

111TH CONGRESS
2D SESSION

S. 3711

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish, promote, and support a comprehensive prevention, education, research, and medical management referral program for viral hepatitis infection that will lead to a marked reduction in the disease burden associated with chronic viral hepatitis and liver cancer.

IN THE SENATE OF THE UNITED STATES

AUGUST 5, 2010

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 direct the Secretary of Health and Human Services to establish, promote, and support a comprehensive prevention, education, research, and medical management referral program for viral hepatitis infection that will lead to a marked reduction in the disease burden associated with chronic viral hepatitis and liver cancer.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Viral Hepatitis and
3 Liver Cancer Control and Prevention Act of 2010”.

4 **SEC. 2. FINDINGS.**

5 Congress finds the following:

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

11 (2) In the United States, chronic viral hepatitis
12 is the most common cause of liver cancer, one of the
13 most lethal and fastest growing cancers in this coun-
14 try. It is the most common cause of chronic liver
15 disease, liver cirrhosis, and the most common indica-
16 tion for liver transplantation. It is also a leading
17 cause of death in Americans living with HIV/AIDS,
18 many of whom are coinfectd with chronic hepatitis
19 B, hepatitis C, or both. At least 15,000 deaths per
20 year in the United States can be attributed to chron-
21 ic viral hepatitis.

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

1 ognized HCV as the Nation’s most common chronic
2 bloodborne virus infection.

3 (4) Hepatitis B is easily transmitted and is 100
4 times more infectious than HIV. According to the
5 CDC, HBV is transmitted through percutaneous
6 (i.e., puncture through the skin) or mucosal contact
7 with infectious blood or body fluids. Hepatitis C is
8 transmitted by percutaneous (i.e., passage through
9 the skin) exposures to infectious blood.

10 (5) The CDC conservatively estimates that in
11 2007 approximately 17,000 Americans were newly
12 infected with HCV and more than 40,000 Americans
13 were newly infected with HBV. The number of peo-
14 ple in the United States with chronic hepatitis B
15 and chronic hepatitis C is believed to be increasing
16 each year.

17 (6) Chronic hepatitis B and chronic hepatitis C
18 usually do not cause symptoms early in the course
19 of the disease, but after many years of a clinically
20 “silent” phase, as many as 25 percent of infected in-
21 dividuals may develop cirrhosis, end-stage liver dis-
22 ease, or liver cancer. Since most of those with chron-
23 ic viral hepatitis are unaware of their infection, they
24 do not know to take precautions to prevent the

1 spread of their infection and can unknowingly exac-
2 erbate their own disease progression.

3 (7) Hepatitis B and hepatitis C disproportion-
4 ately affect certain populations in the United States.
5 Although representing only 4 percent of the popu-
6 lation, Asian and Pacific Islanders account for over
7 half of the 1,400,000 domestic chronic hepatitis B
8 cases. Baby boomers (those born between 1946 and
9 1964) account for more than half of domestic chron-
10 ic hepatitis C cases. In addition, African-Americans,
11 Latinos, and American Indian/Native Alaskans are
12 among the groups which have disproportionately
13 high rates of HBV and HCV infections in the
14 United States.

15 (8) Hepatitis A (referred to in this section as
16 “HAV”) and HBV infection are preventable through
17 currently available vaccinations. The hepatitis B vac-
18 cine is safe and effective and has the designation of
19 being the “first anti-cancer vaccine” since preven-
20 tion of HBV infection also prevents HBV-related
21 liver cancer. There is currently no vaccine available
22 to prevent HCV infection.

23 (9) For both chronic hepatitis B and chronic
24 hepatitis C, behavioral changes can slow disease pro-
25 gression if diagnosis is made early. Early diagnosis,

1 which is available through simple tests, can reduce
2 the risk of transmission and disease progression
3 through education and vaccination of household
4 members and other susceptible persons at risk.

5 (10) 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 cure is still
8 possible. Liver cancer is one of the deadliest types
9 of cancer and one that has received little funding for
10 research, prevention, and treatment.

