

111TH CONGRESS  
1ST SESSION

# S. 717

To modernize cancer research, increase access to preventative cancer services, provide cancer treatment and survivorship initiatives, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

MARCH 26, 2009

Mr. KENNEDY (for himself, Mrs. HUTCHISON, and Mrs. FEINSTEIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To modernize cancer research, increase access to preventative cancer services, provide cancer treatment and survivorship initiatives, 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 “21st Century Cancer  
5 ALERT (Access to Life-Saving Early detection, Research  
6 and Treatment) Act”.

7 **SEC. 2. FINDINGS AND PURPOSE.**

8 (a) FINDINGS.—Congress makes the following find-  
9 ings:

1           (1) One in 2 men and one in 3 women are ex-  
2           pected to develop cancer in their lifetimes.

3           (2) Cancer is the leading cause of death for  
4           people under the age of 85 and is expected to claim  
5           more than 1,500 lives per day in 2008.

6           (3) At least 30 percent of all cancer deaths and  
7           87 percent of lung cancer deaths are attributed to  
8           smoking.

9           (4) The National Institutes of Health estimates  
10          that in 2007 alone, the overall cost of cancer to the  
11          United States was more than \$219,000,000,000.

12          (5) In recent decades, the biomedical research  
13          enterprise has made considerable advances in the  
14          knowledge required to understand, prevent, diag-  
15          nose, and treat cancer; however, it still takes 17  
16          years, on average, to translate these discoveries into  
17          viable treatment options.

18          (6) While clinical trials are vital to the dis-  
19          covery and implementation of new preventative, di-  
20          agnostic, and treatment options, only 3 to 5 percent  
21          of the more than 10,000,000 adults with cancer in  
22          the United States participate in cancer clinical  
23          trials.

24          (7) Where people reside should not determine  
25          whether they live, yet women in rural areas are less

1 likely to obtain preventative cancer screenings than  
2 those residing in urban areas.

3 (8) Two-thirds of childhood cancer survivors are  
4 likely to experience at least one late effect from  
5 treatment and one-fourth are expected to experience  
6 a late effect that is life threatening.

7 (9) In 1971, there were only 3,000,000 cancer  
8 survivors. Today, cancer survivors account for 3 per-  
9 cent of the United States population, approximately  
10 12,000,000.

11 (10) The National Cancer Act of 1971 (Public  
12 Law 92-218) advanced the ability of the United  
13 States to develop new scientific leads and help in-  
14 crease the rate of cancer survivorship.

15 (11) Yet in the 37 years since the national dec-  
16 laration of the War on Cancer, the age adjusted  
17 mortality rate for cancer is still extraordinarily high.  
18 Eight forms of cancer have a 5-year survival rate of  
19 less than 50 percent (pancreatic, liver, lung, esopha-  
20 geal, stomach, brain, multiple myeloma, and ovar-  
21 ian).

22 (12) While there have been substantial achieve-  
23 ments since the crusade began, we are far from win-  
24 ning the war on cancer.

1           (13) Many obstacles have hindered our progress  
2           in cancer prevention, research, and treatment.

3           (b) PURPOSES.—The purposes of this Act are as fol-  
4           lows:

5           (1) To reauthorize the National Cancer Insti-  
6           tute and National Cancer Program in order to en-  
7           hance and improve the cancer research conducted  
8           and supported by the National Cancer Institute and  
9           the National Cancer Program in order to benefit  
10          cancer patients.

11          (2) To recognize that with an increased under-  
12          standing of cancer as more than 200 different dis-  
13          eases with genetic and molecular variations, there is  
14          a need for increased coordination and greater flexi-  
15          bility in how cancer research is conducted and co-  
16          ordinated in order to maximize the return the  
17          United States receives on its investment in such re-  
18          search.

19          (3) To prepare for the looming impact of an  
20          aging population of the United States and the an-  
21          ticipated financial burden associated with medical  
22          treatment and lost productivity, along with the toll  
23          of human suffering that accompanies a cancer diag-  
24          nosis.

1           (4) To support the National Cancer Institute in  
2           establishing relationships and scientific consortia  
3           with an emphasis on public-private partnership de-  
4           velopment, which will further the development of ad-  
5           vanced technologies that will improve the prevention,  
6           diagnosis, and treatment of cancer.

7   **SEC. 3. ADVANCEMENT OF THE NATIONAL CANCER PRO-**  
8                                   **GRAM.**

9           Section 411 of the Public Health Service Act (42  
10          U.S.C. 285a) is amended to read as follows:

11   **“SEC. 411. NATIONAL CANCER PROGRAM.**

12           “(a) IN GENERAL.—There shall be established a Na-  
13          tional Cancer Program (referred to in this section as the  
14          ‘Program’) that shall consist of—

15                   “(1) an expanded, intensified, and coordinated  
16          cancer research program encompassing the research  
17          programs conducted and supported by the Institute  
18          and the related research programs of the other na-  
19          tional research institutes, including an expanded and  
20          intensified research program for the prevention of  
21          cancer caused by occupational or environmental ex-  
22          posure to carcinogens; and

23                   “(2) the other programs and activities of the  
24          Institute.

1       “(b) COLLABORATION.—In carrying out the Pro-  
2 gram—

3               “(1) the Secretary and the Director of the In-  
4 stitute shall identify relevant Federal agencies that  
5 shall collaborate with respect to activities conducted  
6 under the Program (including the Institute, the  
7 other Institutes and Centers of the National Insti-  
8 tutes of Health, the Office of the Director of the Na-  
9 tional Institutes of Health, the Food and Drug Ad-  
10 ministration, the Centers for Medicare & Medicaid  
11 Services, the Centers for Disease Control and Pre-  
12 vention, the Department of Defense, the Department  
13 of Energy, the Agency for Healthcare Research and  
14 Quality, the Office for Human Research Protections,  
15 the Health Resources and Services Administration,  
16 and the Office for Human Research Protections);  
17 and

18               “(2) the Secretary shall ensure that the policies  
19 related to the promotion of cancer research of all  
20 agencies within the Department of Health and  
21 Human Services (including the Institute, the Food  
22 and Drug Administration, and the Centers for Medi-  
23 care & Medicaid Services) are harmonized, and shall  
24 ensure that such agencies collaborate with regard to  
25 cancer research and development.

1 “(c) TRANSPARENCY AND EFFICIENCY.—

2 “(1) BUDGETING.—In carrying out the Pro-  
3 gram, the Director of the Institute shall, in pre-  
4 paring and submitting to the President the annual  
5 budget estimate for the Program—

6 “(A) develop the budgetary needs of the  
7 entire Program and submit the budget estimate  
8 relating to such needs to the National Cancer  
9 Advisory Board for review prior to submitting  
10 such estimate to the President; and

11 “(B) submit such budget estimate to the  
12 Committee on the Budget and the Committee  
13 on Appropriations of the Senate and the Com-  
14 mittee on the Budget and Committee on Appro-  
15 priations of the House of Representatives at the  
16 same time that such estimate is submitted to  
17 the President.

18 “(2) NATIONAL CANCER ADVISORY BOARD.—In  
19 establishing the priorities of the Program, the Na-  
20 tional Cancer Advisory Board shall provide for in-  
21 creased coordination by increasing the participation  
22 of representatives (to the extent practicable, rep-  
23 resentatives who have appropriate decision making  
24 authority) of appropriate Federal agencies, includ-  
25 ing—

1                   “(A) the Centers for Medicare & Medicaid  
2                   Services;

3                   “(B) the Health Resources and Services  
4                   Administration;

5                   “(C) the Centers for Disease Control and  
6                   Prevention; and

7                   “(D) the Agency for Healthcare Research  
8                   and Quality.

9                   “(d) PROGRAMS TO ENCOURAGE EARLY DETECTION  
10                  RESEARCH.—The Director of the Institute shall develop  
11                  a standard process through which Federal agencies, in-  
12                  cluding the Department of Defense, and administrators of  
13                  federally funded programs may engage in early cancer de-  
14                  tection research.

15                  “(e)           IDENTIFICATION           OF           PROMISING  
16                  TRANSLATIONAL RESEARCH OPPORTUNITIES.—

17                  “(1) IN GENERAL.—The Director of the Insti-  
18                  tute, acting through the Program and in accordance  
19                  with the NIH Reform Act of 2007, shall continue to  
20                  identify promising translational research opportuni-  
21                  ties across all disease sites, populations, and path-  
22                  ways to clinical goals through a transparent, inclu-  
23                  sive process by—

24                         “(A) continuing to support efforts to de-  
25                         velop a robust number of public or nonprofit

1 entities to carry out early translational research  
2 activities;

3 “(B) emphasizing the role of the young re-  
4 searcher in the program under this section; and

5 “(C) modifying guidelines for multiproject,  
6 collaborative, early translational research  
7 awards to focus research and reward collabo-  
8 rative team science.

9 “(2) MATCHING FUNDS FOR RESEARCH.—

10 “(A) IN GENERAL.—The Secretary may  
11 provide assistance to eligible entities to match  
12 the amount of non-Federal funds made avail-  
13 able by such entity for translational research of  
14 the type described in paragraph (1) relating to  
15 cancer.

16 “(B) ELIGIBILITY.—To be eligible to re-  
17 ceive assistance under subparagraph (A), an en-  
18 tity shall submit to the Secretary an application  
19 at such time, in such manner, and containing  
20 such information as the Secretary may require.

21 “(C) RECOMMENDATIONS AND  
22 PRIORITIZATION.—In providing assistance  
23 under subparagraph (A), the Secretary shall—

24 “(i) select entities based on the rec-  
25 ommendations of—

1 “(I) the Director of NIH; and

2 “(II) a peer review process; and

3 “(ii) give priority to those entities  
4 submitting applications under subpara-  
5 graph (B) that demonstrate that the re-  
6 search involved is high risk or translational  
7 research (as determined by the Secretary).

8 “(D) AMOUNT.—The amount of assistance  
9 to be provided to an entity under subparagraph  
10 (A) shall be at the discretion of the Secretary  
11 but shall not exceed an amount equal to 100  
12 percent of the amount of non-Federal funds (\$1  
13 for each \$2 of non-Federal funds) made avail-  
14 able for research described in subparagraph  
15 (A).

16 “(E) DETERMINATION OF AMOUNT OF  
17 NON-FEDERAL CONTRIBUTION.—Non-Federal  
18 funds to be matched under subparagraph (A)  
19 may be in cash or in kind, fairly evaluated, in-  
20 cluding plant, equipment, or services. Amounts  
21 provided by the Federal Government, and any  
22 portion of any service subsidized by the Federal  
23 Government, may not be included in deter-  
24 mining the amount of such non-Federal funds.

1       “(f) BIOLOGICAL RESOURCE COORDINATION AND  
2   ADVANCEMENT OF TECHNOLOGIES FOR CANCER RE-  
3   SEARCH.—

4           “(1) ESTABLISHMENT.—The Director of the  
5   Institute, acting through the Program, shall estab-  
6   lish an entity within the Institute to augment ongo-  
7   ing efforts to advance new technologies in cancer re-  
8   search, support the national collection of tissues for  
9   cancer research purposes, and ensure the quality of  
10   tissue collection.

