of
12 acute hepatitis C increased in every age group when
13 compared with 2010 and 2011, with the largest in-
14 creases among persons aged 0–19 years (from 0.05
15 to 0.11 cases per 100,000 population) and 20–29
16 years (from 0.75 to 1.73 cases per 100,000 popu-
17 lation).

18 (6) In 2012, CDC released new guidelines rec-
19 ommending every person born from 1945 through
20 1965 receive a one-time HCV test. Among the esti-
21 mated 102 million (1.6 million chronically HCV-in-
22 fected) eligible for screening, birth-cohort screening
23 leads to 74,000 fewer cases of decompensated cir-
24 rhosis, 46,000 fewer cases of hepatocellular car-
25 cinoma, 15,000 fewer liver transplants and 120,000

1 fewer HCV-related deaths versus risk-based screen-
2 ing.

3 (7) In 2013, the United States Preventative
4 Services Task Force (USPSTF) issued a Grade B
5 rating for screening for hepatitis C virus (HCV) in-
6 fection in persons at high risk for infection and
7 adults born between 1945 and 1965. In 2009, the
8 USPSTF issued a Grade A for screening pregnant
9 women for the hepatitis B virus (HBV) during their
10 first prenatal visit. In 2014, the USPSTF issued a
11 Grade B for screening for HBV in individuals at
12 high risk.

13 (8) There were 35 outbreaks (19 of HBV, 16
14 of HCV) reported to CDC for investigation from
15 2008–2012 related to health care acquired infection
16 of HBV and HCV, 33 of which occurred in nonhos-
17 pital settings. There were more than 99,975 patients
18 potentially exposed to one of the viruses.

19 (9) Chronic HBV and chronic HCV usually do
20 not cause symptoms early in the course of the dis-
21 ease, but after many years of a clinically “silent”
22 phase, CDC estimates show more than 33 percent of
23 infected individuals will develop cirrhosis, end-stage
24 liver disease, or liver cancer. Since most individuals
25 with chronic HBV, HCV, or both are unaware of

1 their infection, they do not know to take precautions
2 to prevent the spread of their infection and can un-
3 knowingly exacerbate their own disease progression.

4 (10) HBV and HCV disproportionately affect
5 certain populations in the United States. Although
6 representing about 6 percent of the population,
7 Asian and Pacific Islanders account for over half of
8 up to 1,400,000 domestic chronic HBV cases. Baby
9 boomers (those born between 1945 and 1965) ac-
10 count for more than 75 percent of domestic chronic
11 HCV cases. In addition, African-Americans, Latinos
12 (Latinas), and American Indians/Alaskan Natives
13 are among the groups which have disproportionately
14 high rates of HBV infections, HCV infections, or
15 both in the United States.

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

23 (12) Advancements have led to the development
24 of improved diagnostic tests for viral hepatitis.
25 These tests, including rapid, point-of-care testing

1 and others in development, can facilitate testing, no-
2 tification of results and posttest counseling, and re-
3 ferral to care at the time of the testing visit. In par-
4 ticular, these tests are also advantageous because
5 they can be used simultaneously with HIV rapid
6 testing for persons at risk for both HCV and HIV
7 infections.

8 (13) For those chronically infected with HBV
9 or HCV, regular monitoring can lead to the early de-
10 tection of liver cancer at a stage where a cure is still
11 possible. Liver cancer is the second deadliest cancer
12 in the world; however, liver cancer has received little
13 funding for research, prevention, or treatment.

14 (14) Treatment for chronic HCV can eradicate
15 the disease in approximately 95 percent or more of
16 those currently treated. The treatment of chronic
17 HBV can effectively suppress viral replication in the
18 overwhelming majority (over 80 percent) of those
19 treated, thereby reducing the risk of transmission
20 and progression to liver scarring or liver cancer,
21 even though a complete cure is much less common
22 than for HCV.

23 (15) To combat the viral hepatitis epidemic in
24 the United States, in May 2011, the Department of
25 Health and Human Services released, “Combating

1 the Silent Epidemic of Viral Hepatitis: Action Plan
2 for the Prevention, Care & Treatment of Viral Hepa-
3 titis”.

