

112TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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.

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IN THE SENATE OF THE UNITED STATES

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Mr. KERRY introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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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 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 2011”.

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 the most common cause of liver cancer,  
8 one of the most lethal and fastest growing cancers  
9 in the United States. Chronic HBV and HCV are  
10 the most common cause of chronic liver disease, liver  
11 cirrhosis, and the most common indication for liver  
12 transplantation. Chronic HCV is also a leading  
13 cause of death in Americans living with HIV/AIDS,  
14 many of whom are coinfecting with chronic HBV,  
15 HCV, or both. At least 15,000 deaths per year in  
16 the United States can be attributed to chronic HBV  
17 and HCV.

18           (3) According to the Centers for Disease Con-  
19 trol and Prevention (referred to in this section as  
20 the “CDC”), approximately 2 percent of the popu-  
21 lation of the United States is living with chronic  
22 HBV, HCV, or both. The CDC has recognized HCV  
23 as the Nation’s most common chronic bloodborne  
24 virus infection and HBV as the deadliest vaccine-  
25 preventable disease.

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

7           (5) The CDC conservatively estimates that in  
8 2008 approximately 18,000 Americans were newly  
9 infected with HCV and more than 38,000 Americans  
10 were newly infected with HBV.

11           (6) There were 15 outbreaks reported to CDC  
12 for investigation during 2009 and 2010 related to  
13 healthcare acquired infection of HBV and HCV, po-  
14 tentially exposing 30,000 people to the viruses.

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

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

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

20           (10) Advancements have led to the development  
21 of improved diagnostic tests for viral hepatitis.  
22 These tests, including rapid, point of care testing  
23 and others in development can facilitate testing, no-  
24 tification of results and post-test counseling, and re-  
25 ferral to care at the time of the testing visit. In par-

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

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

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

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

1 Academies produced a 2010 report on the Federal  
2 response to HBV and HCV titled: Hepatitis and  
3 Liver Cancer: A National Strategy for Prevention  
4 and Control of Hepatitis B and C. The recommenda-  
5 tions and guidelines provide a framework for HBV  
6 and HCV prevention, education, control, research,  
7 and medical management programs.

8 (14) The annual health care costs attributable  
9 to viral hepatitis in the United States are signifi-  
10 cant. For HBV, it is estimated to be approximately  
11 \$2,500,000,000 (\$2,000 per infected person). In  
12 2000, the lifetime cost of HBV—before the avail-  
13 ability of most of the current therapies—was ap-  
14 proximately \$80,000 per chronically infected person,  
15 or more than \$100,000,000,000. For HCV, medical  
16 costs for patients are expected to increase from  
17 \$30,000,000,000 in 2009 to over \$85,000,000,000  
18 in 2024. Avoiding these costs by screening and diag-  
19 nosing individuals earlier—and connecting them to  
20 appropriate treatment and care will save lives and  
21 critical health care dollars. Currently, without a  
22 comprehensive screening, testing and diagnosis pro-  
23 gram, most patients are diagnosed too late when  
24 they need a liver transplant costing at least  
25 \$314,000 for uncomplicated cases or when they have

1 liver cancer or end stage liver disease which costs  
2 between \$30,980 to \$110,576 per hospital admis-  
3 sion. As health care costs continue to grow, it is crit-  
4 ical that the Federal Government invests in effective  
5 mechanisms to avoid documented cost drivers.

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

16 (16) Screening and testing for chronic HBV  
17 and HCV are aligned with the Healthy People 2020  
18 goal to increase immunization rates and reduce pre-  
19 ventable infectious diseases. Awareness of disease  
20 and access to prevention and treatment remain es-  
21 sential components for reducing infectious disease  
22 transmission.

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

1 in reducing the morbidity and mortality of these  
2 epidemics.

3 (18) The Secretary of Health and Human Serv-  
4 ices has the discretion to carry out this Act directly  
5 and through whichever of the agencies of the Public  
6 Health Service the Secretary determines to be ap-  
7 propriate, which may (in the Secretary’s discretion)  
8 include the Centers for Disease Control and Preven-  
9 tion, the Health Resources and Services Administra-  
10 tion, the Substance Abuse and Mental Health Serv-  
11 ices Administration, the National Institutes of  
12 Health (including the National Institute on Minority  
13 Health and Health Disparities), and other agencies  
14 of such Service.

