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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''21st Century Cancer ALERT (Access to Life-Saving Early detection, Research and Treatment) Act''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress makes the following findings:

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

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

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

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

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

(6) While clinical trials are vital to the discovery and implementation of new preventative, diagnostic, and treatment options, only 3 to 5 percent of the more than 10,000,000 adults with cancer in the United States participate in cancer clinical trials.

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

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

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

(9) In 1971, there were only 3,000,000 cancer survivors. Today, cancer survivors account for 3 percent of the United States population, approximately 12,000,000.

(10) The National Cancer Act of 1971 (Public Law 92–218) advanced the ability of the United States to develop new scientific leads and help increase the rate of cancer survivorship.

(11) Yet in the 37 years since the national declaration of the War on Cancer, the age adjusted mortality rate for cancer is still extraordinarily high. Eight forms of cancer have a 5-year survival rate of less than 50 percent (pancreatic, liver, lung, esophageal, stomach, brain, multiple myeloma, and ovarian).

(12) While there have been substantial achievements since the crusade began, we are far from winning the war on cancer.

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

(b) PURPOSES.—The purposes of this Act are as follows:

(1) To reauthorize the National Cancer Institute and National Cancer Program in order to enhance and improve the cancer research conducted and supported by the National Cancer Institute and the National Cancer Program in order to benefit cancer patients.

(2) To recognize that with an increased understanding of cancer as more than 200 different diseases with genetic and molecular variations, there is a need for increased coordination and greater flexibility in how cancer research is conducted and coordinated in order to maximize the return the United States receives on its investment in such research.

(3) To prepare for the looming impact of an aging population of the United States and the anticipated financial burden associated with medical treatment and lost productivity, along with the toll of human suffering that accompanies a cancer diagnosis.

(4) To support the National Cancer Institute in establishing relationships and scientific consortia with an emphasis on public-private partnership development, which will further the development of advanced technologies that will improve the prevention, diagnosis, and treatment of cancer.

SEC. 3. ADVANCEMENT OF THE NATIONAL CANCER PROGRAM.

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

"SEC. 411. NATIONAL CANCER PROGRAM.

''(a) IN GENERAL.—There shall be established a National Cancer Program (referred to in this section as the 'Program') that shall consist of—

''(1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens; and

''(2) the other programs and activities of the Institute.

''(b) COLLABORATION.—In carrying out the Program—

''(1) the Secretary and the Director of the Institute shall identify relevant Federal agencies that shall collaborate with respect to activities conducted under the Program (including the Institute, the other Institutes and Centers of the National Institutes of Health, the Office of the Director of the National Institutes of Health, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Energy, the Agency for Healthcare Research and Quality, the Office for Human Research Protections, the Health Resources and Services Administration, and the Office for Human Research Protections); and

''(2) the Secretary shall ensure that the policies related to the promotion of cancer research of all agencies within the Department of Health and Human Services (including the Institute, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services) are harmonized, and shall ensure that such agencies collaborate with regard to cancer research and development.

''(c) TRANSPARENCY AND EFFICIENCY.—

''(1) BUDGETING.—In carrying out the Program, the Director of the Institute shall, in preparing and submitting to the President the annual budget estimate for the Program—

''(A) develop the budgetary needs of the entire Program and submit the budget estimate relating to such needs to the National Cancer Advisory Board for review prior to submitting such estimate to the President; and

''(B) submit such budget estimate to the Committee on the Budget and the Committee on Appropriations of the Senate and the Committee on the Budget and Committee on Appropriations of the House of Representatives at the same time that such estimate is submitted to the President.

''(2) NATIONAL CANCER ADVISORY BOARD.—In establishing the priorities of the Program, the National Cancer Advisory Board shall provide for increased coordination by increasing the participation of representatives (to the extent practicable, representatives who have appropriate decision making authority) of appropriate Federal agencies, including—

''(A) the Centers for Medicare & Medicaid Services;

''(B) the Health Resources and Services Administration;

''(C) the Centers for Disease Control and Prevention; and

''(D) the Agency for Healthcare Research and Quality.

''(d) PROGRAMS TO ENCOURAGE EARLY DETECTION RESEARCH.—The Director of the Institute shall develop a standard process through which Federal agencies, including the Department of Defense, and administrators of federally funded programs may engage in early cancer detection research.

''(e) IDENTIFICATION OF PROMISING TRANSLATIONAL RESEARCH OPPORTUNITIES.—

''(1) IN GENERAL.—The Director of the Institute, acting through the Program and in accordance with the NIH Reform Act of 2007, shall continue to identify promising translational research opportunities across all disease sites, populations, and pathways to clinical goals through a transparent, inclusive process by—

''(A) continuing to support efforts to develop a robust number of public or nonprofit

entities to carry out early translational research activities;

''(B) emphasizing the role of the young researcher in the program under this section; and

''(C) modifying guidelines for multiproject, collaborative, early translational research awards to focus research and reward collaborative team science.

''(2) MATCHING FUNDS FOR RESEARCH.—

''(A) IN GENERAL.—The Secretary may provide assistance to eligible entities to match the amount of non-Federal funds made available by such entity for translational research of the type described in paragraph (1) relating to cancer.