11 (11) Treatment for chronic hepatitis C is cura-
12 tive and can eradicate the disease in approximately
13 50 percent of those who are treated. Treatment for
14 chronic hepatitis B is not curative, but can reduce
15 the level of virus in about 50 percent of those treat-
16 ed. Treatment for both chronic hepatitis B and
17 chronic hepatitis C can reduce the risk of progres-
18 sion to cirrhosis and liver cancer.

19 (12) To combat the HCV epidemic in the
20 United States, the CDC developed Recommendations
21 for Prevention and Control of Hepatitis C Virus
22 (HCV) Infection and HCV-Related Chronic Disease
23 in 1998 and the National Hepatitis C Prevention
24 Strategy in 2001. To combat the HBV epidemic, the
25 CDC developed Recommendations for Identification

1 and Public Health Management of Persons with
2 Chronic Hepatitis B Virus Infection in 2008. The
3 National Institutes of Health convened Consensus
4 Development Conferences on the Management of
5 Hepatitis C in 1997 and 2002 and the Management
6 of Hepatitis B in 2008. These recommendations and
7 guidelines provide a framework for HBV and HCV
8 prevention, education, control, research, and medical
9 management referral programs.

10 (13) Although the costs of education, research,
11 and treatment are not trivial, they are substantially
12 less than the annual health care cost attributable to
13 viral hepatitis in the United States. For HBV, it is
14 estimated to be approximately \$2,500,000,000
15 (\$2,000 per infected person). The lifetime cost of
16 HBV in 2000—before the availability of most of the
17 current therapies—was approximately \$80,000 per
18 person chronically infected, or more than
19 \$100,000,000,000. For HCV, medical costs alone
20 for patients are expected to increase from
21 \$30,000,000,000 in 2009 to over \$85,000,000,000
22 in 2024. Such costs will undoubtedly increase in the
23 absence of expanded prevention and treatment ef-
24 forts.

1 (14) Federal support is necessary to increase
 2 knowledge and awareness of HBV and HCV and to
 3 assist State and local prevention and control efforts
 4 in reducing the morbidity and mortality of these
 5 epidemics.

6 **SEC. 3. COMPREHENSIVE HEPATITIS B AND HEPATITIS C**
 7 **PREVENTION, EDUCATION, RESEARCH, AND**
 8 **MEDICAL MANAGEMENT REFERRAL PRO-**
 9 **GRAM.**

10 Title III of the Public Health Service Act (42 U.S.C.
 11 241 et seq.) is amended—

12 (1) by striking section 317N (42 U.S.C. 247b–
 13 15); and

14 (2) by adding at the end the following:

15 **“PART S—COMPREHENSIVE HEPATITIS B AND**
 16 **HEPATITIS C PREVENTION, EDUCATION, RE-**
 17 **SEARCH, AND MEDICAL MANAGEMENT RE-**
 18 **FERRAL PROGRAM**

19 **“SEC. 399FF. PROGRAM DEVELOPMENT.**

20 “(a) IN GENERAL.—The Secretary shall develop and
 21 implement a plan for the prevention, control, and medical
 22 management of hepatitis B and hepatitis C, which in-
 23 cludes strategies for expanded vaccination programs for
 24 hepatitis B in adults, primary and secondary preventive

1 education and training, surveillance, screening, early de-
 2 tection, and research.

3 “(b) INPUT IN DEVELOPMENT OF PLAN.—In devel-
 4 oping the plan under subsection (a), the Secretary shall—

5 “(1) be guided by existing recommendations of
 6 the Department of Health and Human Services, the
 7 Centers for Disease Control and Prevention, and the
 8 National Institutes of Health; and

9 “(2) consult with—

10 “(A) the Director of the Centers for Dis-
 11 ease Control and Prevention;

12 “(B) the Director of the National Insti-
 13 tutes of Health;

14 “(C) the Director of the National Cancer
 15 Institute;

