

113TH CONGRESS
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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

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 2013”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

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

8 (2) In the United States, chronic HBV and
9 HCV are among the most common causes of liver
10 cancer, one of the most lethal and fastest growing
11 cancers in the United States. Chronic HBV and
12 HCV are among the most common causes of chronic
13 liver disease, liver cirrhosis, and the most common
14 indication for liver transplantation. More than
15 15,000 deaths per year in the United States can be
16 attributed to chronic HBV and HCV. Chronic HCV
17 is also a leading cause of death in Americans living
18 with HIV/AIDS. Many of those living with HIV/
19 AIDS are coinfected with chronic HBV, HCV, or
20 both.

21 (3) According to the Centers for Disease Con-
22 trol and Prevention (referred to in this section as
23 the “CDC”), approximately 2 percent of the popu-
24 lation of the United States is living with chronic
25 HBV, HCV, or both. The CDC has recognized HCV

1 as the Nation's most common chronic bloodborne
2 virus infection.

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

10 (5) The CDC conservatively estimates that in
11 2011 approximately 16,600 Americans were newly
12 infected with HCV and more than 18,800 Americans
13 were newly infected with HBV. These estimates
14 could be much higher due to many reasons, includ-
15 ing lack of screening education and awareness, and
16 perceived marginalization of the populations at risk.

17 (6) In 2012 CDC released new guidelines rec-
18 commending every person born from 1945 through
19 1965 receive a one-time HCV test. Among the esti-
20 mated 102 million (1.6 million chronically HCV-in-
21 fected) eligible for screening, birth-cohort screening
22 leads to 74,000 fewer cases of decompensated cir-
23 rhosis, 46,000 fewer cases of hepatocellular car-
24 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 Task Force (USPSTF) issued a Grade B rating for
5 screening for hepatitis C virus (HCV) infection in
6 persons at high risk for infection and adults born
7 between 1945 and 1965. In 2009, the USPSTF
8 issued a Grade A for screening pregnant women for
9 the hepatitis B virus (HBV) during their first pre-
10 natal visit.

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

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

1 to prevent the spread of their infection and can un-
2 knowingly exacerbate their own disease progression.

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

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

22 (12) Advancements have led to the development
23 of improved diagnostic tests for viral hepatitis.
24 These tests, including rapid, point of care testing
25 and others in development, can facilitate testing, no-

1 tification of results and post-test counseling, and re-
2 ferral to care at the time of the testing visit. In par-
3 ticular, these tests are also advantageous because
4 they can be used simultaneously with HIV rapid
5 testing for persons at risk for both HCV and HIV
6 infections.

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

14 (14) Treatment for chronic HCV can eradicate
15 the disease in approximately 75 percent of those cur-
16 rently treated. The treatment of chronic HBV can
17 effectively suppress viral replication in the over-
18 whelming majority (over 80 percent) of those treat-
19 ed, thereby reducing the risk of transmission and
20 progression to liver scarring or liver cancer, even
21 though a complete cure is much less common than
22 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 the

1 Silent Epidemic of Viral Hepatitis: Action Plan for
2 the Prevention, Care & Treatment of Viral Hepa-
3 titis. The Institute of Medicine of the National
4 Academies produced a 2010 report on the Federal
5 response to HBV and HCV titled: Hepatitis and
6 Liver Cancer: A National Strategy for Prevention
7 and Control of Hepatitis B and C. The recommenda-
8 tions and guidelines provide a framework for HBV
9 and HCV prevention, education, control, research,
10 and medical management programs.

11 (16) The annual health care costs attributable
12 to viral hepatitis in the United States are signifi-
13 cant. For HBV, it is estimated to be approximately
14 \$2,500,000,000 (\$2,000 per infected person). In
15 2000, the lifetime cost of HBV—before the avail-
16 ability of most current therapies—was approximately
17 \$80,000 per chronically infected person, totaling
18 more than \$100,000,000,000. For HCV, medical
19 costs for patients are expected to increase from
20 \$30,000,000,000 in 2009 to over \$85,000,000,000
21 in 2024. Avoiding these costs by screening and diag-
22 nosing individuals earlier—and connecting them to
23 appropriate treatment and care will save lives and
24 critical health care dollars. Currently, without a
25 comprehensive screening, testing and diagnosis pro-

1 gram, most patients are diagnosed too late when
2 they need a liver transplant costing at least
3 \$314,000 for uncomplicated cases or when they have
4 liver cancer or end stage liver disease which costs
5 between \$30,980 to \$110,576 per hospital admis-
6 sion. As health care costs continue to grow, it is crit-
7 ical that the Federal Government invests in effective
8 mechanisms to avoid documented cost drivers.