''(B) ELIGIBILITY.—To be eligible to receive assistance under subparagraph (A), an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(C) RECOMMENDATIONS AND PRIORITIZATION.—In providing assistance under subparagraph (A), the Secretary shall—

''(i) select entities based on the recommendations of—

"(I) the Director of NIH; and

"(II) a peer review process; and

"(ii) give priority to those entities submitting applications under subparagraph (B) that demonstrate that the research involved is high risk or translational research (as determined by the Secretary).

"(D) AMOUNT.—The amount of assistance to be provided to an entity under subparagraph (A) shall be at the discretion of the Secretary but shall not exceed an amount equal to 100 percent of the amount of non-Federal funds ($1 for each $2 of non-Federal funds) made available for research described in subparagraph (A).

"(E) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal funds to be matched under subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal funds.

''(f) BIOLOGICAL RESOURCE COORDINATION AND ADVANCEMENT OF TECHNOLOGIES FOR CANCER RESEARCH.—

''(1) ESTABLISHMENT.—The Director of the Institute, acting through the Program, shall establish an entity within the Institute to augment ongoing efforts to advance new technologies in cancer research, support the national collection of tissues for cancer research purposes, and ensure the quality of tissue collection.

''(2) GOALS.—The entity established under paragraph (1) shall—

''(A) be designed to expand the access of researchers to biospecimens for cancer research purposes;

''(B) establish uniform standards for the handling and preservation of patient tissue specimens by entities participating in the network established under paragraph (3);

''(C) require adequate annotation of all relevant clinical data while assuring patient privacy;

''(D) facilitate the linkage of public and private entities into the national network under 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-

tives to establish an interconnected network of biorepositories (referred to in this subsection as the 'Network') with consistent, interoperable systems for the collection and storage of tissues and information, the annotation of such information, and the sharing of such information through an interoperable information system.

''(B) GUIDELINES.—A biorepository in the Network that receives Federal funds shall adopt the Institute's Best Practices for Biospecimen Resources for Institute-supported biospecimen resources (as published by the Institute and including any successor guidelines) for the collection of biospecimens and any accompanying data.

''(C) REPRESENTATION.—The composition of any leadership entity of the Network shall be determined by the Director of the Institute and shall, at a minimum, include a representative of—

''(i) private sector entities and individuals, including cancer researchers and health care providers;

''(ii) the Centers for Disease Control and Prevention;

"(iii) the Agency for Healthcare Research and Quality;

"(iv) the Office of National Coordination of Health Information Technology;

"(v) the National Library of Medicine;

"(vi) the Office for the Protection of Research Subjects; and

"(vii) the National Science Foundation.

"(D) PARTNERSHIPS WITH TISSUE SOURCE SITES.—The Director of the Institute may enter into contracts with tissue source sites to acquire data from such sites. Any such data shall be acquired through the use of protocols and closely monitored, transparent procedures within appropriate ethical and legal frameworks.

"(4) COLLECTION OF DATA.—

"(A) HOSPITALS.—A hospital or ambulatory cancer center that receives Federal funds shall offer patients the opportunity to contribute their biospecimens and clinical data to the entity established under paragraph (1).

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

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

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

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

(b) IMPROVED PRIVACY STANDARDS IN CLINICAL RESEARCH.—

(1) PERMITTED DISCLOSURE UNDER THE PRIVACY RULE.—For purposes of the Privacy Rule (as referred to in section 411(f)(2)(F) of the Public Health Service Act, as amended by this Act), a covered entity (as defined for purposes of such Rule) shall be in compliance with such Rule relating to the disclosure of de-identified patient information if such 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

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

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

(i) make recommendations concerning the conduct of international research to determine the boundaries and applications of extraterritorially under the Privacy Rule (as referred to in section 411(f)(2)(F) of the Public Health Service Act, as amended by this Act); and

(ii) include biorepository storage information when obtaining patient consent.

(D) REPORT.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committee of Congress, a report concerning the recommendations made under this paragraph.

(3) APPLICATION OF PRIVACY RULE TO EXTERNAL RESEARCHERS.—

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

(B) DEFINITION.—

(i) IN GENERAL.—In this paragraph, the term ''external researcher'' means a researcher who is on the staff of a covered entity (as defined in the Privacy Rule) but who is not actually employed by such covered entity.

(ii) INTERNAL AND EXTERNAL RESEARCHERS.—With respect to determining the distinction of whether or not a researcher has the ability to use protected health information under the provisions of this paragraph, such determination shall be based on whether the covered entity involved exercises effective control over that researcher's activities. For purposes of the preceding sentence, effective control may include membership and privileges of staff or the ability to terminate staff membership or discipline staff.

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

SEC. 5. ENHANCED FOCUS AND REPORTING ON CANCER RESEARCH.

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

"SEC. 417B. ENHANCED FOCUS AND REPORTING ON CANCER RESEARCH.

''(a) ANNUAL INDEPENDENT REPORT.—

''(1) IN GENERAL.—The Director of the Institute shall complete an annual independent report that shall be submitted to Congress on the same date that the annual budget estimate described in section 413(b)(9) is submitted to the President.