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

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

19 (1) by amending the heading to read as follows:  
20 **“SURVEILLANCE, EDUCATION, AND TESTING**  
21 **REGARDING HEPATITIS VIRUS”**;

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

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

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

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

15           “(1) To determine the incidence and prevalence  
16       of such infections, including providing for the report-  
17       ing of chronic cases.

18           “(2) With respect to the population of individ-  
19       uals who have such an infection, to carry out testing  
20       programs to increase the number of individuals who  
21       are aware of their infection to 50 percent by 2014  
22       and to 75 percent by 2016.

23           “(3) To develop and disseminate public infor-  
24       mation and education programs for the detection  
25       and control of such infections, with priority given to

1 changing behaviors that place individuals at risk of  
2 infection.

3 “(4) To provide appropriate referrals for coun-  
4 seling and medical treatment of infected individuals  
5 and to ensure, to the extent practicable, the provi-  
6 sion of appropriate follow-up services.

7 “(5) To improve the education, training, and  
8 skills of health professionals in the detection, con-  
9 trol, and treatment of such infections, with priority  
10 given to pediatricians and other primary care physi-  
11 cians, and obstetricians and gynecologists.

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

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

18 “(A) For HBV, individuals born in coun-  
19 tries in which 2 percent or more of the popu-  
20 lation has HBV.

21 “(B) For HCV, individuals born between  
22 1945 and 1965.

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

1 individuals, are family members of such individ-  
2 uals, or are sexual partners of such individuals.

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

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

9 “(B) to education, and referrals for coun-  
10 seling and medical treatment, for individuals di-  
11 agnosed under subparagraph (A) in order to—

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

15 “(ii) determine the appropriateness  
16 for treatment to reduce the risk of progres-  
17 sion to cirrhosis and liver cancer;

18 “(iii) receive ongoing medical manage-  
19 ment, including regular monitoring of liver  
20 function and screenings for liver cancer;

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

23 “(v) in the case of women of child-  
24 bearing age, receive education on how to  
25 prevent HBV perinatal infection, and to al-

1           leviate fears associated with pregnancy or  
2           raising a family; and

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

5           “(3) CULTURAL CONTEXT.—In providing for  
6           services pursuant to paragraph (2) for individuals  
7           who are diagnosed under subparagraph (A) of such  
8           paragraph, the Secretary shall seek to ensure that  
9           the services are provided in a culturally and linguis-  
10          tically appropriate manner.”.

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

13               (1) REFERENCES.—For purposes of this sub-  
14               section, the term “CDC Director” means the Direc-  
15               tor of the Centers for Disease Control and Preven-  
16               tion, and the term “AHRQ Director” means the Di-  
17               rector of the Agency for Healthcare Research and  
18               Quality.

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

21                   (A) IN GENERAL.—Not later than March  
22               1, 2012, the CDC Director shall complete the  
23               revision of the guidelines of the Centers for Dis-  
24               ease Control and Prevention for screening indi-  
25               viduals for the hepatitis C virus infection (in

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

8 (B) CERTAIN FACTORS.—In revising guide-  
9 lines pursuant to subparagraph (A), the CDC  
10 Director shall take into account—

11 (i) the effectiveness issues that have  
12 been raised with respect to the current  
13 guidelines of the Centers for Disease Con-  
14 trol and Prevention for screenings for  
15 HCV;

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

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

23 (3) AGENCY FOR HEALTHCARE RESEARCH AND  
24 QUALITY.—

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

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

11 (ii) new and improved treatments for  
12 HCV.

13 (B) HBV GUIDELINES.—The AHRQ Direc-  
14 tor shall, in developing the recommendations for  
15 screenings for the hepatitis B virus infection (in  
16 this section referred to as “HBV”) that the  
17 AHRQ Director will provide to the Preventive  
18 Services Task Force referred to in subpara-  
19 graph (A), take into account the guidelines for  
20 screenings for HBV that the CDC Director rec-  
21 ommended in 2008.

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

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—

2 “(1) IN GENERAL.—For the purpose of testing,  
3 education, and referrals under this section, there are  
4 authorized to be appropriated \$25,000,000 for fiscal  
5 year 2012, \$35,000,000 for fiscal year 2013,  
6 \$20,000,000 for fiscal year 2014, and \$15,000,000  
7 for each of the fiscal years 2015 and 2016.

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

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