9 (17) According to the Institute of Medicine re-
10 port in 2010 (described in paragraph (13)), chronic
11 HBV and HCV infections cause substantial mor-
12 bidity and mortality despite being preventable and
13 treatable. Deficiencies in the implementation of es-
14 tablished guidelines for the prevention, diagnosis,
15 and medical management of chronic HBV and HCV
16 infections perpetuate personal and economic bur-
17 dens. Existing grants are not sufficient to address
18 the scale of the health burden presented by HBV
19 and HCV.

20 (18) The Secretary of Health and Human Serv-
21 ices has the discretion to carry out this Act directly
22 and through whichever of the agencies of the Public
23 Health Service the Secretary determines to be ap-
24 propriate, which may (in the Secretary's discretion)
25 include the Centers for Disease Control and Preven-

1 tion, the Health Resources and Services Administra-
2 tion, the Substance Abuse and Mental Health Serv-
3 ices Administration, the National Institutes of
4 Health (including the National Institute on Minority
5 Health and Health Disparities), and other agencies
6 of such Service.

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

1 **SEC. 3. REVISION AND EXTENSION OF HEPATITIS SURVEIL-**2 **LANCE, EDUCATION, AND TESTING PROGRAM.**

3 (a) IN GENERAL.—Section 317N of the Public

4 Health Service Act (42 U.S.C. 247b–15) is amended—

5 (1) by amending the section heading to read as

6 follows: “**SURVEILLANCE, EDUCATION, TESTING,**7 **AND LINKAGE TO CARE REGARDING HEPATITIS**8 **VIRUS”;**

9 (2) by redesignating subsections (b) and (c) as

10 subsections (d) and (e), respectively; and

11 (3) by striking subsection (a) and inserting the
12 following:13 “(a) IN GENERAL.—The Secretary shall, in accord-
14 ance with this section, carry out surveillance, education,
15 and testing programs with respect to hepatitis B and hep-
16 atitis C virus infections (referred to in this section as
17 ‘HBV’ and ‘HCV’, respectively). The Secretary may carry
18 out such programs directly and through grants to public
19 and nonprofit private entities, including States, political
20 subdivisions of States, territories, Indian tribes, and pub-
21 lic-private partnerships.22 “(b) NATIONAL SYSTEM.—In carrying out subsection
23 (a), the Secretary shall, in consultation with States and
24 other public or nonprofit private entities and public-pri-
25 vate partnerships described in subsection (d), establish a

1 national system with respect to HBV and HCV with the
2 following goals:

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

6 “(2) With respect to the population of individ-
7 uals who have such an infection, to carry out testing
8 programs to increase the number of individuals who
9 are aware of their infection to 50 percent by Decem-
10 ber 31, 2014, and to 75 percent by December 31,
11 2016.

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

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

18 “(5) To provide appropriate referrals for coun-
19 seling and medical care and treatment of infected in-
20 dividuals and to ensure, to the extent practicable,
21 the provision of appropriate follow-up services.

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

23 “(1) IN GENERAL.—The Secretary shall deter-
24 mine the populations that, for purposes of this sec-
25 tion, are considered at high-risk for HBV or HCV.

1 The Secretary shall include the following among
2 those considered at high-risk:

3 “(A) For HBV, individuals born in coun-
4 tries in which 2 percent or more of the popu-
5 lation has HBV or who are a part of a high-
6 risk category as identified by the Centers for
7 Disease Control and Prevention.

8 “(B) For HCV, individuals born between
9 1945 and 1965 or who are a part of a high-risk
10 category as identified by the Centers for Dis-
11 ease Control and Prevention.

12 “(C) Those who have been exposed to the
13 blood of infected individuals or of high-risk in-
14 dividuals or who are family members of such in-
15 dividuals.

16 “(2) PRIORITY IN PROGRAMS.—In providing for
17 programs under this section, the Secretary shall give
18 priority—

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

22 “(B) to education, and referrals for coun-
23 seling and medical care and treatment, for indi-
24 viduals diagnosed under subparagraph (A) in
25 order to—

- 1 “(i) reduce their risk of dying from
2 end-stage liver disease and liver cancer,
3 and of transmitting the infection to others;
- 4 “(ii) determine the appropriateness
5 for treatment to reduce the risk of progres-
6 sion to cirrhosis and liver cancer;
- 7 “(iii) receive ongoing medical manage-
8 ment, including regular monitoring of liver
9 function and screenings for liver cancer;
- 10 “(iv) receive, as appropriate, drug, al-
11 cohol abuse, and mental health treatment;
- 12 “(v) in the case of women of child-
13 bearing age, receive education on how to
14 prevent HBV perinatal infection, and to al-
15 leviate fears associated with pregnancy or
16 raising a family; and
- 17 “(vi) receive such other services as the
18 Secretary determines to be appropriate.

