

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.

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

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);

“(E) provide for the linkage of cancer registries to other administrative Federal Government data sources, including the Centers for Medicare & Medicaid Services, the Social Security Administration, and the Centers for Disease Control and Prevention, with the goal of understanding the determinants of cancer treatment, care, and outcomes by allowing economic, social, genetic, and other factors to be analyzed in an independent manner; and

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

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

“(A) IN GENERAL.—As part of the entity established under paragraph (1), the Director 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—

(A) pursuant to a waiver that had been granted by an institutional review board or privacy board relating to such disclosure; and

(B) the entity informs patients when they make first patient contact with the entity that the entity is a research institution that may conduct research using their de-identified medical records.

(2) SYNCHRONIZATION OF STANDARDS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall study the advantages and disadvantages of the synchronization of the standards for research under the Common Rule (under part 46 of title 45, Code of Federal Regulations) and the Privacy Rule (as defined in section 411(f)(2)(F) of the Public Health Service Act, as amended by this Act) in order to determine the appropriate data elements that should be omitted under the strict de-identification standards relating to personal information.

(B) REVIEW OF RECOMMENDATIONS.—In carrying out subparagraph (A), the Secretary of Health and Human Services shall conduct a review 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

percent relevance to each of the categories of cancer described in paragraph (1), including the total number of awards granted to experienced investigators and the total number of awards granted to investigators receiving their first grant from the National Institutes of Health.

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

“(b) GRANT PROGRAM.—

“(1) IN GENERAL.—The Director of the Institute, in cooperation with the Director of the Fogarty International Center for Advanced Study in the Health Sciences and the Directors of other Institutes, as appropriate, shall award grants to researchers to conduct research regarding cancers for which—

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

“(B) the 5-year survival rate is less than 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.—

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

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

“(i) IN GENERAL.—Non-Federal contributions required in subparagraph (A) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, 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-

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

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

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

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

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

“(A) IN GENERAL.—Subject to subparagraph (B), upon the request of an eligible entity receiving a grant under subsection (a), the Secretary, for the purpose of aiding the eligible entity 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 ceipt 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.—

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

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

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

SEC. 12. CANCER SURVIVORSHIP AND COMPLETE RECOVERY INITIATIVES.

(a) CANCER SURVIVORSHIP PROGRAMS.—Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.), as amended by subsection (c), is 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 lingu-
14 tically 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

efficient workplace-based learning approaches.

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

(iv) Strengthening the emphasis on psychosocial healthcare in educational accreditation standards and professional licensing and certification exams by recommending revisions to the relevant oversight organizations.

(c) TECHNICAL AMENDMENT.—

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

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as if included in section 3 of the Hematological Cancer Research Investment and Education Act of 2002 (Public Law 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.

○