4 (16) The annual health care costs attributable
5 to viral hepatitis in the United States are signifi-
6 cant. For HBV, it is estimated to be approximately
7 \$2,500,000,000 (\$2,000 per infected person). In
8 2000, the lifetime cost of HBV—before the avail-
9 ability of most current therapies—was approximately
10 \$80,000 per chronically infected person, totaling
11 more than \$100,000,000,000. For HCV, medical
12 costs for patients are expected to increase from
13 \$30,000,000,000 in 2009 to over \$85,000,000,000
14 in 2024. Avoiding these costs by screening and diag-
15 nosing individuals earlier—and connecting them to
16 appropriate treatment and care will save lives and
17 critical health care dollars. Currently, without a
18 comprehensive screening, testing, and diagnosis pro-
19 gram, most patients are diagnosed too late when
20 they need a liver transplant costing at least
21 \$314,000 for uncomplicated cases or when they have
22 liver cancer or end-stage liver disease which costs be-
23 tween \$30,980 to \$110,576 per hospital admission.
24 As health care costs continue to grow, it is critical

1 that the Federal Government invests in effective
2 mechanisms to avoid documented cost drivers.

3 (17) According to the Institute of Medicine re-
4 port in 2010, “Hepatitis and Liver Cancer: A Na-
5 tional Strategy for Prevention and Control of Hepa-
6 titis B and C”, chronic HBV and HCV infections
7 cause substantial morbidity and mortality despite
8 being preventable and treatable. Deficiencies in the
9 implementation of established guidelines for the pre-
10 vention, diagnosis, and medical management of
11 chronic HBV and HCV infections perpetuate per-
12 sonal and economic burdens. Existing grants are not
13 sufficient to address the scale of the health burden
14 presented by HBV and HCV.

15 (18) The Secretary of Health and Human Serv-
16 ices has the discretion to carry out this Act directly
17 and through whichever of the agencies of the Public
18 Health Service the Secretary determines to be ap-
19 propriate, which may (in the Secretary’s discretion)
20 include the Centers for Disease Control and Preven-
21 tion, the Health Resources and Services Administra-
22 tion, the Substance Abuse and Mental Health Serv-
23 ices Administration, the National Institutes of
24 Health (including the National Institute on Minority
25 Health and Health Disparities), and other agencies.

1 (19) For over a decade, the Centers for Disease
 2 Control and Prevention’s Viral Hepatitis Prevention
 3 Coordinator (VHPC) Program has been the only na-
 4 tional program dedicated to the prevention and con-
 5 trol of the viral hepatitis epidemics administering
 6 the duties currently specified by section 317N of the
 7 Public Health Service Act (42 U.S.C. 247b–15) at
 8 State and local health departments. VHPCs provide
 9 the technical expertise necessary for the manage-
 10 ment and coordination of activities to prevent viral
 11 hepatitis infection and disease with little to no Fed-
 12 eral funding for program implementation or develop-
 13 ment. Further, these coordinators help integrate
 14 viral hepatitis prevention services into health care
 15 settings and public health programs that serve
 16 adults at risk for viral hepatitis.

17 **SEC. 3. REVISION AND EXTENSION OF HEPATITIS SURVEIL-**
 18 **LANCE, EDUCATION, AND TESTING PROGRAM.**

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

21 (1) by amending the section heading to read as
 22 follows: “**SURVEILLANCE, EDUCATION, TESTING,**
 23 **AND LINKAGE TO CARE REGARDING HEPATITIS**
 24 **VIRUS**”;

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

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

5 “(a) IN GENERAL.—The Secretary shall, in accord-
6 ance with this section, carry out surveillance, education,
7 and testing programs with respect to hepatitis B and hep-
8 atitis C virus infections (referred to in this section as
9 ‘HBV’ and ‘HCV’, respectively). The Secretary may carry
10 out such programs directly and through grants to public
11 and nonprofit private entities, including States, political
12 subdivisions of States, territories, Indian tribes, and pub-
13 lic-private partnerships.

14 “(b) NATIONAL SYSTEM.—In carrying out subsection
15 (a), the Secretary shall, in consultation with States and
16 other public or nonprofit private entities and public-pri-
17 vate partnerships described in subsection (d), establish a
18 national system with respect to HBV and HCV with the
19 following goals:

20 “(1) To determine the incidence and prevalence
21 of such infections, including providing for the report-
22 ing of acute and chronic cases.

23 “(2) With respect to the individuals who are
24 tested for such an infection, to demonstrate success
25 in increasing the number of individuals tested and

1 made aware of their status, including those who test
2 positive.

3 “(3) To develop and disseminate public infor-
4 mation and education programs for the detection
5 and control of such infections.

6 “(4) To improve the education, training, and
7 skills of health professionals in the detection, con-
8 trol, and care and treatment, of such infections.

9 “(5) To provide appropriate referrals for coun-
10 seling and medical care and treatment of infected in-
11 dividuals and to ensure, to the extent practicable,
12 the provision of appropriate followup services.