19 “(3) CULTURAL CONTEXT.—In providing for
20 services pursuant to paragraph (2) for individuals
21 who are diagnosed under subparagraph (A) of such
22 paragraph, the Secretary shall seek to ensure that
23 the services are provided in a culturally and linguis-
24 tically appropriate manner.

25 “(d) PUBLIC-PRIVATE PARTNERSHIPS.—

1 “(1) IN GENERAL.—In carrying out this sec-
2 tion, and not later than 60 days after the date of
3 the enactment of the Viral Hepatitis Testing Act of
4 2013, the Secretary shall, in consultation with the
5 Assistant Secretary for Health, the Director of the
6 Centers for Disease Control and Prevention, the
7 Health Resources and Services Administration, the
8 Substance Abuse and Mental Health Services Ad-
9 ministration, the Office of Minority Health, the In-
10 dian Health Service, other relevant agencies, and
11 non-government stakeholder entities, establish and
12 support public-private partnerships that facilitate
13 the surveillance, education, screening, testing, and
14 linkage to care programs authorized by this section.

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

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

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

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

4 “(D) include corporate and industry enti-
5 ties, academic institutions, public and non-prof-
6 it organizations, community and faith-based or-
7 ganizations, foundations, and other govern-
8 mental and non-governmental organizations;
9 and

10 “(E) advance the core goals of each of the
11 partners of the partnership as determined by
12 the Secretary in development of the partner-
13 ship.

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

18 “(A) the number of public-private partner-
19 ships established;

20 “(B) specific and quantifiable information
21 on the surveillance, education, screening, test-
22 ing, and linkage to care activities conducted as
23 well as the outcomes achieved through each of
24 the public-private partnerships;

1 “(C) the amount of Federal funding or re-
2 sources dedicated to the public-private partner-
3 ships;

4 “(D) the amount of non-Federal funding
5 or resources leveraged through the public-pri-
6 vate partnerships; and

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

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

13 “(5) LINKAGE TO CARE.—For purposes of this
14 section, the term ‘linkage to care’ means, with re-
15 spect to an individual with a diagnosis of HBV or
16 HCV, the referral of such individual to clinical care
17 for a thorough evaluation of their clinical status to
18 determine the need for treatment, vaccination for
19 HBV, or other therapy.

20 “(e) AGENCY FOR HEALTHCARE RESEARCH AND
21 QUALITY HBV AND HCV GUIDELINES.—Due to the rap-
22 idly evolving standard of care associated with diagnosing
23 and treating viral hepatitis infection, the Director of the
24 Agency for Healthcare Research and Quality shall convene
25 the Preventive Services Task Force under section 915(a)

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

3 “(f) FUNDING.—

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

7 “(A) \$25,000,000 for fiscal year 2014;

8 “(B) \$35,000,000 for fiscal year 2015; and

9 “(C) \$20,000,000 for fiscal year 2016.

10 “(2) GRANTS.—Of the amounts appropriated
11 pursuant to paragraph (1) for a fiscal year, the Sec-
12 etary shall reserve not less than 80 percent for
13 making grants under subsection (a).

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

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

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

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

6 **“§ 1720H. Hepatitis C screening and evaluation of**
7 **needed care for veterans**

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

11 “(A) a risk assessment for the hepatitis C
12 virus; and

13 “(B) if a veteran is diagnosed with such virus—
14 “(i) a thorough evaluation of the clinical
15 status of the veteran to determine the need for
16 treatment, vaccination, or other therapy; and

17 “(ii) information with respect to the needs
18 determined under clause (i).

19 “(2) Veterans described in this paragraph are vet-
20 erans who—

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

23 “(B) were born between 1945 and 1965.

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

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

3 “(2) If the Secretary determines that a medical facil-
4 ity of the Department complies with the plan established
5 under subsection (a)(1) at a rate less than 100 percent,
6 the Secretary shall treat the director of such medical facil-
7 ity as ‘less than fully successful’with respect to the per-
8 formance appraisal that is used for the basis for deter-
9 mining performance awards under the handbook described
10 in paragraph (1).

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

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

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