16 “(D) the Administrator of the Health Re-
 17 sources and Services Administration;

18 “(E) the Administrator of the Substance
 19 Abuse and Mental Health Services Administra-
 20 tion;

21 “(F) the Director of the Agency for
 22 Healthcare Research and Quality;

23 “(G) the heads of other Federal agencies
 24 or offices providing education services to indi-
 25 viduals with viral hepatitis;

1 “(H) the director of the Department of
2 Veterans Affairs;

3 “(I) medical advisory bodies that address
4 issues related to viral hepatitis; and

5 “(J) the public, including—

6 “(i) individuals infected with hepatitis
7 B, hepatitis C, or both; and

8 “(ii) advocates concerned with issues
9 related to chronic hepatitis B and chronic
10 hepatitis C.

11 “(c) BIENNIAL UPDATE OF THE PLAN.—

12 “(1) IN GENERAL.—The Secretary shall con-
13 duct a biennial assessment of the plan developed
14 under subsection (a) for the purposes of—

15 “(A) incorporating into such plan new
16 knowledge or observations relating to hepatitis
17 B and hepatitis C (such as knowledge and ob-
18 servations that may be derived from clinical,
19 laboratory, and epidemiological research and
20 disease detection, prevention, and surveillance
21 outcomes);

22 “(B) addressing gaps in the coverage or ef-
23 fectiveness of the plan; and

24 “(C) evaluating and, if appropriate, updat-
25 ing recommendations, guidelines, or educational

1 materials of the Centers for Disease Control
2 and Prevention or the National Institutes of
3 Health for health care providers or the public
4 on viral hepatitis in order to be consistent with
5 the plan.

6 “(2) PUBLICATION OF NOTICE OF ASSESS-
7 MENTS.—Not later than October 1 of the first even
8 numbered year beginning after the date of the enact-
9 ment of this part, and October 1 of each even num-
10 bered year thereafter, the Secretary shall publish in
11 the Federal Register a notice of the results of the
12 assessments conducted under paragraph (1). Such
13 notice shall include—

14 “(A) a description of any revisions to the
15 plan developed under subsection (a) as a result
16 of the assessment;

17 “(B) an explanation of the basis for any
18 such revisions, including the ways in which such
19 revisions can reasonably be expected to further
20 promote the original goals and objectives of the
21 plan; and

22 “(C) in the case of a determination by the
23 Secretary that the plan does not need revision,
24 an explanation of the basis for such determina-
25 tion.

1 **“SEC. 399GG. ELEMENTS OF PROGRAM.**

2 “(a) EDUCATION AND AWARENESS PROGRAMS.—The
3 Secretary, acting through the Director of the Centers for
4 Disease Control and Prevention, the Administrator of the
5 Health Resources and Services Administration, and the
6 Administrator of the Substance Abuse and Mental Health
7 Services Administration, and in accordance with the plan
8 developed under section 399FF, shall implement programs
9 to increase awareness and enhance knowledge and under-
10 standing of hepatitis B and hepatitis C. Such programs
11 shall include—

12 “(1) the conduct of culturally and language ap-
13 propriate health education in primary and secondary
14 schools, college campuses, public awareness cam-
15 paigns, and community outreach activities (especially
16 to the ethnic communities with high rates of chronic
17 hepatitis B and chronic hepatitis C and other high-
18 risk groups) to promote public awareness and knowl-
19 edge about the value of hepatitis A and hepatitis B
20 immunization, risk factors, the transmission and
21 prevention of hepatitis B and hepatitis C, the value
22 of screening for the early detection of hepatitis B
23 and hepatitis C, and options available for the treat-
24 ment of chronic hepatitis B and chronic hepatitis C;

25 “(2) the promotion of immunization programs
26 that increase awareness and access to hepatitis A

1 and hepatitis B vaccines for susceptible adults and
2 children;

3 “(3) the training of health care professionals
4 regarding the importance of vaccinating individuals
5 infected with hepatitis C and individuals who are at
6 risk for hepatitis C infection against hepatitis A and
7 hepatitis B;