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

14 “(1) IN GENERAL.—The Secretary shall deter-
15 mine the populations that, for purposes of this sec-
16 tion, are considered at high-risk for HBV or HCV.
17 The Secretary shall include the following among
18 those considered at high-risk:

19 “(A) For HBV, individuals born in coun-
20 tries in which 2 percent or more of the popu-
21 lation has HBV or who are a part of a high-
22 risk category as identified by the Centers for
23 Disease Control and Prevention and the United
24 States Preventive Services Task Force.

1 “(B) For HCV, individuals born between
2 1945 and 1965 or who are a part of a high-risk
3 category as identified by the Centers for Dis-
4 ease Control and Prevention and the United
5 States Preventive Services Task Force.

6 “(C) Those who have been exposed to the
7 blood of infected individuals or of high-risk in-
8 dividuals or who are family members of such in-
9 dividuals.

10 “(2) PRIORITY IN PROGRAMS.—In providing for
11 programs under this section, the Secretary shall give
12 priority—

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

16 “(B) to education, and referrals for coun-
17 seling and medical care and treatment, for indi-
18 viduals diagnosed under subparagraph (A) in
19 order to—

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

23 “(ii) determine the appropriateness
24 for treatment to reduce the risk of progres-
25 sion to cirrhosis and liver cancer;

1 “(iii) receive ongoing medical manage-
 2 ment, including regular monitoring of liver
 3 function and screenings for liver cancer;

4 “(iv) receive, as appropriate, drug, al-
 5 cohol abuse, and mental health treatment;

6 “(v) in the case of women of child-
 7 bearing age, receive education on how to
 8 prevent HBV perinatal infection, and to al-
 9 leviate fears associated with pregnancy or
 10 raising a family; and

11 “(vi) receive such other services as the
 12 Secretary determines to be appropriate.

13 “(3) CULTURAL CONTEXT.—In providing for
 14 services pursuant to paragraph (2) for individuals
 15 who are diagnosed under subparagraph (A) of such
 16 paragraph, the Secretary shall seek to ensure that
 17 the services are provided in a culturally and linguis-
 18 tically appropriate manner.

19 “(d) ACTION PLAN IMPLEMENTATION.—

20 “(1) BENCHMARKS.—The Secretary shall de-
 21 velop benchmarks for evaluating the effectiveness of
 22 the programs and activities conducted under the ‘Ac-
 23 tion Plan for the Prevention, Care, & Treatment of
 24 Viral Hepatitis’ of the Department of Health and

1 Human Services and make determinations as to
2 whether such benchmarks have been achieved.

3 “(2) ANNUAL REPORTING.—

4 “(A) IN GENERAL.—The Secretary shall
5 report annually to the Congress on the bench-
6 marks developed under paragraph (1), including
7 the amount of funding used by each agency of
8 the Department of Health and Human Services
9 to achieve each benchmark.

10 “(B) CONTENTS.—Each report under sub-
11 paragraph (A) shall include reporting on—

12 “(i) the number of people tested for
13 hepatitis B and hepatitis C;

14 “(ii) the number of individuals who
15 test positive for hepatitis B and C;

16 “(iii) the number of individuals who
17 are tested and then made aware of their
18 health status;

19 “(iv) the number of individuals re-
20 ferred to care or treatment followup;

21 “(v) improvements in surveillance ac-
22 tivities;

23 “(vi) provider and community edu-
24 cation activities;

1 “(vii) the reduction in the number of
2 infants born with hepatitis B;

3 “(viii) estimates on the reduction, as
4 a result of prevention measures, in the
5 number of new hepatitis B and hepatitis C
6 infections; and

7 “(ix) estimates on the reduction in
8 liver cancer resulting from hepatitis B or
9 hepatitis C infection.

10 “(e) PUBLIC-PRIVATE PARTNERSHIPS.—

11 “(1) IN GENERAL.—In carrying out this sec-
12 tion, and not later than 60 days after the date of
13 the enactment of the Viral Hepatitis Testing Act of
14 2015, the Secretary shall, in consultation with the
15 Assistant Secretary for Health, the Director of the
16 Centers for Disease Control and Prevention, the
17 Health Resources and Services Administration, the
18 Substance Abuse and Mental Health Services Ad-
19 ministration, the Office of Minority Health, the In-
20 dian Health Service, other relevant agencies, and
21 nongovernment stakeholder entities, establish and
22 support public-private partnerships that facilitate
23 the surveillance, education, screening, testing, and
24 linkage to care programs authorized by this section.

1 “(2) DUTIES.—Public-private partnerships es-
2 tablished or supported under paragraph (1) shall—

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

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

12 “(C) allow for investments in such pro-
13 grams of financial or in-kind resources by each
14 of the partners involved in the partnership;

15 “(D) include corporate and industry enti-
16 ties, academic institutions, public and nonprofit
17 organizations, community and faith-based orga-
18 nizations, foundations, and other governmental
19 and nongovernmental organizations; and

20 “(E) advance the core goals of each of the
21 partners of the partnership as determined by
22 the Secretary in development of the partner-
23 ship.