11          “(2) GOALS.—The entity established under  
12   paragraph (1) shall—

13           “(A) be designed to expand the access of  
14   researchers to biospecimens for cancer research  
15   purposes;

16           “(B) establish uniform standards for the  
17   handling and preservation of patient tissue  
18   specimens by entities participating in the net-  
19   work established under paragraph (3);

20           “(C) require adequate annotation of all rel-  
21   evant clinical data while assuring patient pri-  
22   vacy;

23           “(D) facilitate the linkage of public and  
24   private entities into the national network under  
25   paragraph (3);

1           “(E) provide for the linkage of cancer reg-  
2           istries to other administrative Federal Govern-  
3           ment data sources, including the Centers for  
4           Medicare & Medicaid Services, the Social Secu-  
5           rity Administration, and the Centers for Dis-  
6           ease Control and Prevention, with the goal of  
7           understanding the determinants of cancer treat-  
8           ment, care, and outcomes by allowing economic,  
9           social, genetic, and other factors to be analyzed  
10          in an independent manner; and

11          “(F) develop strategies to ensure patient  
12          rights and privacy, including an assessment of  
13          the regulations promulgated pursuant to part C  
14          of title XI of the Social Security Act and sec-  
15          tion 264(e) of the Health Insurance Portability  
16          and Accountability Act of 1996 (42 U.S.C.  
17          1320d–2 note) (referred to in this section as  
18          the ‘HIPAA Privacy Rule’), while facilitating  
19          advances in medical research.

20          “(3) ADVANCEMENT OF NEW TECHNOLOGIES  
21          FOR CANCER RESEARCH AND EXPANSION OF CANCER  
22          BIOREPOSITORY NETWORKS.—

23          “(A) IN GENERAL.—As part of the entity  
24          established under paragraph (1), the Director  
25          of the Institute shall build upon existing initia-

1 tives to establish an interconnected network of  
2 biorepositories (referred to in this subsection as  
3 the ‘Network’) with consistent, interoperable  
4 systems for the collection and storage of tissues  
5 and information, the annotation of such infor-  
6 mation, and the sharing of such information  
7 through an interoperable information system.

8 “(B) GUIDELINES.—A biorepository in the  
9 Network that receives Federal funds shall adopt  
10 the Institute’s Best Practices for Biospecimen  
11 Resources for Institute-supported biospecimen  
12 resources (as published by the Institute and in-  
13 cluding any successor guidelines) for the collec-  
14 tion of biospecimens and any accompanying  
15 data.

16 “(C) REPRESENTATION.—The composition  
17 of any leadership entity of the Network shall be  
18 determined by the Director of the Institute and  
19 shall, at a minimum, include a representative  
20 of—

21 “(i) private sector entities and individ-  
22 uals, including cancer researchers and  
23 health care providers;

24 “(ii) the Centers for Disease Control  
25 and Prevention;

1 “(iii) the Agency for Healthcare Re-  
2 search and Quality;

3 “(iv) the Office of National Coordina-  
4 tion of Health Information Technology;

5 “(v) the National Library of Medicine;

6 “(vi) the Office for the Protection of  
7 Research Subjects; and

8 “(vii) the National Science Founda-  
9 tion.

10 “(D) PARTNERSHIPS WITH TISSUE SOURCE  
11 SITES.—The Director of the Institute may  
12 enter into contracts with tissue source sites to  
13 acquire data from such sites. Any such data  
14 shall be acquired through the use of protocols  
15 and closely monitored, transparent procedures  
16 within appropriate ethical and legal frame-  
17 works.

18 “(4) COLLECTION OF DATA.—

19 “(A) HOSPITALS.—A hospital or ambula-  
20 tory cancer center that receives Federal funds  
21 shall offer patients the opportunity to con-  
22 tribute their biospecimens and clinical data to  
23 the entity established under paragraph (1).

24 “(B) CLINICAL TRIAL DATA.—Clinical trial  
25 data relating to cancer care and treatment shall

1 be provided to the entity established under  
2 paragraph (1).”.

3 **SEC. 4. COMPREHENSIVE AND RESPONSIBLE ACCESS TO**  
4 **RESEARCH, DATA, AND OUTCOMES.**

5 (a) IN GENERAL.—Not later than 180 days after the  
6 date of enactment of this Act, the Director of the Office  
7 for Human Research Protections shall issue guidance to  
8 National Institutes of Health grantees concerning use of  
9 the facilitated review process in conjunction with the cen-  
10 tral institutional review board of the National Cancer In-  
11 stitute as the preferred mechanism to satisfy regulatory  
12 requirements to review ethical or scientific issues for all  
13 National Cancer Institute-supported translational and  
14 clinical research.

15 (b) IMPROVED PRIVACY STANDARDS IN CLINICAL  
16 RESEARCH.—

17 (1) PERMITTED DISCLOSURE UNDER THE PRI-  
18 VACY RULE.—For purposes of the Privacy Rule (as  
19 referred to in section 411(f)(2)(F) of the Public  
20 Health Service Act, as amended by this Act), a cov-  
21 ered entity (as defined for purposes of such Rule)  
22 shall be in compliance with such Rule relating to the  
23 disclosure of de-identified patient information if such  
24 disclosure is—

1 (A) pursuant to a waiver that had been  
2 granted by an institutional review board or pri-  
3 vacy board relating to such disclosure; and

4 (B) the entity informs patients when they  
5 make first patient contact with the entity that  
6 the entity is a research institution that may  
7 conduct research using their de-identified med-  
8 ical records.

9 (2) SYNCHRONIZATION OF STANDARDS.—

10 (A) IN GENERAL.—The Secretary of  
11 Health and Human Services shall study the ad-  
12 vantages and disadvantages of the synchroni-  
13 zation of the standards for research under the  
14 Common Rule (under part 46 of title 45, Code  
15 of Federal Regulations) and the Privacy Rule  
16 (as defined in section 411(f)(2)(F) of the Public  
17 Health Service Act, as amended by this Act) in  
18 order to determine the appropriate data ele-  
19 ments that should be omitted under the strict  
20 de-identification standards relating to personal  
21 information.

22 (B) REVIEW OF RECOMMENDATIONS.—In  
23 carrying out subparagraph (A), the Secretary of  
24 Health and Human Services shall conduct a re-  
25 view of recommendations made by the Advisory

1 Committee on Human Research Protections as  
2 well as recommendations from the appropriate  
3 leadership of the National Committee on Vital  
4 and Health Statistics.

5 (C) ADDITIONAL AREAS.—In carrying out  
6 subparagraph (A), the Secretary of Health and  
7 Human Services shall—

8 (i) make recommendations concerning  
9 the conduct of international research to de-  
10 termine the boundaries and applications of  
11 extraterritorially under the Privacy Rule  
12 (as referred to in section 411(f)(2)(F) of  
13 the Public Health Service Act, as amended  
14 by this Act); and

15 (ii) include biorepository storage infor-  
16 mation when obtaining patient consent.

17 (D) REPORT.—Not later than 180 days  
18 after the date of enactment of this Act, the Sec-  
19 retary of Health and Human Services shall sub-  
20 mit to the appropriate committee of Congress,  
21 a report concerning the recommendations made  
22 under this paragraph.

23 (3) APPLICATION OF PRIVACY RULE TO EXTER-  
24 NAL RESEARCHERS.—

1 (A) IN GENERAL.—Notwithstanding any  
2 other provision of law, the Privacy Rule (as de-  
3 fined in section 411(f)(2)(F) of the Public  
4 Health Service Act, as amended by this Act)  
5 shall apply to external researchers.

6 (B) DEFINITION.—

7 (i) IN GENERAL.—In this paragraph,  
8 the term “external researcher” means a re-  
9 searcher who is on the staff of a covered  
10 entity (as defined in the Privacy Rule) but  
11 who is not actually employed by such cov-  
12 ered entity.

13 (ii) INTERNAL AND EXTERNAL RE-  
14 SEARCHERS.—With respect to determining  
15 the distinction of whether or not a re-  
16 searcher has the ability to use protected  
17 health information under the provisions of  
18 this paragraph, such determination shall  
19 be based on whether the covered entity in-  
20 volved exercises effective control over that  
21 researcher’s activities. For purposes of the  
22 preceding sentence, effective control may  
23 include membership and privileges of staff  
24 or the ability to terminate staff member-  
25 ship or discipline staff.

1 (c) LIABILITY.—The Director of the Office of Human  
 2 Research Protection, the Director of the National Insti-  
 3 tutes of Health, and the Director of the National Cancer  
 4 Institute shall issue guidance for entities awarded grants  
 5 by such Federal agencies to provide instruction on how  
 6 such entities may best address concerns or issues relating  
 7 to the liability that institutions or researchers may incur  
 8 as a result of using the facilitated review process.

9 **SEC. 5. ENHANCED FOCUS AND REPORTING ON CANCER**  
 10 **RESEARCH.**

11 Part C of title IV of the Public Health Service Act  
 12 (42 U.S.C. 285 et seq.) is amended by inserting after sec-  
 13 tion 417A the following:

14 **“SEC. 417B. ENHANCED FOCUS AND REPORTING ON CAN-**  
 15 **CER RESEARCH.**

16 “(a) ANNUAL INDEPENDENT REPORT.—

17 “(1) IN GENERAL.—The Director of the Insti-  
 18 tute shall complete an annual independent report  
 19 that shall be submitted to Congress on the same  
 20 date that the annual budget estimate described in  
 21 section 413(b)(9) is submitted to the President.

22 “(2) CONTENTS OF REPORT.—

23 “(A) CANCER CATEGORIES.—The report  
 24 required under paragraph (1) shall address the  
 25 following categories of cancer:

1           “(i) Cancers that result in a 5-year  
2 survival rate of less than 50 percent.

3           “(ii) Cancers in which the incidence  
4 rate is less than 15 cases per 100,000 peo-  
5 ple, or fewer than 40,000 new cases per  
6 year.

7           “(B) INFORMATION.—With regard to each  
8 of the categories of cancer described in sub-  
9 paragraph (A), the report shall contain infor-  
10 mation regarding—

11           “(i) a strategic plan for reducing the  
12 mortality rate for the annual year, includ-  
13 ing specific research areas of interest and  
14 budget amounts;

15           “(ii) identification of any barriers to  
16 implementing the strategic plan described  
17 in clause (i) for the annual year;

18           “(iii) if the report for the prior year  
19 contained a strategic plan described in  
20 clause (i), an assessment of the success of  
21 such plan;

22           “(iv) the total amount of grant fund-  
23 ing, including the total dollar amount  
24 awarded per grant and per funding year,  
25 under—

1                   “(I) the National Cancer Insti-  
2                   tute; and

3                   “(II) the National Institutes of  
4                   Health;

5                   “(v) the percentage of grant applica-  
6                   tions favorably reviewed by the Institute  
7                   that the Institute funded in the previous  
8                   annual year;

9                   “(vi) the total number of grant appli-  
10                  cations, with greater than 50 percent rel-  
11                  evance to each of the categories of cancer  
12                  described in subparagraph (A), received by  
13                  the Institute for awards in the previous an-  
14                  nual year;

15                  “(vii) the total number of grants  
16                  awarded, with greater than 50 percent rel-  
17                  evance to each of the categories of cancer  
18                  described in subparagraph (A), for the pre-  
19                  vious annual year and the number of  
20                  awards per grant type, including the Com-  
21                  mon Scientific Outline designation specific  
22                  to each such grant; and

23                  “(viii) the total number of primary in-  
24                  vestigators that received grants from the  
25                  Institute for projects with greater than 50

1           percent relevance to each of the categories  
2           of cancer described in paragraph (1), in-  
3           cluding the total number of awards grant-  
4           ed to experienced investigators and the  
5           total number of awards granted to inves-  
6           tigators receiving their first grant from the  
7           National Institutes of Health.