''(2) CONTENTS OF REPORT.—

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

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

"(ii) Cancers in which the incidence rate is less than 15 cases per 100,000 people, or fewer than 40,000 new cases per year.

"(B) INFORMATION.—With regard to each of the categories of cancer described in subparagraph (A), the report shall contain information regarding—

"(i) a strategic plan for reducing the mortality rate for the annual year, including specific research areas of interest and budget amounts;

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

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

"(iv) the total amount of grant funding, including the total dollar amount awarded per grant and per funding year, under—

"(I) the National Cancer Institute; and

"(II) the National Institutes of Health;

"(v) the percentage of grant applications favorably reviewed by the Institute that the Institute funded in the previous annual year;

"(vi) the total number of grant applications, with greater than 50 percent relevance to each of the categories of cancer described in subparagraph (A), received by the Institute for awards in the previous annual year;

"(vii) the total number of grants awarded, with greater than 50 percent relevance to each of the categories of cancer described in subparagraph (A), for the previous annual year and the number of awards per grant type, including the Common Scientific Outline designation specific to each such grant; and

"(viii) the total number of primary investigators that received grants from the 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.

''(2) PRIORITIZATION.—In awarding grants for research regarding cancers described in paragraph (1)(A), the Director of the Institute shall give priority to collaborative research projects between adult and pediatric cancer research, with preference for projects building upon existing multi-institutional research infrastructures.

''(3) TISSUE SAMPLES.—

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

''(B) WAIVER.—The Director of the Institute may grant a waiver of the requirement described in subparagraph (A) to a recipient who receives a grant for research described in paragraph (1)(B) and who submits an application for such waiver to the Director of the Institute, in the manner in which such Director may require.''.

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

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

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

"SEC. 317D–1. COLORECTAL CANCER SCREENING PROGRAM.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award competitive grants to eligible entities to carry out programs—

"(1) to provide screenings for colorectal cancer to individuals according to screening guidelines set by the United States Preventive Services Task Force;

"(2) to provide appropriate referrals for medical treatment of individuals screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services and support services such as case management;

"(3) to develop and disseminate public information and education programs for the detection and control of colon cancer;

"(4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of colon cancer;

''(5) to establish mechanisms through which eligible entities can monitor the quality of screening procedures for colon cancer, including the interpretation of such procedures; and

''(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program-monitoring activities.

''(b) ELIGIBILITY.—

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

''(A) be—

''(i) a State; or

''(ii) an Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act);

''(B) submit to the Secretary as application, at such time, in such manner, and containing such information as the Secretary may require, including—

''(i) a description of the purposes for which the entity intends to expend amounts under the grant; and

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

''(C) provide matching funds in accordance with paragraph (2);

''(D) provide assurances that the entity will—

''(i) establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received under subsection (a);

''(ii) upon request, provide records maintained pursuant to clause (i) to the Secretary or the Comptroller General of the United States for purposes of auditing the expenditures of the grant by the eligible entity; and

''(iii) submit to the Secretary such reports as the Secretary may require with respect to the grant; and

''(E) provide assurances that the entity will comply with the restrictions described in subsection (e).

''(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-

mining the amount of such non-Federal contributions.

''(ii) MAINTENANCE OF EFFORT.—In making a determination of the amount of non-Federal contributions for purposes of subparagraph (A), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the eligible entity involved toward the purpose described in subsection (a) for the 2-year period preceding the first fiscal year for which the eligible entity is applying to receive a grant under such section.

''(iii) INCLUSION OF RELEVANT NON-FEDERAL CONTRIBUTIONS FOR MEDICAID.—In making a determination of the amount of non-Federal contributions for purposes of subparagraph (A), the Secretary shall, subject to clauses (i) and (ii), include any non-Federal amounts expended pursuant to title XIX of the Social Security Act by the eligible entity involved toward the purpose described in paragraphs (1) and (2) of subsection (a).

''(c) PRIORITIZATION.—

''(1) IN GENERAL.—In awarding grants under this section, the Secretary shall give priority to recipients that are safety-net providers.

''(2) DEFINITION.—In this section, the term 'safety-net provider' means a health care provider—

''(A) that by legal mandate or explicitly adopted mission, offers care to individuals without regard to the individual's ability to pay for such services; or

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

''(d) USE OF FUNDS.—

''(1) IN GENERAL.—An eligible entity may, subject to paragraphs (2) and (3), expend amounts received under a grant under subsection (a) to carry out the purposes described in such subsection through the awarding of grants to public and nonprofit private entities and through contracts entered into with public and private entities.

''(2) CERTAIN APPLICATION.—If a nonprofit private entity and a private entity that is not a nonprofit entity both submit applications to a grantee under subsection (a) for a grant or contract as pro-

vided for in paragraph (1), the grantee may give priority to the application submitted by the nonprofit private entity in any case in which the grantee determines that the quality of such application is equivalent to the quality of the application submitted by the other private entity.

''(3) PAYMENTS FOR SCREENINGS.—The amount paid by a grantee under subsection (a) to an entity under this subsection for a screening procedure as described in subsection (a)(1) may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act if payment were made under such part for furnishing the procedure to an individual enrolled under such part.