8 “(4) the training of health care professionals
9 regarding the importance of vaccinating individuals
10 chronically infected with hepatitis B and individuals
11 who are at risk for chronic hepatitis B infection
12 against the hepatitis A virus;

13 “(5) the training of health care professionals
14 and health educators to make them aware of the
15 high rates of chronic hepatitis B and chronic hep-
16 atitis C in certain adult ethnic populations, and the
17 importance of prevention, detection, and medical
18 management of hepatitis B and hepatitis C and of
19 liver cancer screening;

20 “(6) the development and distribution of health
21 education curricula (including information relating
22 to the special needs of individuals infected with hep-
23 atitis B and hepatitis C, such as the importance of
24 prevention and early intervention, regular moni-
25 toring, the recognition of psychosocial needs, appro-

1 piate treatment, and liver cancer screening) for in-
 2 dividuals providing hepatitis B and hepatitis C coun-
 3 seling; and

4 “(7) support for the implementation curricula
 5 described in paragraph (6) by State and local public
 6 health agencies.

7 “(b) IMMUNIZATION, PREVENTION, AND CONTROL
 8 PROGRAMS.—

9 “(1) IN GENERAL.—The Secretary, acting
 10 through the Director of the Centers for Disease
 11 Control and Prevention, shall support the integra-
 12 tion of activities described in paragraph (2) into ex-
 13 isting clinical and public health programs at State,
 14 local, territorial, and tribal levels (including commu-
 15 nity health clinics, programs for the prevention and
 16 treatment of HIV/AIDS, sexually transmitted dis-
 17 eases, and substance abuse, and programs for indi-
 18 viduals in correctional settings).

19 “(2) ACTIVITIES.—

20 “(A) VOLUNTARY TESTING PROGRAMS.—

21 “(i) IN GENERAL.—The Secretary
 22 shall establish a mechanism by which to
 23 support and promote the development of
 24 State, local, territorial, and tribal vol-
 25 untary hepatitis B and hepatitis C testing

1 programs to screen the high-prevalence
2 populations to aid in the early identifica-
3 tion of chronically infected individuals.

4 “(ii) CONFIDENTIALITY OF THE TEST
5 RESULTS.—The Secretary shall prohibit
6 the use of the results of a hepatitis B or
7 hepatitis C test conducted by a testing pro-
8 gram developed or supported under this
9 subparagraph for any of the following:

10 “(I) Issues relating to health in-
11 surance.

12 “(II) To screen or determine
13 suitability for employment.

14 “(III) To discharge a person
15 from employment.

16 “(B) COUNSELING REGARDING VIRAL HEP-
17 ATITIS.—The Secretary shall support State,
18 local, territorial, and tribal programs in a wide
19 variety of settings, including those providing
20 primary and specialty health care services in
21 nonprofit private and public sectors, to—

22 “(i) provide individuals with ongoing
23 risk factors for hepatitis B and hepatitis C
24 infection with client-centered education
25 and counseling which concentrates on—

1 “(I) promoting testing of individ-
2 uals that have been exposed to their
3 blood, family members, and their sex-
4 ual partners; and

5 “(II) changing behaviors that
6 place individuals at risk for infection;

7 “(ii) provide individuals chronically in-
8 fected with hepatitis B or hepatitis C with
9 education, health information, and coun-
10 seling to reduce their risk of—

11 “(I) dying from end-stage liver
12 disease and liver cancer; and

13 “(II) transmitting viral hepatitis
14 to others; and

15 “(iii) provide women chronically in-
16 fected with hepatitis B or hepatitis C who
17 are pregnant or of childbearing age with
18 culturally and language appropriate health
19 information, such as how to prevent hepa-
20 titis B perinatal infection, and to alleviate
21 fears associated with pregnancy or raising
22 a family.