8           “(3) DEFINITION.—In this section, the term  
9           ‘annual year’ means the year for which the strategic  
10          plan described in paragraph (2)(B)(i) applies, which  
11          shall be the same fiscal year for which the Director  
12          of the Institute submits the annual budget estimate  
13          described in section 413(b)(9) for that year.

14          “(b) GRANT PROGRAM.—

15                 “(1) IN GENERAL.—The Director of the Insti-  
16                 tute, in cooperation with the Director of the Fogarty  
17                 International Center for Advanced Study in the  
18                 Health Sciences and the Directors of other Insti-  
19                 tutes, as appropriate, shall award grants to re-  
20                 searchers to conduct research regarding cancers for  
21                 which—

22                         “(A) the incidence is fewer than 40,000  
23                         new cases per year; and

24                         “(B) the 5-year survival rate is less than  
25                         50 percent.

1           “(2) PRIORITIZATION.—In awarding grants for  
 2 research regarding cancers described in paragraph  
 3 (1)(A), the Director of the Institute shall give pri-  
 4 ority to collaborative research projects between adult  
 5 and pediatric cancer research, with preference for  
 6 projects building upon existing multi-institutional re-  
 7 search infrastructures.

8           “(3) TISSUE SAMPLES.—

9           “(A) IN GENERAL.—Except as provided in  
 10 subparagraph (B), the Director of the Institute  
 11 shall require each recipient receiving a grant  
 12 under this subsection to submit tissue samples  
 13 to designated tumor banks.

14           “(B) WAIVER.—The Director of the Insti-  
 15 tute may grant a waiver of the requirement de-  
 16 scribed in subparagraph (A) to a recipient who  
 17 receives a grant for research described in para-  
 18 graph (1)(B) and who submits an application  
 19 for such waiver to the Director of the Institute,  
 20 in the manner in which such Director may re-  
 21 quire.”.

22 **SEC. 6. CONTINUING ACCESS TO CARE FOR PREVENTION**  
 23 **AND EARLY DETECTION.**

24           (a) COLORECTAL CANCER SCREENING PROGRAM.—  
 25 Part B of title III of the Public Health Service Act is

1 amended by inserting after section 317D (42 U.S.C.  
2 247b-5) the following:

3 **“SEC. 317D-1. COLORECTAL CANCER SCREENING PRO-**  
4 **GRAM.**

5 “(a) IN GENERAL.—The Secretary, acting through  
6 the Director of the Centers for Disease Control and Pre-  
7 vention, may award competitive grants to eligible entities  
8 to carry out programs—

9 “(1) to provide screenings for colorectal cancer  
10 to individuals according to screening guidelines set  
11 by the United States Preventive Services Task  
12 Force;

13 “(2) to provide appropriate referrals for medical  
14 treatment of individuals screened pursuant to para-  
15 graph (1) and to ensure, to the extent practicable,  
16 the provision of appropriate follow-up services and  
17 support services such as case management;

18 “(3) to develop and disseminate public informa-  
19 tion and education programs for the detection and  
20 control of colon cancer;

21 “(4) to improve the education, training, and  
22 skills of health professionals (including allied health  
23 professionals) in the detection and control of colon  
24 cancer;

1           “(5) to establish mechanisms through which eli-  
2           gible entities can monitor the quality of screening  
3           procedures for colon cancer, including the interpre-  
4           tation of such procedures; and

5           “(6) to evaluate activities conducted under  
6           paragraphs (1) through (5) through appropriate sur-  
7           veillance or program-monitoring activities.

8           “(b) ELIGIBILITY.—

9           “(1) IN GENERAL.—To be eligible to receive a  
10          grant under this section an entity shall—

11           “(A) be—

12           “(i) a State; or

13           “(ii) an Indian tribe or tribal organi-  
14          zation (as such terms are defined in sec-  
15          tion 4 of the Indian Self-Determination  
16          and Education Assistance Act);

17           “(B) submit to the Secretary as applica-  
18          tion, at such time, in such manner, and con-  
19          taining such information as the Secretary may  
20          require, including—

21           “(i) a description of the purposes for  
22          which the entity intends to expend  
23          amounts under the grant; and

1           “(ii) a description of the populations,  
2           areas, and localities with a need for the  
3           services or activities described in clause (i);

4           “(C) provide matching funds in accordance  
5           with paragraph (2);

6           “(D) provide assurances that the entity  
7           will—

8                   “(i) establish such fiscal control and  
9                   fund accounting procedures as may be nec-  
10                  essary to ensure the proper disbursement of,  
11                  and accounting for, amounts received  
12                  under subsection (a);

13                   “(ii) upon request, provide records  
14                   maintained pursuant to clause (i) to the  
15                   Secretary or the Comptroller General of  
16                   the United States for purposes of auditing  
17                   the expenditures of the grant by the eligi-  
18                   ble entity; and

19                   “(iii) submit to the Secretary such re-  
20                   ports as the Secretary may require with re-  
21                   spect to the grant; and

22           “(E) provide assurances that the entity  
23           will comply with the restrictions described in  
24           subsection (e).

25           “(2) MATCHING REQUIREMENT.—

1           “(A) IN GENERAL.—The Secretary may  
2 not award a grant to an eligible entity under  
3 this section unless the eligible entity involved  
4 agrees, with respect to the costs to be incurred  
5 by the eligible entity in carrying out the pur-  
6 pose described in the application under para-  
7 graph (1)(B)(i), to make available non-Federal  
8 contributions (in cash or in kind under sub-  
9 paragraph (B)) toward such costs in an amount  
10 equal to not less than \$1 for each \$3 of Federal  
11 funds provided in the grant. Such contributions  
12 may be made directly or through donations  
13 from public or private entities.

14           “(B) DETERMINATION OF AMOUNT OF  
15 NON-FEDERAL CONTRIBUTION.—

16           “(i) IN GENERAL.—Non-Federal con-  
17 tributions required in subparagraph (A)  
18 may be in cash or in kind, fairly evaluated,  
19 including equipment or services (and ex-  
20 cluding indirect or overhead costs).  
21 Amounts provided by the Federal Govern-  
22 ment, or services assisted or subsidized to  
23 any significant extent by the Federal Gov-  
24 ernment, may not be included in deter-

1 mining the amount of such non-Federal  
2 contributions.

3 “(ii) MAINTENANCE OF EFFORT.—In  
4 making a determination of the amount of  
5 non-Federal contributions for purposes of  
6 subparagraph (A), the Secretary may in-  
7 clude only non-Federal contributions in ex-  
8 cess of the average amount of non-Federal  
9 contributions made by the eligible entity  
10 involved toward the purpose described in  
11 subsection (a) for the 2-year period pre-  
12 ceding the first fiscal year for which the el-  
13 igible entity is applying to receive a grant  
14 under such section.

15 “(iii) INCLUSION OF RELEVANT NON-  
16 FEDERAL CONTRIBUTIONS FOR MED-  
17 ICAID.—In making a determination of the  
18 amount of non-Federal contributions for  
19 purposes of subparagraph (A), the Sec-  
20 retary shall, subject to clauses (i) and (ii),  
21 include any non-Federal amounts expended  
22 pursuant to title XIX of the Social Secu-  
23 rity Act by the eligible entity involved to-  
24 ward the purpose described in paragraphs  
25 (1) and (2) of subsection (a).

1 “(c) PRIORITIZATION.—

2 “(1) IN GENERAL.—In awarding grants under  
3 this section, the Secretary shall give priority to re-  
4 cipients that are safety-net providers.

5 “(2) DEFINITION.—In this section, the term  
6 ‘safety-net provider’ means a health care provider—

7 “(A) that by legal mandate or explicitly  
8 adopted mission, offers care to individuals with-  
9 out regard to the individual’s ability to pay for  
10 such services; or

11 “(B) for whom a substantial share of the  
12 patients are uninsured, receive Medicaid, or are  
13 otherwise vulnerable.

14 “(d) USE OF FUNDS.—

15 “(1) IN GENERAL.—An eligible entity may, sub-  
16 ject to paragraphs (2) and (3), expend amounts re-  
17 ceived under a grant under subsection (a) to carry  
18 out the purposes described in such subsection  
19 through the awarding of grants to public and non-  
20 profit private entities and through contracts entered  
21 into with public and private entities.

22 “(2) CERTAIN APPLICATION.—If a nonprofit  
23 private entity and a private entity that is not a non-  
24 profit entity both submit applications to a grantee  
25 under subsection (a) for a grant or contract as pro-

1 vided for in paragraph (1), the grantee may give pri-  
2 ority to the application submitted by the nonprofit  
3 private entity in any case in which the grantee deter-  
4 mines that the quality of such application is equiva-  
5 lent to the quality of the application submitted by  
6 the other private entity.

7 “(3) PAYMENTS FOR SCREENINGS.—The  
8 amount paid by a grantee under subsection (a) to an  
9 entity under this subsection for a screening proce-  
10 dure as described in subsection (a)(1) may not ex-  
11 ceed the amount that would be paid under part B  
12 of title XVIII of the Social Security Act if payment  
13 were made under such part for furnishing the proce-  
14 dure to an individual enrolled under such part.

15 “(e) RESTRICTION ON USE OF FUND.—The Sec-  
16 retary may not award a grant to an eligible entity under  
17 subsection (a) unless the entity agrees that—

18 “(1) in providing screenings under subsection  
19 (a)(1), the eligible entity will give priority to low-in-  
20 come individuals who lack adequate coverage under  
21 health insurance and health plans with respect to  
22 screenings for colorectal cancer;

23 “(2) initially and throughout the period during  
24 which amounts are received pursuant to the grant,  
25 not less than 60 percent of the grant shall be ex-

1       pended to provide each of the services or activities  
2       described in subsections (a)(1) and (a)(2);

3               “(3) not more than 10 percent of the grant will  
4       be expended for administrative expenses with respect  
5       to the activities funded under the grant;

6               “(4) funding received under the grant will sup-  
7       plement, and not supplant, the expenditures of the  
8       eligible entity and the value for in-kind contributions  
9       for carrying out the activities for which the grant  
10       was awarded;

11              “(5) funding will not be expended to make pay-  
12       ment for any item or service to the extent that pay-  
13       ment has been made, or can reasonably be expected  
14       to be made, with respect to such item or service—

15                      “(A) under any State compensation pro-  
16                      gram, under an insurance policy, or under any  
17                      Federal or State health benefits program; or

18                      “(B) by an entity that provides health  
19                      services on a prepaid basis; and

20              “(6) funds will not be expended to provide inpa-  
21       tient hospital services for any individual.