24 “(3) ANNUAL REPORTS.—The Secretary shall
25 provide to the Congress an annual report on the

1 public-private partnerships established under this
 2 subsection. Each such report shall include—

3 “(A) the number of public-private partner-
 4 ships established;

5 “(B) specific and quantifiable information
 6 on the surveillance, education, screening, test-
 7 ing, and linkage to care activities conducted as
 8 well as the outcomes achieved through each of
 9 the public-private partnerships;

10 “(C) the amount of Federal funding or re-
 11 sources dedicated to the public-private partner-
 12 ships;

13 “(D) the amount of non-Federal funding
 14 or resources leveraged through the public-pri-
 15 vate partnerships; and

16 “(E) a plan for the following year that out-
 17 lines future activities.

18 “(4) LIMITATION.—No more than 25 percent of
 19 the funds made available to carry out this section
 20 may be used for public-private partnerships estab-
 21 lished or supported under this subsection.

22 “(5) LINKAGE TO CARE.—For purposes of this
 23 section, the term ‘linkage to care’ means, with re-
 24 spect to an individual with a diagnosis of HBV or
 25 HCV, the referral of such individual to clinical care

1 for a thorough evaluation of their clinical status to
 2 determine the need for treatment, vaccination for
 3 HBV, or other therapy.

4 “(f) AGENCY FOR HEALTHCARE RESEARCH AND
 5 QUALITY HBV AND HCV GUIDELINES.—Due to the rap-
 6 idly evolving standard of care associated with diagnosing
 7 and treating viral hepatitis infection, the Director of the
 8 Agency for Healthcare Research and Quality shall convene
 9 the United States Preventive Services Task Force under
 10 section 915(a) to review its recommendation for screening
 11 for HBV and HCV infection every 3 years.

12 “(g) FUNDING.—

13 “(1) IN GENERAL.—In addition to any amounts
 14 otherwise authorized by this Act, there are author-
 15 ized to be appropriated to carry out this section—

16 “(A) \$25,000,000 for fiscal year 2016;

17 “(B) \$35,000,000 for fiscal year 2017; and

18 “(C) \$20,000,000 for fiscal year 2018.

19 “(2) GRANTS.—Of the amounts appropriated
 20 pursuant to paragraph (1) for a fiscal year, the Sec-
 21 retary shall reserve not less than 80 percent for
 22 making grants under subsection (a).

23 “(3) SOURCE OF FUNDS.—The funds made
 24 available to carry out this section shall be derived
 25 exclusively from the funds appropriated or otherwise

1 made available for planning and evaluation under
2 this Act.”.

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

10 **SEC. 4. HEPATITIS B AND HEPATITIS C SCREENING AND**
11 **EVALUATION OF NEEDED CARE FOR VET-**
12 **ERANS.**

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

16 **“§ 1720H. Hepatitis B and Hepatitis C screening and**
17 **evaluation of needed care for veterans**

18 “(a) IN GENERAL.—(1) The Secretary shall establish
19 and carry out a plan to provide veterans described in para-
20 graph (2) with—

21 “(A) a risk assessment for the hepatitis B and
22 hepatitis C virus; and

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

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

4 “(ii) information with respect to the needs
5 determined under clause (i).

6 “(2) Veterans described in this paragraph are vet-
7 erans who—

8 “(A) are enrolled in the health care system es-
9 tablished under section 1705(a) of this title;

10 “(B) were born between 1945 and 1965; and

11 “(C) are considered a high-risk group for hepa-
12 titis B or hepatitis C infection.

13 “(b) COMPLIANCE.—(1) The Secretary shall use the
14 plan established under subsection (a)(1) as a key measure
15 in determining performance under the VA Handbook Per-
16 formance Management System, or the successor to such
17 handbook, to ensure the compliance of such plan.

18 “(2) If the Secretary determines that a medical facil-
19 ity of the Department complies with the plan established
20 under subsection (a)(1) at a rate less than 100 percent,
21 the Secretary shall treat the director of such medical facil-
22 ity as ‘less than fully successful’ with respect to the per-
23 formance appraisal that is used for the basis for deter-
24 mining performance awards under the handbook described
25 in paragraph (1).

1 “(c) ANNUAL REPORT.—The Secretary shall submit
2 annually to Congress a report on the compliance of each
3 medical facility of the Department with the plan estab-
4 lished under subsection (a)(1).”.

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

“1720H. Hepatitis B and Hepatitis C screening and evaluation of needed care
for veterans.”.