23 “(C) IMMUNIZATION.—The Secretary shall
24 support State, local, territorial, and tribal ef-
25 forts to expand the current vaccination pro-

grams to protect every child in the country and all susceptible adults, particularly those infected with hepatitis C and high-prevalence ethnic populations and other high-risk groups, from the risks of acute and chronic hepatitis B infection by—

“(i) ensuring continued funding for hepatitis B vaccination for all children 19 years of age or younger through the Vaccines for Children Program;

“(ii) ensuring that the recommendations of the Advisory Committee on Immunization Practices are followed regarding the birth dose of hepatitis B vaccinations for newborns;

“(iii) requiring proof of hepatitis B vaccination for entry into public or private daycare, preschool, elementary school, secondary school, and institutions of higher education;

“(iv) expanding the availability of hepatitis B vaccination for all susceptible adults to protect them from becoming acutely or chronically infected, including ethnic and other populations with high

1 prevalence rates of chronic hepatitis B in-
2 fection;

3 “(v) expanding the availability of hep-
4 atitis B vaccination for all susceptible
5 adults, particularly those in their reproduc-
6 tive age (women and men less than 45
7 years of age), to protect them from the
8 risk of hepatitis B infection;

9 “(vi) ensuring the vaccination of indi-
10 viduals infected, or at risk for infection,
11 with hepatitis C against hepatitis A, hepa-
12 titis B, and other infectious diseases, as
13 appropriate, for which such individuals
14 may be at increased risk; and

15 “(vii) ensuring the vaccination of indi-
16 viduals infected, or at risk for infection,
17 with hepatitis B against hepatitis A virus
18 and other infectious diseases, as appro-
19 priate, for which such individuals may be
20 at increased risk.

21 “(D) MEDICAL REFERRAL.—The Secretary
22 shall support State, local, territorial, and tribal
23 programs that support—

24 “(i) referral of persons chronically in-
25 fected with hepatitis B or hepatitis C—

1 “(I) for medical evaluation to de-
2 termine the appropriateness for
3 antiviral treatment to reduce the risk
4 of progression to cirrhosis and liver
5 cancer; and

6 “(II) for ongoing medical man-
7 agement including regular monitoring
8 of liver function and screening for
9 liver cancer; and

10 “(ii) referral of persons infected with
11 acute or chronic hepatitis B infection or
12 acute or chronic hepatitis C infection for
13 drug and alcohol abuse treatment where
14 appropriate.

15 “(3) INCREASED SUPPORT FOR ADULT VIRAL
16 HEPATITIS COORDINATORS.—The Secretary, acting
17 through the Director of the Centers for Disease
18 Control and Prevention, shall provide increased sup-
19 port to Adult Viral Hepatitis Coordinators in State,
20 local, territorial, and tribal health departments in
21 order to enhance the additional management, net-
22 working, and technical expertise needed to ensure
23 successful integration of hepatitis B and hepatitis C
24 prevention and control activities into existing public
25 health programs.

1 “(c) EPIDEMIOLOGICAL SURVEILLANCE.—

2 “(1) IN GENERAL.—The Secretary, acting
3 through the Director of the Centers for Disease
4 Control and Prevention, shall support the establish-
5 ment and maintenance of a national chronic and
6 acute hepatitis B and hepatitis C surveillance pro-
7 gram, in order to identify—

8 “(A) trends in the incidence of acute and
9 chronic hepatitis B and acute and chronic hepa-
10 titis C;

11 “(B) trends in the prevalence of acute and
12 chronic hepatitis B and acute and chronic hepa-
13 titis C infection among groups that may be dis-
14 proportionately affected; and

15 “(C) trends in liver cancer and end-stage
16 liver disease incidence and deaths, caused by
17 chronic hepatitis B and chronic hepatitis C in
18 the high-risk ethnic populations.