22       “(f) LIMITATION ON IMPOSITION OF FEES FOR  
23       SERVICES.—The Secretary may not award a grant to an  
24       eligible entity under this section unless the eligible entity  
25       involved agrees that, if a charge is imposed for the provi-

1 sion of services or activities under the grant, such  
2 charge—

3 “(1) will be made according to a schedule of  
4 charges that is made available to the public;

5 “(2) will be adjusted to reflect the income of  
6 the individual involved; and

7 “(3) will not be imposed on any individual with  
8 an income of less than 100 percent of the official  
9 poverty line, as established by the Director of the  
10 Office of Management and Budget and revised by  
11 the Secretary in accordance with section 673(2) of  
12 the Community Services Block Grant Act (42 U.S.C.  
13 9902(2)), including any revision required by such  
14 section.

15 “(g) REQUIREMENT REGARDING MEDICARE.—The  
16 Secretary may not award a grant to an eligible entity  
17 under this section unless the eligible entity involved pro-  
18 vides, as applicable, the following assurances:

19 “(1) Screenings under subsection (a)(1) will be  
20 carried out as preventive health measures in accord-  
21 ance with evidence-based screening guidelines and  
22 procedures as specified in section 1861(pp)(1) of the  
23 Social Security Act.

24 “(2) An individual will be considered high risk  
25 for purposes of subsection (a)(1) only if the indi-

1       vidual is high risk within the meaning of section  
2       1861(pp)(2) of such Act.

3       “(h) REQUIREMENT REGARDING MEDICAID.—The  
4 Secretary may not award a grant to an eligible entity  
5 under subsection (a) unless the State plan under title XIX  
6 of the Social Security Act for the State includes the  
7 screening procedures and referrals specified in subsections  
8 (a)(1) and (a)(2) as medical assistance provided under the  
9 plan.

10       “(i) TECHNICAL ASSISTANCE AND PROVISION OF  
11 SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

12               “(1) TECHNICAL ASSISTANCE.—The Secretary  
13 may provide training and technical assistance with  
14 respect to the planning, development, and operation  
15 of any program funded by a grant under subsection  
16 (a). The Secretary may provide such technical as-  
17 sistance directly to eligible entities or through grants  
18 to, or contracts with, public and private entities.

19               “(2) PROVISION OF SUPPLIES AND SERVICES IN  
20 LIEU OF GRANT FUNDS.—

21               “(A) IN GENERAL.—Subject to subpara-  
22 graph (B), upon the request of an eligible entity  
23 receiving a grant under subsection (a), the Sec-  
24 retary, for the purpose of aiding the eligible en-  
25 tity to carry out a program under this section—

1           “(i) may provide supplies, equipment,  
2           and services to the eligible entity; and

3           “(ii) may detail to the eligible entity  
4           any officer or employee of the Department  
5           of Health and Human Services.

6           “(B) CORRESPONDING REDUCTION IN PAY-  
7           MENTS.—With respect to a request made by an  
8           eligible entity under subparagraph (A), the Sec-  
9           retary shall reduce the amount of payments  
10          made under the grant under subsection (a) to  
11          the eligible entity by an amount equal to the  
12          fair market value of any supplies, equipment, or  
13          services provided by the Secretary and the costs  
14          of detailing personnel (including pay, allow-  
15          ances, and travel expenses) under subparagraph  
16          (A). The Secretary shall, for the payment of ex-  
17          penses incurred in complying with such request,  
18          expend the amounts withheld.

19          “(j) EVALUATIONS AND REPORT.—

20                 “(1) EVALUATIONS.—The Secretary shall, di-  
21                 rectly or through contracts with public or private en-  
22                 tities, provide for annual evaluations of programs  
23                 carried out pursuant to this section. Such evalua-  
24                 tions shall include evaluations of the extent to which

1 eligible entities carrying out such programs are in  
2 compliance with subsection (a)(2).

3 “(2) REPORT TO CONGRESS.—The Secretary  
4 shall, not later than 1 year after the date on which  
5 amounts are first appropriated to carry out this sec-  
6 tion, and annually thereafter, submit to Congress, a  
7 report summarizing evaluations carried out pursuant  
8 to paragraph (1) during the preceding fiscal year  
9 and making such recommendations for administra-  
10 tive and legislative initiatives with respect to this  
11 section as the Secretary determines to be appro-  
12 priate.”.

13 (b) OPTIONAL MEDICAID COVERAGE OF CERTAIN  
14 PERSONS SCREENED AND FOUND TO HAVE COLORECTAL  
15 CANCER.—

16 (1) COVERAGE AS OPTIONAL CATEGORICALLY  
17 NEEDY GROUP.—

18 (A) IN GENERAL.—Section  
19 1902(a)(10)(A)(ii) of the Social Security Act  
20 (42 U.S.C. 1396a(a)(10)(A)(ii)) is amended—

21 (i) in subclause (XVIII), by striking

22 “or” at the end;

23 (ii) in subclause (XIX), by adding

24 “or” at the end; and

1 (iii) by adding at the end the fol-  
2 lowing:

3 “(XX) who are described in  
4 subsection (gg) (relating to cer-  
5 tain persons screened and found  
6 to need treatment from complica-  
7 tions from screening or have  
8 colorectal cancer);”.

9 (B) GROUP DESCRIBED.—Section 1902 of  
10 the Social Security Act (42 U.S.C. 1396a) is  
11 amended by adding at the end the following:

12 “(gg) Individuals described in this subsection are in-  
13 dividuals who—

14 “(1) are not described in subsection  
15 (a)(10)(A)(i);

16 “(2) have not attained age 65;

17 “(3) have been screened for colorectal cancer  
18 and need treatment for complications due to screen-  
19 ing or colorectal cancer; and

20 “(4) are not otherwise covered under creditable  
21 coverage, as defined in section 2701(c) of the Public  
22 Health Service Act.”.

23 (C) LIMITATION ON BENEFITS.—Section  
24 1902(a)(10) of the Social Security Act (42

1 U.S.C. 1396a(a)(10)) is amended in the matter  
2 following subparagraph (G)—

3 (i) by striking “and (XIV)” and in-  
4 serting “(XIV)”; and

5 (ii) by inserting “, and (XV) the med-  
6 ical assistance made available to an indi-  
7 vidual described in subsection (gg) who is  
8 eligible for medical assistance only because  
9 of subparagraph (A)(10)(ii)(XX) shall be  
10 limited to medical assistance provided dur-  
11 ing the period in which such an individual  
12 requires treatment for complications due to  
13 screening or colorectal cancer” before the  
14 semicolon.

15 (D) CONFORMING AMENDMENTS.—Section  
16 1905(a) of the Social Security Act (42 U.S.C.  
17 1396d(a)) is amended in the matter preceding  
18 paragraph (1)—

19 (i) in clause (xii), by striking “or” at  
20 the end;

21 (ii) in clause (xiii), by adding “or” at  
22 the end; and

23 (iii) by inserting after clause (xiii) the  
24 following:

1                   “(xiv) individuals described in  
2                   section 1902(gg),”.

3                   (2) PRESUMPTIVE ELIGIBILITY.—

4                   (A) IN GENERAL.—Title XIX of the Social  
5                   Security Act (42 U.S.C. 1396 et seq.) is  
6                   amended by inserting after section 1920B the  
7                   following:

8                   “OPTIONAL APPLICATION OF PRESUMPTIVE ELIGIBILITY  
9                   PROVISIONS FOR CERTAIN PERSONS WITH  
10                  COLORECTAL CANCER

11                  “SEC. 1920C. A State may elect to apply the provi-  
12                  sions of section 1920B to individuals described in section  
13                  1902(gg) (relating to certain colorectal cancer patients)  
14                  in the same manner as such section applies to individuals  
15                  described in section 1902(aa) (relating to certain breast  
16                  or cervical cancer patients).”.

17                  (B) CONFORMING AMENDMENTS.—

18                  (i) Section 1902(a)(47) of the Social  
19                  Security Act (42 U.S.C. 1396a(a)(47)) is  
20                  amended—

21                                 (I) by striking “and” after “sec-  
22                                 tion 1920” and inserting a comma;

23                                 (II) by striking “and” after  
24                                 “with such section” and inserting a  
25                                 comma; and

1 (III) by inserting before the  
2 semicolon at the end the following: “,  
3 and provide for making medical as-  
4 sistance available to individuals de-  
5 scribed in section 1920C during a pre-  
6 sumptive eligibility period in accord-  
7 ance with such section”.

8 (ii) Section 1903(u)(1)(d)(v) of such  
9 Act (42 U.S.C. 1396b(u)(1)(d)(v)) is  
10 amended—

11 (I) by striking “or for” and in-  
12 serting “, for”; and

13 (II) by inserting before the pe-  
14 riod the following: “, or for medical  
15 assistance provided to an individual  
16 described in section 1920C during a  
17 presumptive eligibility period under  
18 such section”.

19 (3) ENHANCED MATCH.—The first sentence of  
20 section 1905(b) of the Social Security Act (42  
21 U.S.C. 1396d(b)) is amended—

22 (A) by striking “and” before “(4)”; and

23 (B) by inserting before the period at the  
24 end the following: “, and (5) the Federal med-  
25 ical assistance percentage shall be equal to the

1 enhanced FMAP described in section 2105(b)  
2 with respect to medical assistance provided to  
3 individuals who are eligible for such assistance  
4 only on the basis of section  
5 1902(a)(10)(A)(ii)(XX)”.

6 (4) EFFECTIVE DATE.—The amendments made  
7 by this subsection apply to medical assistance for  
8 items and services furnished on or after the date  
9 that is 1 year after the date of enactment of this  
10 Act, without regard to whether final regulations to  
11 carry out such amendments have been promulgated  
12 by such date.

13 (c) MOBILE MEDICAL VAN GRANT PROGRAM.—

14 (1) IN GENERAL.—The Secretary of Health and  
15 Human Services (referred to in this subsection as  
16 the “Secretary”), acting through the Administrator  
17 of the Health Resources and Services Administra-  
18 tion, shall award grants to eligible entities for the  
19 development and implementation of a mobile medical  
20 van program that shall provide cancer screening  
21 services that receive an “A” or “B” recommendation  
22 by the U.S. Preventative Services Task Force of the  
23 Agency for Healthcare Research and Quality to com-  
24 munities that are underserved and suffer from bar-

1 riers to access to high quality cancer prevention  
2 care.

3 (2) ELIGIBLE ENTITIES.—To be eligible to re-  
4 ceive a grant under paragraph (1), and entity  
5 shall—

6 (A) be a consortium of public and private  
7 entities (such as academic medical centers, uni-  
8 versities, hospitals, and non profit organiza-  
9 tions);

10 (B) submit to the Secretary an application  
11 at such time, in such manner, and containing  
12 such information as the Secretary shall require,  
13 including—

14 (i) a description of the manner in  
15 which the applicant intends to use funds  
16 received under the grant;

17 (ii) a description of the manner in  
18 which the applicant will evaluate the im-  
19 pact and effectiveness of the health care  
20 services provided under the program car-  
21 ried out under the grant;

22 (iii) a plan for sustaining activities  
23 and services funded under the grant after  
24 Federal support for the program has  
25 ended;

1 (iv) a plan for the referral of patients  
2 to other health care facilities if additional  
3 services are needed;

4 (v) a protocol for the transfer of pa-  
5 tients in the event of a medical emergency;

6 (vi) a plan for advertising the services  
7 of the mobile medical van to the commu-  
8 nities targeted for health care services; and

9 (vii) a plan to educate patients about  
10 the availability of federally funded medical  
11 insurance programs for which such pa-  
12 tients, or their children, may qualify; and

13 (C) agree that amounts under the grant  
14 will be used to supplement, and not supplant,  
15 other funds (including in-kind contributions)  
16 used by the entity to carry out activities for  
17 which the grant is awarded.

