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111TH CONGRESS
2D SESSION

H. R. 6224

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2010

Mrs. CAPPS (for herself and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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; TABLE OF CONTENTS.

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

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

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, diag-

nose, 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 Program in order to benefit cancer patients by enhancing and improving the cancer research conducted and supported by the National Cancer Institute and the National Cancer Program.

(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 HIPAA privacy and security law (as defined in

section 3009(a)(2)), 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 initiatives 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 the 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 HIPAA privacy and security law (as referred to in section 411(f)(2)(F) of the Public Health Service Act, as amended by section 3), a covered entity (as defined for purposes of such law) shall be in compliance with such law 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) in the case that such entity is a research institution, 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 HIPAA privacy and security law (as described in section

411(f)(2)(F) of the Public Health Service Act, as amended by section 3) 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 extraterritoriality under such HIPAA privacy and security law; and

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

(D) REPORT.—Not later than 180 days after the date of the 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 HIPAA PRIVACY AND SECURITY LAW TO EXTERNAL RESEARCHERS.—

(A) IN GENERAL.—Notwithstanding any other provision of law, the HIPAA privacy and security law (as described in section 411(f)(2)(F) of the Public Health Service Act, as amended by section 3) 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 for purposes of the HIPAA privacy and security law) 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 of the Central Institutional Review Board Initiative, as sponsored by the National Cancer Institute.

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 fewer 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) PREVENTIVE HEALTH MEASURES WITH RESPECT TO COLORECTAL CANCER.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317T the following new section:

''SEC. 317U. PREVENTIVE HEALTH MEASURES WITH RESPECT TO COLORECTAL CANCER.

''(a) GRANT PROGRAM AUTHORIZATION.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to eligible entities for the purpose of carrying out a program described in subsection (b). An eligible entity that is a recipient of a grant under this subsection may use such grant to carry out such programs directly or

through grants to, or contracts with, public and not-for-profit private entities.

''(2) ELIGIBLE ENTITY DEFINED.—For purposes of this section, the term 'eligible entity' includes the following:

''(A) A State, including, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

''(B) An Indian tribe or tribal organization, as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act.

''(b) PROGRAMS DESCRIBED.—

''(1) IN GENERAL.—Subject to paragraph (2), a program described in this subsection is a program for planning or implementing each of the following:

''(A) Providing screenings for colorectal cancer to individuals who—

''(i) are 50 years of age or older; or

''(ii)(I) are under 50 years of age; and

"(II) are at high risk for such cancer, as determined in accordance with subsection (e)(2).

"(B) Providing appropriate case management and referrals for medical treatment of individuals screened pursuant to subparagraph (A).

"(C) Ensuring (directly or through coordination or an arrangement with health care providers or programs) the full continuum of follow-up and cancer care for individuals so screened, including appropriate follow-up for abnormal tests, diagnostic services, therapeutic services, and treatment of detected cancers and management of unanticipated medical complications.

"(D) Carrying out activities to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of colorectal cancer, which activities are carried out pursuant to the participation of the health professionals in the program.

"(E) Establishing mechanisms through which the eligible entity involved can monitor

the quality of screening and diagnostic follow-up procedures for colorectal cancer, including the interpretation of such procedures.

"(F) Evaluating the activities described in this subsection through appropriate surveillance and program monitoring activities.

"(G) Developing and disseminating findings derived through such evaluations and the collection of data on outcomes.

"(H) Developing and disseminating public information and education programs for the detection and control of colorectal cancer and promoting the benefits of receiving screenings through this program.

"(2) SUPPLEMENT NOT SUPPLANT.—In the case of an eligible entity that implements a universal colorectal screening program under which the eligible entity makes available funds for activities described in subparagraph (A), (B), or (C) of paragraph (1), such entity shall be able to receive grant funds under subsection (a) only for purposes of—

"(A) carrying out those activities under this subsection that are not so funded; or

''(B) supplementing (and not supplanting) funds made available by the entity for such funded program.

''(c) PRIORITY FOR LOW-INCOME, UNINSURED, AND UNDERINSURED INDIVIDUALS.—A grant may be made under subsection (a) to an eligible entity only if the eligible entity agrees that, in providing screenings under subsection (b)(1)(A), the eligible entity will give priority to low-income individuals who lack adequate coverage, as determined by the Secretary, under health insurance and health plans with respect to screenings for colorectal cancer.

''(d) SPECIAL CONSIDERATION FOR CERTAIN APPLICANTS.—In making grants under subsection (a) for a fiscal year, the Secretary shall give special consideration to the following eligible entities:

''(1) In the case of services under such subsection for women, to such entities that, for such year, are grantees under title XV.

''(2) In the case of services under such subsection for men, to such entities that, for such year, are grantees under section 317D.

''(3) To such entities that coordinate with other Federal, State, and local colorectal cancer programs.

''(4) To such entities with an existing program to provide cancer screening to individuals.

''(e) USE OF CERTAIN STANDARDS UNDER MEDICARE PROGRAM.—A grant may be made under subsection (a) to an eligible entity only if the eligible entity provides, as applicable, assurances as follows:

''(1) Screenings under subsection (b)(1)(A) will be carried out as preventive health measures in accordance with evidence-based screening guidelines and procedures and in accordance with the standard of care required for purposes of title XVIII of the Social Security Act to carry out colorectal screening tests defined in section 1861(pp)(1) of such Act.

''(2) An individual will be considered high risk for purposes of subsection (b)(1)(A)(ii) only if the individual is high risk within the meaning of section 1861(pp)(2) of such Act.