''(e) RESTRICTION ON USE OF FUND.—The Secretary may not award a grant to an eligible entity under subsection (a) unless the entity agrees that—

''(1) in providing screenings under subsection (a)(1), the eligible entity will give priority to low-income individuals who lack adequate coverage under health insurance and health plans with respect to screenings for colorectal cancer;

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

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

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

''(4) funding received under the grant will supplement, and not supplant, the expenditures of the eligible entity and the value for in-kind contributions for carrying out the activities for which the grant was awarded;

''(5) funding will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

''(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

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

''(6) funds will not be expended to provide inpatient hospital services for any individual.

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

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

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

''(2) will be adjusted to reflect the income of the individual involved; and

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

''(g) REQUIREMENT REGARDING MEDICARE.—The Secretary may not award a grant to an eligible entity under this section unless the eligible entity involved provides, as applicable, the following assurances:

''(1) Screenings under subsection (a)(1) will be carried out as preventive health measures in accordance with evidence-based screening guidelines and procedures as specified in section 1861(pp)(1) of the Social Security Act.

''(2) An individual will be considered high risk 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—

"(i) may provide supplies, equipment, and services to the eligible entity; and

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

"(B) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request made by an eligible entity under subparagraph (A), the Secretary shall reduce the amount of payments made under the grant under subsection (a) to the eligible entity by an amount equal to the fair market value of any supplies, equipment, or services provided by the Secretary and the costs of detailing personnel (including pay, allowances, and travel expenses) under subparagraph (A). The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

"(j) EVALUATIONS AND REPORT.—

"(1) EVALUATIONS.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to this section. Such evaluations shall include evaluations of the extent to which

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

''(2) REPORT TO CONGRESS.—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated to carry out this section, and annually thereafter, submit to Congress, a report summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this section as the Secretary determines to be appropriate.''.

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

(1) COVERAGE AS OPTIONAL CATEGORICALLY NEEDY GROUP.—

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

(i) in subclause (XVIII), by striking ''or'' at the end;

(ii) in subclause (XIX), by adding ''or'' at the end; and

(iii) by adding at the end the following:

"(XX) who are described in subsection (gg) (relating to certain persons screened and found to need treatment from complications from screening or have colorectal cancer);".

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

"(gg) Individuals described in this subsection are individuals who—

"(1) are not described in subsection (a)(10)(A)(i);

"(2) have not attained age 65;

"(3) have been screened for colorectal cancer and need treatment for complications due to screening or colorectal cancer; and

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

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

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

(i) by striking ''and (XIV)'' and inserting ''(XIV)''; and

(ii) by inserting '', and (XV) the medical assistance made available to an individual described in subsection (gg) who is eligible for medical assistance only because of subparagraph (A)(10)(ii)(XX) shall be limited to medical assistance provided during the period in which such an individual requires treatment for complications due to screening or colorectal cancer'' before the semicolon.

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

(i) in clause (xii), by striking ''or'' at the end;

(ii) in clause (xiii), by adding ''or'' at the end; and

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

''(xiv) individuals described in section 1902(gg),''.

(2) PRESUMPTIVE ELIGIBILITY.—

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

''OPTIONAL APPLICATION OF PRESUMPTIVE ELIGIBILITY PROVISIONS FOR CERTAIN PERSONS WITH COLORECTAL CANCER

''SEC. 1920C. A State may elect to apply the provisions of section 1920B to individuals described in section 1902(gg) (relating to certain colorectal cancer patients) in the same manner as such section applies to individuals described in section 1902(aa) (relating to certain breast or cervical cancer patients).''.

(B) CONFORMING AMENDMENTS.—

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

(I) by striking ''and'' after ''section 1920'' and inserting a comma;

(II) by striking ''and'' after ''with such section'' and inserting a comma; and

(III) by inserting before the semicolon at the end the following: ", and provide for making medical assistance available to individuals described in section 1920C during a presumptive eligibility period in accordance with such section".

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

(I) by striking "or for" and inserting ", for"; and

(II) by inserting before the period the following: ", or for medical assistance provided to an individual described in section 1920C during a presumptive eligibility period under such section".

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

(A) by striking "and" before "(4)"; and

(B) by inserting before the period at the end the following: ", and (5) the Federal medical assistance percentage shall be equal to the

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

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

(c) MOBILE MEDICAL VAN GRANT PROGRAM.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary''), acting through the Administrator of the Health Resources and Services Administration, shall award grants to eligible entities for the development and implementation of a mobile medical van program that shall provide cancer screening services that receive an ''A'' or ''B'' recommendation by the U.S. Preventative Services Task Force of the Agency for Healthcare Research and Quality to communities that are underserved and suffer from bar-

riers to access to high quality cancer prevention care.

(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant under paragraph (1), and entity shall—

(A) be a consortium of public and private entities (such as academic medical centers, universities, hospitals, and non profit organizations);

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

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

(ii) a description of the manner in which the applicant will evaluate the impact and effectiveness of the health care services provided under the program carried out under the grant;

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

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

(v) a protocol for the transfer of patients in the event of a medical emergency;

(vi) a plan for advertising the services of the mobile medical van to the communities targeted for health care services; and

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

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

(3) USE OF FUNDS.—An entity shall use amounts received under a grant under this subsection to do any of the following:

(A) Purchase or lease a mobile medical van.