18 (3) USE OF FUNDS.—An entity shall use  
19 amounts received under a grant under this sub-  
20 section to do any of the following:

21 (A) Purchase or lease a mobile medical  
22 van.

23 (B) Make repairs and provide maintenance  
24 for a mobile medical van.

1           (C) Purchase or lease telemedicine equip-  
2           ment that is reasonable and necessary to oper-  
3           ate the mobile medical van.

4           (D) Purchase medical supplies and medica-  
5           tion that are necessary to provide health care  
6           services on the mobile medical van.

7           (E) Retain medical professionals with ex-  
8           pertise and experience in providing cancer  
9           screening services to underserved communities  
10          to provide health care services on the mobile  
11          medical van.

12          (4) MATCHING REQUIREMENTS.—

13           (A) IN GENERAL.—With respect to the  
14           costs of a mobile medical van program to be  
15           carried out under a grant under this subsection,  
16           the grantee shall make available (directly or  
17           through donations from public or private enti-  
18           ties) non-Federal contributions toward such  
19           costs in an amount that is not less than the  
20           amount of the Federal funds provided under  
21           this grant.

22           (B) DETERMINATION OF AMOUNT CON-  
23           TRIBUTED.—Non-Federal contributions re-  
24           quired under subparagraph (A) may be in cash  
25           or in-kind, fairly evaluated, including plant,

1 equipment, or services. Amounts provided by  
2 the Federal Government, or services assisted or  
3 subsidized to any significant extent by the Fed-  
4 eral Government, may not be included in deter-  
5 mining the amount of such non-Federal con-  
6 tributions.

7 (C) WAIVER.—The Secretary may waive  
8 the requirement established in subparagraph  
9 (A) if—

10 (i) the Secretary determines that such  
11 waiver is justified; and

12 (ii) the Secretary publishes the ration-  
13 ale for such waiver in the Federal Register.

14 (D) RETURN OF FUNDS.—An entity that  
15 receives a grant under this section that fails to  
16 comply with subparagraph (A) shall return to  
17 the Secretary an amount equal to the difference  
18 between—

19 (i) the amount provided under the  
20 grant; and

21 (ii) the amount of matching funds ac-  
22 tually provided by the grantee.

23 (5) CONSIDERATIONS IN MAKING GRANTS.—In  
24 awarding grants under this subsection, the Secretary  
25 shall give preference to eligible entities—

1 (A) that will provide cancer screening serv-  
2 ices in underserved areas; and

3 (B) that on the date on which the grant is  
4 awarded, have a mobile medical van that is non-  
5 functioning due to the need for necessary me-  
6 chanical repairs.

7 (6) LIMITATION ON DURATION AND AMOUNT OF  
8 GRANT.—A grant under this subsection shall be for  
9 a 2-year period, except that the Secretary may waive  
10 such limitation and extend the grant period by an  
11 additional year. The amount awarded to an entity  
12 under such grant for a fiscal year shall not exceed  
13 \$200,000.

14 (7) EVALUATION.—Not later than 1 year after  
15 the date on which a grant awarded to an entity  
16 under this subsection expires, the entity shall submit  
17 to the Secretary the results of an evaluation to be  
18 conducted by the entity concerning the effectiveness  
19 of the program carried out under the grant.

20 (8) REPORT.—Not later than 18 months after  
21 grants are first awarded under this subsection, the  
22 Secretary shall submit to the Committee on Appro-  
23 priations of the Senate and the Committee on Ap-  
24 propriations of the House of Representatives a re-

1 port on the results of activities carried out with  
2 amounts received under such grants.

3 (9) DEFINITIONS.—In this section:

4 (A) MOBILE MEDICAL VAN.—The term  
5 “mobile medical van” means a mobile vehicle  
6 that is equipped to provide non-urgent medical  
7 services and health care counseling to patients  
8 in underserved areas.

9 (B) UNDERSERVED AREA.—The term “un-  
10 derserved area”, with respect to the location of  
11 patients receiving medical treatment, means a  
12 “medically underserved community” as defined  
13 in section 799B(6) of the Public Health Service  
14 Act (42 U.S.C. 295p(6)).

15 (d) ACCESS TO PREVENTION AND EARLY DETECTION  
16 FOR CERTAIN CANCERS.—

17 (1) CANCER GENOME ATLAS.—The Secretary of  
18 Health and Human Services, acting through the Na-  
19 tional Cancer Institute, shall provide for the inclu-  
20 sion of cancers with survival rates of less than 25  
21 percent at 5 years in the Cancer Genome Atlas.

22 (2) PHASE IN.—The Director of the National  
23 Cancer Institute shall phase in the participation of  
24 cancers described in paragraph (1) in the Cancer  
25 Genome Atlas Consortium.

1           (3) WORKING GROUPS.—The Secretary of  
2 Health and Human Services, acting through the Na-  
3 tional Cancer Institute, shall establish formal work-  
4 ing groups for cancers with survival rates of less  
5 than 25 percent at 5 years within the Early Detec-  
6 tion Research Network.

7           (4) COMPUTER ASSISTED DIAGNOSTIC, SUR-  
8 GICAL, TREATMENT AND DRUG TESTING INNOVA-  
9 TIONS TO REDUCE MORTALITY FROM CANCERS.—  
10 The Director of the National Institute of Biomedical  
11 Imaging and Bioengineering shall ensure that the  
12 Quantum Grant Program and the Image Guided  
13 Interventions programs expedite the development of  
14 computer assisted diagnostic, surgical, treatment  
15 and drug testing innovations to reduce mortality  
16 from cancers with survival rates of less than 25 per-  
17 cent at 5 years.

18 **SEC. 7. EARLY RECOGNITION AND TREATMENT OF CANCER**  
19 **THROUGH USE OF BIOMARKERS.**

20           (a) PROMOTION OF THE DISCOVERY AND DEVELOP-  
21 MENT OF BIOMARKERS.—

22           (1) IN GENERAL.—The Secretary of Health and  
23 Human Services (referred to in this section as the  
24 “Secretary”), in consultation with appropriate Fed-  
25 eral agencies including the National Institutes of

1 Health, the National Cancer Institute, the Food and  
2 Drug Administration, and the National Institute of  
3 Standards and Technology, and extramural experts  
4 as appropriate, shall establish and coordinate a pro-  
5 gram to award contracts to eligible entities to sup-  
6 port the development of innovative biomarker dis-  
7 covery technologies. All activities under this section  
8 shall be consistent with and complement the ongoing  
9 efforts of the Oncology Biomarker Qualification Ini-  
10 tiative and the Reagan-Udall Foundation of the  
11 Food and Drug Administration.

12 (2) LEAD AGENCY.—Not later than 2 years  
13 after the date of enactment of this Act, the Sec-  
14 retary shall designate a lead Federal agency to ad-  
15 minister and coordinate the program established  
16 under paragraph (1).

17 (3) ELIGIBILITY.—To be eligible to enter into a  
18 contract under paragraph (1), an entity shall submit  
19 to the Secretary an application at such time, in such  
20 manner, and containing such information as the Sec-  
21 retary may require. Such information shall be suffi-  
22 cient to enable the Secretary to—

23 (A) promote the scientific review of such  
24 contracts in a timely fashion; and

1           (B) contain the capacity to perform the  
2           necessary analysis of contract applications, in-  
3           cluding determinations as to the intellectual ex-  
4           pertise of applicants.

5           (4) REQUIREMENT.—In awarding contracts  
6           under this subsection, the lead agency shall consider  
7           whether the research involved will result in the de-  
8           velopment of quantifiable biomarkers of cell sig-  
9           naling pathways that will have the broadest applica-  
10          bility across different tumor types or different dis-  
11          eases.

12          (5) INTERNATIONAL CONSORTIA.—The Sec-  
13          retary shall designate one of the Federal entities de-  
14          scribed in paragraph (1) to establish an inter-  
15          national private-public consortia to develop and  
16          share methods and precompetitive data on the vali-  
17          dation and qualification of cancer biomarkers for  
18          specific uses.

19          (b) CLINICAL STUDY GUIDELINES.—Not later than  
20          1 year after the date of enactment of this Act, the Com-  
21          missioner of Food and Drugs, the Administrator of the  
22          Centers for Medicare & Medicaid Services, and the Direc-  
23          tor of the National Cancer Institute shall jointly develop  
24          guidelines for the conduct of clinical studies designed to  
25          generate clinical data relating to cancer care and treat-

1 ment biomarkers that is adequate for review by each such  
2 Federal entity. Such guidelines shall be designed to assist  
3 in optimizing clinical study design and to strengthen the  
4 evidence base for evaluations of studies related to cancer  
5 biomarkers.

6 (c) DEMONSTRATION PROJECT.—

7 (1) IN GENERAL.—The Secretary, in consulta-  
8 tion with the Commissioner of Food and Drugs and  
9 the Administrator of the Agency for Healthcare Re-  
10 search and Quality, shall carry out a demonstration  
11 project that provides for a limited regional assess-  
12 ment of biomarker tests to facilitate the controlled  
13 and limited use of a risk assessment measure with  
14 an intervention that may consist of a biomarker test.

15 (2) PROCEDURES.—As a component of the  
16 demonstration project under paragraph (1), the  
17 Commissioner of Food and Drugs, in consultation  
18 with other relevant agencies, shall establish proce-  
19 dures that independent research entities shall follow  
20 in conducting high quality assessments of efficacy of  
21 biomarker tests.

22 (d) POSTMARKET SURVEILLANCE.—The Food and  
23 Drug Administration and the Centers for Medicare &  
24 Medicaid Services shall assess quality and accuracy of bio-  
25 marker tests through appropriate postmarket surveillance

1 and other means, as necessary and appropriate to the mis-  
2 sion of each such agency.

3 (e) SENSE OF THE SENATE.—It is the sense of the  
4 Senate that the Commissioner of Food and Drugs and the  
5 Director of the National Cancer Institute should continue  
6 to place high priority upon the identification and use of  
7 biomarkers to—

8 (1) determine the role of genetic polymorphisms  
9 on drug activity and toxicity;

10 (2) establish effective strategies for selecting  
11 patients for treatment with specific drugs; and

12 (3) identify early biomarkers of clinical benefit.

13 (f) DEFINITION.—In this section, the term “bio-  
14 marker” means any characteristic that can be objectively  
15 measured and evaluated as an indicator of normal biologic  
16 processes, pathogenic processes, or pharmacological re-  
17 sponses to therapeutic interventions.