19 “(2) SEROPREVALENCE AND LIVER CANCER
20 STUDIES.—The Secretary, acting through the Direc-
21 tor of the Centers for Disease Control and Preven-
22 tion, shall prepare a report outlining the population-
23 based seroprevalence studies currently underway, fu-
24 ture planned studies, the criteria involved in deter-
25 mining which seroprevalence studies to conduct,

1 defer, or suspend, and the scope of those studies, the
2 economic and clinical impact of hepatitis B and hep-
3 atitis C, and the impact of chronic hepatitis B and
4 chronic hepatitis C infections on the quality of life.
5 Not later than one year after the date of the enact-
6 ment of this part, the Secretary shall submit the re-
7 port to the Committee on Energy and Commerce of
8 the House of Representatives and the Committee on
9 Health, Education, Labor, and Pensions of the Sen-
10 ate.

11 “(3) CONFIDENTIALITY.—The Secretary shall
12 not disclose any individually identifiable information
13 identified under paragraph (1) or derived through
14 studies under paragraph (2).

15 “(d) RESEARCH.—The Secretary, acting through the
16 Director of the Centers for Disease Control and Preven-
17 tion, the Director of the National Cancer Institute, and
18 the Director of the National Institutes of Health, shall—

19 “(1) conduct epidemiologic and community-
20 based research to develop, implement, and evaluate
21 best practices for hepatitis B and hepatitis C pre-
22 vention especially in the ethnic populations with high
23 rates of chronic hepatitis B and chronic hepatitis C
24 and other high-risk groups;

1 “(2) conduct research on hepatitis B and hepa-
2 titis C natural history, pathophysiology, improved
3 treatments and prevention (such as the hepatitis C
4 vaccine), and noninvasive tests that help to predict
5 the risk of progression to liver cirrhosis and liver
6 cancer;

7 “(3) conduct research that will lead to better
8 noninvasive or blood tests to screen for liver cancer,
9 and more effective treatments of liver cancer caused
10 by chronic hepatitis B and chronic hepatitis C; and

11 “(4) conduct research comparing the effective-
12 ness of screening, diagnostic, management, and
13 treatment approaches for chronic hepatitis B, chron-
14 ic hepatitis C, and liver cancer in the affected com-
15 munities.

16 “(e) UNDERSERVED AND DISPROPORTIONATELY AF-
17 FECTED POPULATIONS.—In carrying out this section, the
18 Secretary shall provide expanded support for individuals
19 with limited access to health education, testing, and health
20 care services and groups that may be disproportionately
21 affected by hepatitis B and hepatitis C.

22 “(f) EVALUATION OF PROGRAM.—The Secretary
23 shall develop benchmarks for evaluating the effectiveness
24 of the programs and activities conducted under this sec-

1 tion and make determinations as to whether such bench-
 2 marks have been achieved.

3 **“SEC. 399HH. GRANTS.**

4 “(a) IN GENERAL.—The Secretary may award grants
 5 to, or enter into contracts or cooperative agreements with,
 6 States, political subdivisions of States, territories, Indian
 7 tribes, or nonprofit entities that have special expertise re-
 8 lating to hepatitis B, hepatitis C, or both, to carry out
 9 activities under this part.

10 “(b) APPLICATION.—To be eligible for a grant, con-
 11 tract, or cooperative agreement under subsection (a), an
 12 entity shall prepare and submit to the Secretary an appli-
 13 cation at such time, in such manner, and containing such
 14 information as the Secretary may require.

15 **“SEC. 399II. AUTHORIZATION OF APPROPRIATIONS.**

16 “There are authorized to be appropriated to carry out
 17 this part \$90,000,000 for fiscal year 2011, \$90,000,000
 18 for fiscal year 2012, \$110,000,000 for fiscal year 2013,
 19 \$130,000,000 for fiscal year 2014, and \$150,000,000 for
 20 fiscal year 2015.”.

21 **SEC. 4. ENHANCING SAMHSA’S ROLE IN HEPATITIS ACTIVI-**
 22 **TIES.**

23 Paragraph (6) of section 501(d) of the Public Health
 24 Service Act (42 U.S.C. 290aa(d)) is amended by striking

- 1 “HIV or tuberculosis” and inserting “HIV, tuberculosis,
- 2 or hepatitis”.