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

(C) Purchase or lease telemedicine equipment that is reasonable and necessary to operate the mobile medical van.

(D) Purchase medical supplies and medication that are necessary to provide health care services on the mobile medical van.

(E) Retain medical professionals with expertise and experience in providing cancer screening services to underserved communities to provide health care services on the mobile medical van.

(4) MATCHING REQUIREMENTS.—

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

(B) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required under subparagraph (A) may be in cash or in-kind, fairly evaluated, including plant,

equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

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

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

(ii) the Secretary publishes the rationale for such waiver in the Federal Register.

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

(i) the amount provided under the grant; and

(ii) the amount of matching funds actually provided by the grantee.

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

(A) that will provide cancer screening services in underserved areas; and

(B) that on the date on which the grant is awarded, have a mobile medical van that is nonfunctioning due to the need for necessary mechanical repairs.

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

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

(8) REPORT.—Not later than 18 months after grants are first awarded under this subsection, the Secretary shall submit to the Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives a re-

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

(9) DEFINITIONS.—In this section:

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

(B) UNDERSERVED AREA.—The term ''underserved area'', with respect to the location of patients receiving medical treatment, means a ''medically underserved community'' as defined in section 799B(6) of the Public Health Service Act (42 U.S.C. 295p(6)).

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

(1) CANCER GENOME ATLAS.—The Secretary of Health and Human Services, acting through the National Cancer Institute, shall provide for the inclusion of cancers with survival rates of less than 25 percent at 5 years in the Cancer Genome Atlas.

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

(3) WORKING GROUPS.—The Secretary of Health and Human Services, acting through the National Cancer Institute, shall establish formal working groups for cancers with survival rates of less than 25 percent at 5 years within the Early Detection Research Network.

(4) COMPUTER ASSISTED DIAGNOSTIC, SURGICAL, TREATMENT AND DRUG TESTING INNOVATIONS TO REDUCE MORTALITY FROM CANCERS.—The Director of the National Institute of Biomedical Imaging and Bioengineering shall ensure that the Quantum Grant Program and the Image Guided Interventions programs expedite the development of computer assisted diagnostic, surgical, treatment and drug testing innovations to reduce mortality from cancers with survival rates of less than 25 percent at 5 years.

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

(a) PROMOTION OF THE DISCOVERY AND DEVELOPMENT OF BIOMARKERS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in consultation with appropriate Federal agencies including the National Institutes of

Health, the National Cancer Institute, the Food and Drug Administration, and the National Institute of Standards and Technology, and extramural experts as appropriate, shall establish and coordinate a program to award contracts to eligible entities to support the development of innovative biomarker discovery technologies. All activities under this section shall be consistent with and complement the ongoing efforts of the Oncology Biomarker Qualification Initiative and the Reagan-Udall Foundation of the Food and Drug Administration.

(2) LEAD AGENCY.—Not later than 2 years after the date of enactment of this Act, the Secretary shall designate a lead Federal agency to administer and coordinate the program established under paragraph (1).

(3) ELIGIBILITY.—To be eligible to enter into a contract under paragraph (1), an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require. Such information shall be sufficient to enable the Secretary to—

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

(B) contain the capacity to perform the necessary analysis of contract applications, including determinations as to the intellectual expertise of applicants.

(4) REQUIREMENT.—In awarding contracts under this subsection, the lead agency shall consider whether the research involved will result in the development of quantifiable biomarkers of cell signaling pathways that will have the broadest applicability across different tumor types or different diseases.

(5) INTERNATIONAL CONSORTIA.—The Secretary shall designate one of the Federal entities described in paragraph (1) to establish an international private-public consortia to develop and share methods and precompetitive data on the validation and qualification of cancer biomarkers for specific uses.

(b) CLINICAL STUDY GUIDELINES.—Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs, the Administrator of the Centers for Medicare & Medicaid Services, and the Director of the National Cancer Institute shall jointly develop guidelines for the conduct of clinical studies designed to generate clinical data relating to cancer care and treat-

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

(c) DEMONSTRATION PROJECT.—

(1) IN GENERAL.—The Secretary, in consultation with the Commissioner of Food and Drugs and the Administrator of the Agency for Healthcare Research and Quality, shall carry out a demonstration project that provides for a limited regional assessment of biomarker tests to facilitate the controlled and limited use of a risk assessment measure with an intervention that may consist of a biomarker test.

(2) PROCEDURES.—As a component of the demonstration project under paragraph (1), the Commissioner of Food and Drugs, in consultation with other relevant agencies, shall establish procedures that independent research entities shall follow in conducting high quality assessments of efficacy of biomarker tests.

(d) POSTMARKET SURVEILLANCE.—The Food and Drug Administration and the Centers for Medicare & Medicaid Services shall assess quality and accuracy of biomarker tests through appropriate postmarket surveillance

and other means, as necessary and appropriate to the mission of each such agency.