18 **SEC. 8. CANCER CLINICAL TRIALS.**

19 (a) COVERAGE FOR INDIVIDUALS PARTICIPATING IN  
20 APPROVED CANCER CLINICAL TRIALS.—

21 (1) ERISA AMENDMENT.—Subpart B of part 7  
22 of subtitle B of title I of the Employee Retirement  
23 Income Security Act of 1974 (29 U.S.C. 1185 et  
24 seq.) is amended by adding at the end the following:

1 **“SEC. 715. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**  
2 **APPROVED CANCER CLINICAL TRIALS.**

3 “(a) COVERAGE.—

4 “(1) IN GENERAL.—If a group health plan (or  
5 a health insurance issuer offering health insurance  
6 coverage in connection with the plan) provides cov-  
7 erage to a qualified individual (as defined in sub-  
8 section (b)), the plan or issuer—

9 “(A) may not deny the individual partici-  
10 pation in the clinical trial referred to in sub-  
11 section (b)(2);

12 “(B) subject to subsection (c), may not  
13 deny (or limit or impose additional conditions  
14 on) the coverage of routine patient costs for  
15 items and services furnished in connection with  
16 participation in the trial; and

17 “(C) may not discriminate against the in-  
18 dividual on the basis of the individual’s partici-  
19 pation in such trial.

20 “(2) EXCLUSION OF CERTAIN COSTS.—For pur-  
21 poses of paragraph (1)(B), subject to subparagraph  
22 (B), routine patient costs include all items and serv-  
23 ices consistent with the coverage provided in the  
24 plan (or coverage) that is typically covered for a  
25 qualified individual who is not enrolled in a clinical

1 trial and that was not necessitated solely because of  
2 the trial, except—

3 “(A) the investigational item, device or  
4 service, itself; or

5 “(B) items and services that are provided  
6 solely to satisfy data collection and analysis  
7 needs and that are not used in the direct clin-  
8 ical management of the patient.

9 “(3) USE OF IN-NETWORK PROVIDERS.—If one  
10 or more participating providers is participating in a  
11 clinical trial, nothing in paragraph (1) shall be con-  
12 strued as preventing a plan or issuer from requiring  
13 that a qualified individual participate in the trial  
14 through such a participating provider if the provider  
15 will accept the individual as a participant in the  
16 trial.

17 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-  
18 poses of subsection (a), the term ‘qualified individual’  
19 means an individual who is a participant or beneficiary  
20 in a group health plan and who meets the following condi-  
21 tions:

22 “(1)(A) The individual has been diagnosed with  
23 cancer.

1           “(B) The individual is eligible to participate in  
2           an approved clinical trial according to the trial pro-  
3           tocol with respect to treatment of such illness.

4           “(2) Either—

5                   “(A) the referring health care professional  
6                   is a participating health care provider and has  
7                   concluded that the individual’s participation in  
8                   such trial would be appropriate based upon the  
9                   individual meeting the conditions described in  
10                  paragraph (1); or

11                   “(B) the participant or beneficiary pro-  
12                   vides medical and scientific information estab-  
13                   lishing that the individual’s participation in  
14                   such trial would be appropriate based upon the  
15                   individual meeting the conditions described in  
16                  paragraph (1).

17           “(c) LIMITATIONS ON COVERAGE.—This section shall  
18           not be construed to require a group health plan, or a  
19           health insurance issuer in connection with a group health  
20           plan, to provide benefits for routine patient care services  
21           provided outside of the plan’s (or coverage’s) health care  
22           provider network unless out-of-network benefits are other-  
23           wise provided under the plan (or coverage).

24           “(d) APPROVED CLINICAL TRIAL DEFINED.—

1           “(1) IN GENERAL.—In this section, the term  
2           ‘approved clinical trial’ means a phase I, phase II,  
3           phase III, or phase IV clinical trial that relates to  
4           the prevention and treatment of cancer (including  
5           related symptoms) and is described in any of the fol-  
6           lowing subparagraphs:

7                   “(A) FEDERALLY FUNDED TRIALS.—The  
8                   study or investigation is approved or funded  
9                   (which may include funding through in-kind  
10                   contributions) by one or more of the following:

11                           “(i) The National Institutes of  
12                           Health.

13                           “(ii) The Centers for Disease Control  
14                           and Prevention.

15                           “(iii) The Agency for Health Care Re-  
16                           search and Quality.

17                           “(iv) The Centers for Medicare &  
18                           Medicaid Services.

19                           “(v) cooperative group or center of  
20                           any of the entities described in clauses (i)  
21                           through (iv) or the Department of Defense  
22                           or the Department of Veterans Affairs.

23                           “(vi) A qualified non-governmental re-  
24                           search entity identified in the guidelines

1 issued by the National Institutes of Health  
2 for center support grants.

3 “(vii) Any of the following if the con-  
4 ditions described in paragraph (2) are met:

5 “(I) The Department of Veterans  
6 Affairs.

7 “(II) The Department of De-  
8 fense.

9 “(III) The Department of En-  
10 ergy.

11 “(B) The study or investigation is con-  
12 ducted under an investigational new drug appli-  
13 cation reviewed by the Food and Drug Adminis-  
14 tration.

15 “(C) The study or investigation is a drug  
16 trial that is exempt from having such an inves-  
17 tigational new drug application.

18 “(2) CONDITIONS FOR DEPARTMENTS.—The  
19 conditions described in this paragraph, for a study  
20 or investigation conducted by a Department, are  
21 that the study or investigation has been reviewed  
22 and approved through a system of peer review that  
23 the Secretary determines—

1           “(A) to be comparable to the system of  
2           peer review of studies and investigations used  
3           by the National Institutes of Health, and

4           “(B) assures unbiased review of the high-  
5           est scientific standards by qualified individuals  
6           who have no interest in the outcome of the re-  
7           view.

8           “(e) CONSTRUCTION.—Nothing in this section shall  
9           be construed to limit a plan’s or issuer’s coverage with  
10          respect to clinical trials.

11          “(f) PREEMPTION.—Notwithstanding any other pro-  
12          vision of this Act, nothing in this section shall preempt  
13          State laws that require a clinical trials policy for State  
14          regulated health insurance plans.”.

15          (2) CLERICAL AMENDMENTS.—

16                 (A) Section 732(a) of such Act (29 U.S.C.  
17                 1191a(a)) is amended by striking “section 711”  
18                 and inserting “sections 711 and 715”.

19                 (B) The table of contents in section 1 of  
20                 such Act is amended by inserting after the item  
21                 relating to section 714 the following new item:

                  “Sec. 715. Coverage for individuals participating in approved cancer clinical  
                  trials.”.

22          (b) CLINICAL TRIALS.—The Director of the National  
23          Cancer Institute shall—

1           (1) collaborate with the Director of the Na-  
2           tional Institutes of Health to engage in a campaign  
3           to educate the public on the value of clinical trials  
4           for oncology patients, which shall be implemented on  
5           the local level and focus on patient populations that  
6           traditionally are underrepresented in clinical trials;

7           (2) conduct an educational campaign for health  
8           care professionals to educate them to consider clin-  
9           ical trials as treatment options for their patients;  
10          and

11          (3) conduct research to document and dem-  
12          onstrate promising practices in cancer clinical trial  
13          recruitment and retention efforts, particularly for  
14          patient populations that traditionally are underrep-  
15          resented in clinical trials.

16 **SEC. 9. HEALTH PROFESSIONS WORKFORCE.**

17          (a) INCREASE NURSE FACULTY.—Section 811(f)(2)  
18          of the Public Health Service Act (42 U.S.C. 296j(f)(2))  
19          is amended to read as follows:

20                 “(2) BENEFITS FOR RETIRING NURSE OFFI-  
21                 CERS QUALIFIED AS FACULTY.—

22                         “(A) IN GENERAL.—The Secretary of De-  
23                         fense shall provide to any individual described  
24                         in subparagraph (B) the payment of retired or  
25                         retirement pay without reduction based on re-

1 receipt of pay or other compensation from the in-  
2 stitution of higher education concerned.

3 “(B) COVERED INDIVIDUALS.—An indi-  
4 vidual described in this subparagraph is an in-  
5 dividual who—

6 “(i) is retired from the Armed Forces  
7 after service as a commissioned officer in  
8 the nurse corps of the Armed Forces;

9 “(ii) holds a graduate degree in nurs-  
10 ing; and

11 “(iii) serves as a part- or full-time  
12 faculty member of an accredited school of  
13 nursing.

14 “(C) NURSE CORPS.—Any accredited  
15 school of nursing that employs a retired nurse  
16 officer as faculty under this paragraph shall  
17 agree to provide financial assistance to individ-  
18 uals undertaking an educational program at  
19 such school leading to a degree in nursing who  
20 agree, upon completion of such program, to ac-  
21 cept a commission as an officer in the nurse  
22 corps of the Armed Forces.”.

23 (b) ONCOLOGY WORKFORCE.—

24 (1) STUDY.—The Secretary of Health and  
25 Human Services (referred to in this subsection as

1 the “Secretary”) shall conduct a study on the cur-  
2 rent and future cancer care workforce needs in the  
3 following areas:

4 (A) Cancer research.

5 (B) Care and treatment of cancer patients  
6 and survivors.

7 (C) Quality of life, symptom management,  
8 and pain management.

9 (D) Early detection and diagnosis.

10 (E) Cancer prevention.

11 (F) Genetic testing, counseling, and ethical  
12 considerations related to such testing.

13 (G) Diversity and appropriate care for dis-  
14 parity populations.

15 (H) Palliative and end-of-life care.

16 (2) REPORT.—Not later than 1 year after the  
17 date of enactment of this Act, the Secretary shall  
18 submit to Congress a report that describes the find-  
19 ings of the study conducted under paragraph (2).

20 **SEC. 10. PATIENT NAVIGATOR PROGRAM.**

21 Section 340A of the Public Health Service Act (42  
22 U.S.C. 256a) is amended—

23 (1) in subsection (e), by adding at the end the  
24 following:

1           “(3) MINIMUM CORE PROFICIENCIES.—The  
 2 Secretary shall not award a grant to an entity under  
 3 this section unless such entity provides assurances  
 4 that patient navigators recruited, assigned, trained,  
 5 or employed using grant funds meet minimum core  
 6 proficiencies that are tailored for the main focus or  
 7 intervention of the navigation program involved.”;  
 8 and

9           (2) in subsection (m)—

10           (A) in paragraph (1), by inserting before  
 11 the period the following “, and such sums as  
 12 may be necessary for each of fiscal years 2011  
 13 through 2015.”; and

14           (B) in paragraph (2), by striking “2010”  
 15 and replacing with “2015.”

16 **SEC. 11. CANCER CARE AND COVERAGE UNDER MEDICAID**  
 17 **AND MEDICARE.**

18           (a) COVERAGE OF ROUTINE COSTS ASSOCIATED  
 19 WITH CLINICAL TRIALS UNDER MEDICARE.—

20           (1) COVERAGE UNDER PART A.—Section 1814  
 21 of the Social Security Act (42 U.S.C. 1395f) is  
 22 amended by adding at the end the following new  
 23 subsection:

24           “(m) COVERAGE OF ROUTINE COSTS ASSOCIATED  
 25 WITH CLINICAL TRIALS.—The Secretary shall not exclude

1 from payment for items and services provided under a  
2 clinical trial payment for coverage of routine costs of care  
3 (as defined by the Secretary) furnished to an individual  
4 entitled to benefits under this part who participates in  
5 such a trial to the extent the Secretary provides payment  
6 for such costs as of the date of enactment of this sub-  
7 section.”.