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

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

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

(3) identify early biomarkers of clinical benefit.

(f) DEFINITION.—In this section, the term ''biomarker'' means any characteristic that can be objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacological responses to therapeutic interventions.

SEC. 8. CANCER CLINICAL TRIALS.

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

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

"SEC. 715. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

"(a) COVERAGE.—

"(1) IN GENERAL.—If a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

"(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

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

"(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

"(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical

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

"(A) the investigational item, device or service, itself; or

"(B) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient.

"(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

"(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

"(1)(A) The individual has been diagnosed with cancer.

''(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

''(2) Either—

''(A) the referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

''(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

''(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer in connection with a group health plan, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

''(d) APPROVED CLINICAL TRIAL DEFINED.—

"(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a phase I, phase II, phase III, or phase IV clinical trial that relates to the prevention and treatment of cancer (including related symptoms) and is described in any of the following subparagraphs:

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

"(i) The National Institutes of Health.

"(ii) The Centers for Disease Control and Prevention.

"(iii) The Agency for Health Care Research and Quality.

"(iv) The Centers for Medicare & Medicaid Services.

"(v) cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.

"(vi) A qualified non-governmental research entity identified in the guidelines

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

''(vii) Any of the following if the conditions described in paragraph (2) are met:

''(I) The Department of Veterans Affairs.

''(II) The Department of Defense.

''(III) The Department of Energy.

''(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

''(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

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

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

''(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

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

''(f) PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this section shall preempt State laws that require a clinical trials policy for State regulated health insurance plans.''.

(2) CLERICAL AMENDMENTS.—

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

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

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

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

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

(2) conduct an educational campaign for health care professionals to educate them to consider clinical trials as treatment options for their patients; and

(3) conduct research to document and demonstrate promising practices in cancer clinical trial recruitment and retention efforts, particularly for patient populations that traditionally are underrepresented in clinical trials.

SEC. 9. HEALTH PROFESSIONS WORKFORCE.

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

''(2) BENEFITS FOR RETIRING NURSE OFFICERS QUALIFIED AS FACULTY.—

''(A) IN GENERAL.—The Secretary of Defense shall provide to any individual described in subparagraph (B) the payment of retired or retirement pay without reduction based on re-

ceipt of pay or other compensation from the institution of higher education concerned.

''(B) COVERED INDIVIDUALS.—An individual described in this subparagraph is an individual who—

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

''(ii) holds a graduate degree in nursing; and

''(iii) serves as a part- or full-time faculty member of an accredited school of nursing.

''(C) NURSE CORPS.—Any accredited school of nursing that employs a retired nurse officer as faculty under this paragraph shall agree to provide financial assistance to individuals undertaking an educational program at such school leading to a degree in nursing who agree, upon completion of such program, to accept a commission as an officer in the nurse corps of the Armed Forces.''.

(b) ONCOLOGY WORKFORCE.—

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

the ''Secretary'') shall conduct a study on the current and future cancer care workforce needs in the following areas:

(A) Cancer research.

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

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

(D) Early detection and diagnosis.

(E) Cancer prevention.

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

(G) Diversity and appropriate care for disparity populations.

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

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

SEC. 10. PATIENT NAVIGATOR PROGRAM.

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

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

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

(2) in subsection (m)—

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

(B) in paragraph (2), by striking ''2010'' and replacing with ''2015.''

SEC. 11. CANCER CARE AND COVERAGE UNDER MEDICAID AND MEDICARE.

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

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

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

from payment for items and services provided under a clinical trial payment for coverage of routine costs of care (as defined by the Secretary) furnished to an individual entitled to benefits under this part who participates in such a trial to the extent the Secretary provides payment for such costs as of the date of enactment of this subsection.''.

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

(A) by striking ''PAYMENT.—The Secretary'' and inserting ''PAYMENT AND COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CLINICAL TRIALS.—

''(1) METHODS OF PAYMENT.—Subject to paragraph (2), the Secretary''; and

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

''(2) COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CLINICAL TRIALS.—The Secretary shall not exclude from payment for items and services provided under a clinical trial payment for coverage of routine costs of care (as defined by the Secretary)

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

(3) PROVIDER OUTREACH.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall conduct an outreach campaign to providers of services and suppliers under the Medicare program under title XVIII of the Social Security Act regarding coverage of routine costs of care furnished to Medicare beneficiaries participating in clinical trials in accordance with sections 1814(m) and 1833(w)(2) of the Social Security Act (as added by paragraphs (1) and (2), respectively).

(b) DEMONSTRATION PROJECT TO PROVIDE COMPREHENSIVE CANCER CARE PLANNING SERVICES UNDER MEDICARE.—

(1) IN GENERAL.—Beginning not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall conduct a 3-year demonstration project (referred to in this subsection as the ''demonstration project'') under title XVIII of the Social Security Act (42

U.S.C. 1395 et seq.) under which payment for comprehensive cancer care planning services furnished by eligible entities shall be made.

(2) COMPREHENSIVE CANCER CARE PLANNING SERVICES.—For purposes of this subsection, the term ''comprehensive cancer care planning services'' means—

(A) with respect to an individual who is diagnosed with cancer, the development of a plan of care that—

(i) details, to the greatest extent practicable, all aspects of the care to be provided to the individual, with respect to the treatment of such cancer, including any curative treatment and comprehensive symptom management (such as palliative care) involved;

(ii) is documented in the patient's medical record and furnished to the individual in person within a period specified by the Secretary that is as soon as practicable after the date on which the individual is so diagnosed;

(iii) is furnished, to the greatest extent practicable, in a form that appro-

priately takes into account cultural and linguistic needs of the individual in order to make the plan accessible to the individual; and

(iv) is in accordance with standards determined by the Secretary to be appropriate;

(B) with respect to an individual for whom a plan of care has been developed under subparagraph (A), the revision of such plan of care as necessary to account for any substantial change in the condition of the individual, if such revision—

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

(ii) is documented in the patient's medical record and furnished to the individual within a period specified by the Secretary that is as soon as practicable after the date of such revision;

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

velopment of a follow-up cancer care plan that—

(i) describes the elements of the primary treatment, including symptom management, furnished to such individual;

(ii) provides recommendations for the subsequent care of the individual with respect to the cancer involved;

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

(iv) is documented in the patient's medical record and furnished to the individual in person within a period specified by the Secretary that is as soon as practicable after the completion of such primary treatment;

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

(vi) is in accordance with standards determined by the Secretary to be appropriate; and

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

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

(ii) is documented in the patient's medical record and furnished to the individual within a period specified by the Secretary that is as soon as practicable after the date of such revision.

(3) QUALIFICATIONS AND SELECTION OF ELIGIBLE ENTITIES.—

(A) QUALIFICATIONS.—For purposes of this subsection, the term ''eligible entity'' means a physician office, hospital, outpatient department, or community health center. Qualified providers include physicians, nurse practitioners, and other health care professionals who

develop or revise a comprehensive cancer care plan.

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

(4) EVALUATION AND REPORT.—

(A) EVALUATION.—The Secretary shall conduct a comprehensive evaluation of the demonstration project to determine—

(i) the effectiveness of the project in improving patient outcomes and increasing efficiency and reducing error in the delivery of cancer care;

(ii) the cost of providing comprehensive cancer care planning services; and

(iii) the potential savings to the Medicare program demonstrated by the project, including the utility of the demonstration project in reducing duplicative cancer care services and decreasing the use of unnecessary medical services for cancer patients.

(B) REPORT.—

(i) IN GENERAL.—Not later than the date that is 1 year after the date on which the demonstration project concludes, the Secretary shall submit to Congress a report on the evaluation conducted under subparagraph (A).

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

(iii) DEMONSTRATION OF SUBSTANTIAL BENEFIT.—If the evaluation conducted under subparagraph (A) indicates substantial benefit from the demonstration project, as measured by improved patient outcomes and more efficient delivery of healthcare services, such report shall include a legislative proposal to Congress for coverage of comprehensive cancer care

planning services under the Medicare program, developed on the basis of information from the demonstration project and in consultation with the Administrator of the Agency for Healthcare Research and Quality, the Director of the Institute of Medicine, and the Director of the Centers for Disease Control and Prevention.

(iv) NO SUBSTANTIAL BENEFIT.—If the evaluation conducted under subparagraph (A) does not indicate substantial benefit from the demonstration project, as measured by improved patient outcomes and more efficient delivery of healthcare services, such report shall document, to the extent possible, the reasons why the demonstration project did not result in substantial benefit, and such report—

(I) shall include a legislative proposal for Medicare coverage of comprehensive cancer care planning services in a manner that will lead to substantial benefit; or

(II) shall include recommendations for additional demonstration

projects or studies to evaluate the delivery of comprehensive cancer care planning services in a manner that will lead to substantial benefit and eventual Medicare coverage.

(5) FUNDING.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) of the amount necessary to carry out the demonstration project and report under this subsection.

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

(1) SERVICES DESCRIBED.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended by adding at the end the following new subsection:

''(y)(1) Subject to paragraph (2), for purposes of this title, the term 'counseling and pharmacotherapy for cessation of tobacco use' means diagnostic, therapy, and counseling services and pharmacotherapy (including the coverage of prescription and nonprescription tobacco cessation agents approved by the Food and Drug Administration) for cessation of tobacco use for individuals who use

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

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

''(B) by any other health care professional who—

''(i) is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished; and

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

''(2) Such term is limited to—

''(A) services recommended in 'Treating Tobacco Use and Dependence: A Clinical Practice Guideline', published by the Public Health Service in June 2000, or any subsequent modification of such Guideline; and

''(B) such other services that the Secretary recognizes to be effective.''.

(2) DROPPING EXCEPTION FROM MEDICAID PRESCRIPTION DRUG COVERAGE FOR TOBACCO CESSATION MEDICATIONS.—Section 1927(d)(2) of the

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

(A) by striking subparagraph (E);

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

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

(3) REQUIRING COVERAGE OF TOBACCO CESSATION COUNSELING AND PHARMACOTHERAPY SERVICES FOR PREGNANT WOMEN.—Section 1905(a)(4) of the Social Security Act (42 U.S.C. 1396d(a)(4)) is amended—

(A) by striking "and" before "(C)"; and

(B) by inserting before the semicolon at the end the following: "; and (D) counseling and pharmacotherapy for cessation of tobacco use for pregnant women".