8           (2) COVERAGE UNDER PART B.—Section  
9           1833(w) of the Social Security Act (42 U.S.C.  
10           1395l(w)), as added by section 184 of the Medicare  
11           Improvements for Patients and Providers Act of  
12           2008 (Public Law 110–275), is amended—

13                   (A) by striking “PAYMENT.—The Sec-  
14                   retary” and inserting “PAYMENT AND COV-  
15                   ERAGE OF ROUTINE COSTS ASSOCIATED WITH  
16                   CLINICAL TRIALS.—

17                   “(1) METHODS OF PAYMENT.—Subject to para-  
18                   graph (2), the Secretary”; and

19                   (B) by adding at the end the following new  
20                   paragraph:

21                   “(2) COVERAGE OF ROUTINE COSTS ASSOCI-  
22                   ATED WITH CLINICAL TRIALS.—The Secretary shall  
23                   not exclude from payment for items and services  
24                   provided under a clinical trial payment for coverage  
25                   of routine costs of care (as defined by the Secretary)

1 furnished to an individual enrolled under this part  
2 who participates in such a trial to the extent the  
3 Secretary provides payment for such costs as of the  
4 date of enactment of this subsection.”.

5 (3) PROVIDER OUTREACH.—The Secretary of  
6 Health and Human Services, acting through the Ad-  
7 ministrator of the Centers for Medicare & Medicaid  
8 Services, shall conduct an outreach campaign to pro-  
9 viders of services and suppliers under the Medicare  
10 program under title XVIII of the Social Security Act  
11 regarding coverage of routine costs of care furnished  
12 to Medicare beneficiaries participating in clinical  
13 trials in accordance with sections 1814(m) and  
14 1833(w)(2) of the Social Security Act (as added by  
15 paragraphs (1) and (2), respectively).

16 (b) DEMONSTRATION PROJECT TO PROVIDE COM-  
17 PREHENSIVE CANCER CARE PLANNING SERVICES UNDER  
18 MEDICARE.—

19 (1) IN GENERAL.—Beginning not later than  
20 180 days after the date of enactment of this Act, the  
21 Secretary of Health and Human Services (referred  
22 to in this subsection as the “Secretary”) shall con-  
23 duct a 3-year demonstration project (referred to in  
24 this subsection as the “demonstration project”)   
25 under title XVIII of the Social Security Act (42

1 U.S.C. 1395 et seq.) under which payment for com-  
2 prehensive cancer care planning services furnished  
3 by eligible entities shall be made.

4 (2) COMPREHENSIVE CANCER CARE PLANNING  
5 SERVICES.—For purposes of this subsection, the  
6 term “comprehensive cancer care planning services”  
7 means—

8 (A) with respect to an individual who is di-  
9 agnosed with cancer, the development of a plan  
10 of care that—

11 (i) details, to the greatest extent prac-  
12 ticable, all aspects of the care to be pro-  
13 vided to the individual, with respect to the  
14 treatment of such cancer, including any  
15 curative treatment and comprehensive  
16 symptom management (such as palliative  
17 care) involved;

18 (ii) is documented in the patient’s  
19 medical record and furnished to the indi-  
20 vidual in person within a period specified  
21 by the Secretary that is as soon as prac-  
22 ticable after the date on which the indi-  
23 vidual is so diagnosed;

24 (iii) is furnished, to the greatest ex-  
25 tent practicable, in a form that appro-

1           priately takes into account cultural and  
2           linguistic needs of the individual in order  
3           to make the plan accessible to the indi-  
4           vidual; and

5                   (iv) is in accordance with standards  
6           determined by the Secretary to be appro-  
7           priate;

8           (B) with respect to an individual for whom  
9           a plan of care has been developed under sub-  
10          paragraph (A), the revision of such plan of care  
11          as necessary to account for any substantial  
12          change in the condition of the individual, if  
13          such revision—

14                   (i) is in accordance with clauses (i)  
15                   and (iii) of such subparagraph; and

16                   (ii) is documented in the patient's  
17                   medical record and furnished to the indi-  
18                   vidual within a period specified by the Sec-  
19                   retary that is as soon as practicable after  
20                   the date of such revision;

21           (C) with respect to an individual who has  
22           completed the primary treatment for cancer, as  
23           defined by the Secretary (such as completion of  
24           chemotherapy or radiation treatment), the de-

1           velopment of a follow-up cancer care plan  
2           that—

3                   (i) describes the elements of the pri-  
4                   mary treatment, including symptom man-  
5                   agement, furnished to such individual;

6                   (ii) provides recommendations for the  
7                   subsequent care of the individual with re-  
8                   spect to the cancer involved;

9                   (iii) identifies, to the greatest extent  
10                  possible, a healthcare provider to oversee  
11                  subsequent care and follow-up as needed  
12                  and to whom the individual may direct  
13                  questions or concerns;

14                  (iv) is documented in the patient's  
15                  medical record and furnished to the indi-  
16                  vidual in person within a period specified  
17                  by the Secretary that is as soon as prac-  
18                  ticable after the completion of such pri-  
19                  mary treatment;

20                  (v) is furnished, to the greatest extent  
21                  practicable, in a form that appropriately  
22                  takes into account cultural and linguistic  
23                  needs of the individual in order to make  
24                  the plan accessible to the individual; and

1 (vi) is in accordance with standards  
2 determined by the Secretary to be appro-  
3 priate; and

4 (D) with respect to an individual for whom  
5 a follow-up cancer care plan has been developed  
6 under subparagraph (C), the revision of such  
7 plan as necessary to account for any substantial  
8 change in the condition of the individual, if  
9 such revision—

10 (i) is in accordance with clauses (i),  
11 (ii), and (iv) of such subparagraph; and

12 (ii) is documented in the patient's  
13 medical record and furnished to the indi-  
14 vidual within a period specified by the Sec-  
15 retary that is as soon as practicable after  
16 the date of such revision.

17 (3) QUALIFICATIONS AND SELECTION OF ELIGI-  
18 BLE ENTITIES.—

19 (A) QUALIFICATIONS.—For purposes of  
20 this subsection, the term “eligible entity”  
21 means a physician office, hospital, outpatient  
22 department, or community health center. Quali-  
23 fied providers include physicians, nurse practi-  
24 tioners, and other health care professionals who

1 develop or revise a comprehensive cancer care  
2 plan.

3 (B) SELECTION.—The Secretary shall se-  
4 lect at least 6 eligible entities to participate in  
5 the demonstration project. Such entities shall  
6 be selected so that the demonstration project is  
7 conducted in different regions across the United  
8 States, in urban and rural locations, and across  
9 various sites of care.

10 (4) EVALUATION AND REPORT.—

11 (A) EVALUATION.—The Secretary shall  
12 conduct a comprehensive evaluation of the dem-  
13 onstration project to determine—

14 (i) the effectiveness of the project in  
15 improving patient outcomes and increasing  
16 efficiency and reducing error in the deliv-  
17 ery of cancer care;

18 (ii) the cost of providing comprehen-  
19 sive cancer care planning services; and

20 (iii) the potential savings to the Medi-  
21 care program demonstrated by the project,  
22 including the utility of the demonstration  
23 project in reducing duplicative cancer care  
24 services and decreasing the use of unneces-  
25 sary medical services for cancer patients.

1 (B) REPORT.—

2 (i) IN GENERAL.—Not later than the  
3 date that is 1 year after the date on which  
4 the demonstration project concludes, the  
5 Secretary shall submit to Congress a re-  
6 port on the evaluation conducted under  
7 subparagraph (A).

8 (ii) PREVENTION OF FRAUDULENT  
9 BILLING.—The Secretary shall consult  
10 with the Medicare Fraud Task Force in  
11 the design of the demonstration project to  
12 identify and address concerns about fraud-  
13 ulent billing of comprehensive cancer care  
14 planning services. The Secretary's actions  
15 on prevention of fraud shall be included in  
16 the report under this subparagraph.

17 (iii) DEMONSTRATION OF SUBSTAN-  
18 TIAL BENEFIT.—If the evaluation con-  
19 ducted under subparagraph (A) indicates  
20 substantial benefit from the demonstration  
21 project, as measured by improved patient  
22 outcomes and more efficient delivery of  
23 healthcare services, such report shall in-  
24 clude a legislative proposal to Congress for  
25 coverage of comprehensive cancer care

1 planning services under the Medicare pro-  
2 gram, developed on the basis of informa-  
3 tion from the demonstration project and in  
4 consultation with the Administrator of the  
5 Agency for Healthcare Research and Qual-  
6 ity, the Director of the Institute of Medi-  
7 cine, and the Director of the Centers for  
8 Disease Control and Prevention.

9 (iv) NO SUBSTANTIAL BENEFIT.—If  
10 the evaluation conducted under subpara-  
11 graph (A) does not indicate substantial  
12 benefit from the demonstration project, as  
13 measured by improved patient outcomes  
14 and more efficient delivery of healthcare  
15 services, such report shall document, to the  
16 extent possible, the reasons why the dem-  
17 onstration project did not result in sub-  
18 stantial benefit, and such report—

19 (I) shall include a legislative pro-  
20 posal for Medicare coverage of com-  
21 prehensive cancer care planning serv-  
22 ices in a manner that will lead to sub-  
23 stantial benefit; or

24 (II) shall include recommenda-  
25 tions for additional demonstration

1 projects or studies to evaluate the de-  
2 livery of comprehensive cancer care  
3 planning services in a manner that  
4 will lead to substantial benefit and  
5 eventual Medicare coverage.

6 (5) FUNDING.—The Secretary shall provide for  
7 the transfer from the Federal Supplementary Med-  
8 ical Insurance Trust Fund established under section  
9 1841 of the Social Security Act (42 U.S.C. 1395t)  
10 of the amount necessary to carry out the demonstra-  
11 tion project and report under this subsection.

12 (c) PROMOTING CESSATION OF TOBACCO USE  
13 UNDER MEDICAID.—

14 (1) SERVICES DESCRIBED.—Section 1905 of  
15 the Social Security Act (42 U.S.C. 1396d) is amend-  
16 ed by adding at the end the following new sub-  
17 section:

18 “(y)(1) Subject to paragraph (2), for purposes of this  
19 title, the term ‘counseling and pharmacotherapy for ces-  
20 sation of tobacco use’ means diagnostic, therapy, and  
21 counseling services and pharmacotherapy (including the  
22 coverage of prescription and nonprescription tobacco ces-  
23 sation agents approved by the Food and Drug Administra-  
24 tion) for cessation of tobacco use for individuals who use

1 tobacco products or who are being treated for tobacco use  
 2 which are furnished—

3 “(A) by or under the supervision of a physician;

4 or

5 “(B) by any other health care professional  
 6 who—

7 “(i) is legally authorized to furnish such  
 8 services under State law (or the State regu-  
 9 latory mechanism provided by State law) of the  
 10 State in which the services are furnished; and

11 “(ii) is authorized to receive payment for  
 12 other medical assistance under this title or is  
 13 designated by the Secretary for this purpose.

14 “(2) Such term is limited to—

15 “(A) services recommended in ‘Treating To-  
 16 bacco Use and Dependence: A Clinical Practice  
 17 Guideline’, published by the Public Health Service in  
 18 June 2000, or any subsequent modification of such  
 19 Guideline; and

20 “(B) such other services that the Secretary rec-  
 21 ognizes to be effective.”.