(4) REMOVAL OF COST-SHARING FOR TOBACCO CESSATION COUNSELING AND PHARMACOTHERAPY 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:

"SEC. 417E. EXPANSION OF CANCER SURVIVORSHIP ACTIVITIES.

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

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

"(1) Comprehensive assessment of the prevalence and etiology of late effects of cancer treatment, including physical, neurocognitive, and psychosocial late effects. Such assessment shall include—

"(A) development of a system for patient tracking and analysis;

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

"(C) coordination of, and resources for, assessment and data collection.

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

"(3) Identification of predictors of neurocognitive and psychosocial outcomes, including quality of life, in cancer survivors and identification

of qualify of life and other outcomes in family members.

''(4) Development and implementation of intervention studies for cancer survivors and their families, including studies focusing on—

''(A) preventive interventions during treatment;

''(B) interventions to lessen the impact of late effects of cancer treatment;

''(C) rehabilitative or remediative interventions following cancer treatment;

''(D) interventions to promote health behaviors in long-term survivors; and

''(E) interventions to improve health care utilization and access to linguistically and culturally competent long-term follow-up care for childhood cancer survivors in minority and other medically underserved populations.

''(c) GRANTS FOR RESEARCH ON CAUSES OF HEALTH DISPARITIES IN CHILDHOOD CANCER SURVIVORSHIP.—

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

''(A) needs and outcomes of pediatric cancer survivors within minority or other medically underserved populations; and

''(B) health disparities in cancer survivorship outcomes within minority or other medically underserved populations.

''(2) BALANCED APPROACH.—In making grants for research under paragraph (1)(A) on pediatric cancer survivors within minority populations, the Director of NIH shall ensure that such research addresses both the physical and the psychological needs of such survivors.

''(3) HEALTH DISPARITIES.—In making grants for research under paragraph (1)(B) on health disparities in cancer survivorship outcomes within minority populations, the Director of NIH shall ensure that such research examines each of the following:

''(A) Key adverse events after childhood cancer.

''(B) Assessment of health and quality of life in childhood cancer survivors.

''(C) Barriers to follow-up care to childhood cancer survivors.

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

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

''(d) RESEARCH TO EVALUATE FOLLOW-UP CARE FOR CHILDHOOD CANCER SURVIVORS.—The Director of NIH shall conduct or support research to evaluate systems of follow-up care for childhood cancer survivors, with special emphasis given to—

''(1) transitions in care for childhood cancer survivors;

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

''(3) training of professionals to provide linguistically and culturally competent follow-up care to childhood cancer survivors; and

''(4) different models of follow-up care.''.

(b) COMPLETE RECOVERY CARE.—

(1) DEFINITION.—In this subsection, the term ''complete recovery care'' means care intended to address the secondary effects of cancer and its treatment, including late, psychosocial, neurocognitive, psychiatric, psychological, physical, and other effects associated with cancer and cancer survivorship beyond the impairment of bodily function directly caused by the disease, as described in the report by

the Institute of Medicine of the National Academies entitled ''Cancer Care for the Whole Patient''.

(2) EXPANSION OF ACTIVITIES.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall—

(A) coordinate the activities of Federal agencies, including the National Institutes of Health, the National Cancer Institute, the National Institute of Mental Health, the Centers for Medicare and Medicaid Services, the Veterans Health Administration, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office for Human Research Protections, and the Health Resources and Services Administration to improve the provision of complete recovery care in the treatment of cancer; and

(B) solicit input from professional and patient organizations, payors, and other relevant institutions and organizations regarding the status of provision of complete recovery care in the treatment of cancer.

(3) IMPROVING THE COMPLETE RECOVERY CARE WORKFORCE.—

(A) CHRONIC DISEASE WORKFORCE DEVELOPMENT COLLABORATIVE.—The Secretary shall, not later than 1 year after the date of enactment of this Act, convene a Workforce Development Collaborative on Psychosocial Care During Chronic Medical Illness (referred to in this paragraph as the ''Collaborative''). The Collaborative shall be a cross-specialty, multidisciplinary group composed of educators, consumer and family advocates, and providers of psychosocial and biomedical health services.

(B) GOALS AND REPORT.—The Collaborative shall submit to the Secretary a report establishing a plan to meet the following objectives for psychosocial care workforce development:

(i) Identifying, refining, and broadly disseminating to healthcare educators information about workforce competencies, models, and preservices curricula relevant to providing psychosocial services to persons with chronic medical illnesses and their families.

(ii) Adapting curricula for continuing 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).

SEC. 13. ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION.

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

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

(2) consider alternatives or surrogates to traditional clinical trial endpoints (for example, other than survival) that are acceptable for regulatory approval as evidence of clinical benefit to patients; and

(3) modernize the Office of Oncology Drug Products by examining and addressing internal barriers that exist within the current organizational structure.

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