22 (2) DROPPING EXCEPTION FROM MEDICAID  
 23 PRESCRIPTION DRUG COVERAGE FOR TOBACCO CES-  
 24 SATION MEDICATIONS.—Section 1927(d)(2) of the

1 Social Security Act (42 U.S.C. 1396r–8(d)(2)) is  
2 amended—

3 (A) by striking subparagraph (E);

4 (B) by redesignating subparagraphs (F)  
5 through (K) as subparagraphs (E) through (J),  
6 respectively; and

7 (C) in subparagraph (F) (as redesignated  
8 by subparagraph (B)), by inserting before the  
9 period at the end the following: “, except agents  
10 approved by the Food and Drug Administration  
11 for purposes of promoting, and when used to  
12 promote, tobacco cessation”.

13 (3) REQUIRING COVERAGE OF TOBACCO CES-  
14 SATION COUNSELING AND PHARMACOTHERAPY  
15 SERVICES FOR PREGNANT WOMEN.—Section  
16 1905(a)(4) of the Social Security Act (42 U.S.C.  
17 1396d(a)(4)) is amended—

18 (A) by striking “and” before “(C)”; and

19 (B) by inserting before the semicolon at  
20 the end the following: “; and (D) counseling  
21 and pharmacotherapy for cessation of tobacco  
22 use for pregnant women”.

23 (4) REMOVAL OF COST-SHARING FOR TOBACCO  
24 CESSATION COUNSELING AND PHARMACOTHERAPY  
25 SERVICES FOR PREGNANT WOMEN.—

1 (A) IN GENERAL.—Section 1916 of the So-  
2 cial Security Act (42 U.S.C. 1396o) is amended  
3 in each of subsections (a)(2)(B) and (b)(2)(B),  
4 by inserting “, and counseling and  
5 pharmacotherapy for cessation of tobacco use”  
6 after “complicate the pregnancy”.

7 (B) CONFORMING AMENDMENT.—Section  
8 1916A(b)(3)(B)(iii) of such Act (42 U.S.C.  
9 1396o–1(b)(3)(B)(iii)) is amended by inserting  
10 “, and counseling and pharmacotherapy for ces-  
11 sation of tobacco use” after “complicate the  
12 pregnancy”.

13 (5) EFFECTIVE DATE.—The amendments made  
14 by this subsection take effect 1 year after the date  
15 of enactment of this Act and apply to medical assist-  
16 ance provided under a State Medicaid program on or  
17 after that date.

18 **SEC. 12. CANCER SURVIVORSHIP AND COMPLETE RECOV-**  
19 **ERY INITIATIVES.**

20 (a) CANCER SURVIVORSHIP PROGRAMS.—Subpart 1  
21 of part C of title IV of the Public Health Service Act (42  
22 U.S.C. 285 et seq.), as amended by subsection (c), is  
23 amended by adding at the end the following:

1 **“SEC. 417E. EXPANSION OF CANCER SURVIVORSHIP ACTIVI-**  
2 **TIES.**

3 “(a) EXPANSION OF ACTIVITIES.—The Director of  
4 the Institute shall coordinate the activities of the National  
5 Institutes of Health with respect to cancer survivorship,  
6 including childhood cancer survivorship.

7 “(b) PRIORITY AREAS.—In carrying out subsection  
8 (a), the Director of the Institute shall give priority to the  
9 following:

10 “(1) Comprehensive assessment of the preva-  
11 lence and etiology of late effects of cancer treatment,  
12 including physical, neurocognitive, and psychosocial  
13 late effects. Such assessment shall include—

14 “(A) development of a system for patient  
15 tracking and analysis;

16 “(B) establishment of a system of tissue  
17 collection, banking, and analysis for childhood  
18 cancers, using guidelines from the Office of  
19 Biorepositories and Biospecimen Research; and

20 “(C) coordination of, and resources for, as-  
21 sessment and data collection.

22 “(2) Identification of risk and protective factors  
23 related to the development of late effects of cancer.

24 “(3) Identification of predictors of  
25 neurocognitive and psychosocial outcomes, including  
26 quality of life, in cancer survivors and identification

1 of qualify of life and other outcomes in family mem-  
2 bers.

3 “(4) Development and implementation of inter-  
4 vention studies for cancer survivors and their fami-  
5 lies, including studies focusing on—

6 “(A) preventive interventions during treat-  
7 ment;

8 “(B) interventions to lessen the impact of  
9 late effects of cancer treatment;

10 “(C) rehabilitative or remediative interven-  
11 tions following cancer treatment;

12 “(D) interventions to promote health be-  
13 haviors in long-term survivors; and

14 “(E) interventions to improve health care  
15 utilization and access to linguistically and cul-  
16 turally competent long-term follow-up care for  
17 childhood cancer survivors in minority and  
18 other medically underserved populations.

19 “(c) GRANTS FOR RESEARCH ON CAUSES OF  
20 HEALTH DISPARITIES IN CHILDHOOD CANCER SURVI-  
21 VORSHIP.—

22 “(1) GRANTS.—The Director of NIH, acting  
23 through the Director of the Institute, shall make  
24 grants to entities to conduct research relating to—

1           “(A) needs and outcomes of pediatric can-  
2           cer survivors within minority or other medically  
3           underserved populations; and

4           “(B) health disparities in cancer survivor-  
5           ship outcomes within minority or other medi-  
6           cally underserved populations.

7           “(2) BALANCED APPROACH.—In making grants  
8           for research under paragraph (1)(A) on pediatric  
9           cancer survivors within minority populations, the Di-  
10          rector of NIH shall ensure that such research ad-  
11          dresses both the physical and the psychological  
12          needs of such survivors.

13          “(3) HEALTH DISPARITIES.—In making grants  
14          for research under paragraph (1)(B) on health dis-  
15          parities in cancer survivorship outcomes within mi-  
16          nority populations, the Director of NIH shall ensure  
17          that such research examines each of the following:

18                 “(A) Key adverse events after childhood  
19                 cancer.

20                 “(B) Assessment of health and quality of  
21                 life in childhood cancer survivors.

22                 “(C) Barriers to follow-up care to child-  
23                 hood cancer survivors.

24                 “(D) Data regarding the type of provider  
25                 and treatment facility where the patient re-

1           ceived cancer treatment and how the provider  
2           and treatment facility may impact treatment  
3           outcomes and survivorship.

4           “(d) RESEARCH TO EVALUATE FOLLOW-UP CARE  
5 FOR CHILDHOOD CANCER SURVIVORS.—The Director of  
6 NIH shall conduct or support research to evaluate systems  
7 of follow-up care for childhood cancer survivors, with spe-  
8 cial emphasis given to—

9           “(1) transitions in care for childhood cancer  
10 survivors;

11           “(2) those professionals who should be part of  
12 care teams for childhood cancer survivors;

13           “(3) training of professionals to provide linguisti-  
14 cally and culturally competent follow-up care to  
15 childhood cancer survivors; and

16           “(4) different models of follow-up care.”.

17 (b) COMPLETE RECOVERY CARE.—

18           (1) DEFINITION.—In this subsection, the term  
19 “complete recovery care” means care intended to ad-  
20 dress the secondary effects of cancer and its treat-  
21 ment, including late, psychosocial, neurocognitive,  
22 psychiatric, psychological, physical, and other effects  
23 associated with cancer and cancer survivorship be-  
24 yond the impairment of bodily function directly  
25 caused by the disease, as described in the report by

1 the Institute of Medicine of the National Academies  
2 entitled “Cancer Care for the Whole Patient”.

3 (2) EXPANSION OF ACTIVITIES.—The Secretary  
4 of Health and Human Services (referred to in this  
5 subsection as the “Secretary”) shall—

6 (A) coordinate the activities of Federal  
7 agencies, including the National Institutes of  
8 Health, the National Cancer Institute, the Na-  
9 tional Institute of Mental Health, the Centers  
10 for Medicare and Medicaid Services, the Vet-  
11 erans Health Administration, the Centers for  
12 Disease Control and Prevention, the Food and  
13 Drug Administration, the Agency for  
14 Healthcare Research and Quality, the Office for  
15 Human Research Protections, and the Health  
16 Resources and Services Administration to im-  
17 prove the provision of complete recovery care in  
18 the treatment of cancer; and

19 (B) solicit input from professional and pa-  
20 tient organizations, payors, and other relevant  
21 institutions and organizations regarding the  
22 status of provision of complete recovery care in  
23 the treatment of cancer.

24 (3) IMPROVING THE COMPLETE RECOVERY  
25 CARE WORKFORCE.—

1           (A) CHRONIC DISEASE WORKFORCE DE-  
2 VELOPMENT COLLABORATIVE.—The Secretary  
3 shall, not later than 1 year after the date of en-  
4 actment of this Act, convene a Workforce De-  
5 velopment Collaborative on Psychosocial Care  
6 During Chronic Medical Illness (referred to in  
7 this paragraph as the “Collaborative”). The  
8 Collaborative shall be a cross-specialty, multi-  
9 disciplinary group composed of educators, con-  
10 sumer and family advocates, and providers of  
11 psychosocial and biomedical health services.

12           (B) GOALS AND REPORT.—The Collabo-  
13 rative shall submit to the Secretary a report es-  
14 tablishing a plan to meet the following objec-  
15 tives for psychosocial care workforce develop-  
16 ment:

17           (i) Identifying, refining, and broadly  
18 disseminating to healthcare educators in-  
19 formation about workforce competencies,  
20 models, and preservices curricula relevant  
21 to providing psychosocial services to per-  
22 sons with chronic medical illnesses and  
23 their families.

24           (ii) Adapting curricula for continuing  
25 education of the existing workforce using

1 efficient workplace-based learning ap-  
2 proaches.

3 (iii) Developing the skills of faculty  
4 and other trainers in teaching psychosocial  
5 health care using evidence-based teaching  
6 strategies.

7 (iv) Strengthening the emphasis on  
8 psychosocial healthcare in educational ac-  
9 creditation standards and professional li-  
10 censing and certification exams by recom-  
11 mending revisions to the relevant oversight  
12 organizations.

13 (c) TECHNICAL AMENDMENT.—

14 (1) IN GENERAL.—Section 3 of the  
15 Hematological Cancer Research Investment and  
16 Education Act of 2002 (Public Law 107–172; 116  
17 Stat. 541) is amended by striking “section 419C”  
18 and inserting “section 417C”.

19 (2) EFFECTIVE DATE.—The amendment made  
20 by paragraph (1) shall take effect as if included in  
21 section 3 of the Hematological Cancer Research In-  
22 vestment and Education Act of 2002 (Public Law  
23 107–172; 116 Stat. 541).

1 **SEC. 13. ACTIVITIES OF THE FOOD AND DRUG ADMINISTRA-**  
2 **TION.**

3 It is the sense of the Senate that the Food and Drug  
4 Administration should—

5 (1) integrate policies and structures to facilitate  
6 the concurrent development of drugs and diagnostics  
7 for cancer diagnosis, prevention, and therapy;

8 (2) consider alternatives or surrogates to tradi-  
9 tional clinical trial endpoints (for example, other  
10 than survival) that are acceptable for regulatory ap-  
11 proval as evidence of clinical benefit to patients; and

12 (3) modernize the Office of Oncology Drug  
13 Products by examining and addressing internal bar-  
14 riers that exist within the current organizational  
15 structure.

○