''(3) The payment made from the grant for a screening procedure under subsection (b)(1)(A) will not exceed the amount that would be paid under part B of title XVIII of such Act if payment were made under such part for furnishing the procedure to an individual enrolled under such part.

''(f) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—A grant under subsection (a) may

be made to an eligible entity only if the eligible entity, as applicable, provides assurances that the grant 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—

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

"(2) by an entity that provides health services on a prepaid basis.

"(g) RECORDS AND AUDITS.—A grant under subsection (a) may be made to an eligible entity only if the eligible entity provides assurances that the eligible entity will—

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

"(2) upon request, provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller General of the United States for purposes of auditing the expenditures of the grant by the eligible entity.

"(h) REQUIREMENT OF MATCHING FUNDS.—

''(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) to an eligible entity for a fiscal year unless the eligible entity agrees, with respect to the costs to be incurred by the eligible entity for such fiscal year in carrying out the activities described in subsection (b), to make available non-Federal contributions (in cash or in kind under paragraph (2)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant for such fiscal year. Such contributions may be made directly or through donations from public or private entities.

''(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

''(A) IN GENERAL.—Non-Federal contributions required in paragraph (1) 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 determining the amount of such non-Federal contributions.

''(B) MAINTENANCE OF EFFORT.—In making a determination of the amount of non-

Federal contributions for purposes of paragraph (1), 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 activities described in subsection (b) for the 2-year period preceding the first fiscal year for which the eligible entity is applying to receive a grant under subsection (a).

''(C) INCLUSION OF RELEVANT NON-FEDERAL CONTRIBUTIONS FOR MEDICAID.—In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary shall, subject to subparagraphs (A) and (B) of this paragraph, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act by the eligible entity involved toward the activities described in subparagraphs (A) and (B) of subsection (b)(1).

''(i) ADDITIONAL REQUIREMENTS.—

''(1) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant to an eligible entity under subsection (a) unless the eligible entity provides assurances that not more than

10 percent of the grant will be expended for administrative expenses with respect to the activities funded by the grant.

''(2) STATEWIDE PROVISION OF SERVICES.—

''(A) IN GENERAL.—Subject to subparagraph (B), the Secretary may not make a grant under subsection (a) to an eligible entity unless the eligible entity provides assurances that any program funded by such grant will be made available throughout the State, including availability to members of an Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

''(B) WAIVER.—The Secretary may waive the requirement under subparagraph (A) for an eligible entity if the Secretary determines that compliance by the eligible entity with the requirement would result in an inefficient allocation of resources with respect to carrying out the purposes described in subsection (a).

''(j) 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 subsection (b)—

''(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.

''(k) REPORTS.—A grant under subsection (a) may be made only if the applicant involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

''(l) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated—

''(A) for fiscal year 2012, $50,000,000;

''(B) for fiscal year 2013, $75,000,000;

''(C) for fiscal year 2014, $150,000,000;

''(D) for fiscal year 2015, $200,000,000; and

''(E) for fiscal year 2016, $250,000,000.

''(2) SET-ASIDE FOR TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES.—Of the amount appropriated under paragraph (1) for a fiscal year, the Secretary shall reserve not to exceed 20 percent for carrying out subsection (j).''.

(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)), as amended by section 2402(d)(1) of the Patient Protection and Affordable Care Act (Public Law 111–148) is further amended—

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

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

(iii) by adding at the end the following:

''(XXIII) who are described in subsection (kk) (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), as amended by section 211(a)(1)(A)(ii) of Public

Law 111–3, section 5006(b)(1) of division B of Public Law 111–5, and section 1202 of the Patient Protection and Affordable Care Act (Public Law 111–148), is further amended by adding at the end the following:

''(kk) 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 2704(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 ''(XV)'' and inserting '', (XV)'';

(ii) by striking ''and (XVI) the medical assistance'' and inserting '', (XVI) the medical assistance'';

(iii) by striking ''and (XVI) if an individual'' and inserting '', (XVII) if an individual''; and

(iv) by inserting '', and (XVIII) the medical assistance made available to an individual described in subsection (kk) who is eligible for medical assistance only because of subparagraph (A)(10)(ii)(XXIII) 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)), as amended by section 2402(d)(2)(B) of the Patient Protection and Affordable Care Act (Public Law 111–148) is further amended in the matter preceding paragraph (1)—

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

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

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

"(xviii) individuals described in section 1902(kk),".

(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 1920C, as inserted by section 2303(b) of the Patient Protection and Affordable Care Act (Public Law 111–148), the following:

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

"SEC. 1920D. A State may elect to apply the provisions of section 1920B to individuals described in section 1902(kk) (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)), as amended by section 2303(b)(2) of the Patient Protection and Affordable Care Act (Public Law 111–148), is amended—

(I) in subparagraph (A)—

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

(bb) by striking ''and'' after ''with such section'' each place it occurs and inserting a comma each such place; and

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

(II) in subparagraph (B), by striking ''or 1920C'' and inserting ''1920C, or 1920D''.

(ii) Section 1903(u)(1)(d)(v) of such Act (42 U.S.C. 1396b(u)(1)(d)(v)), as amended by section 2202(b) of the Patient Protection and Affordable Care Act (Public Law 111–148), is further 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 1920D 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)(XXIII)''.

(4) EFFECTIVE DATE.—The amendments made by this section apply to medical assistance for items and services furnished on or after October 1, 2011, 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 are recommended with a grade of A or B by the United States Preventative Services Task Force of the Agency for Healthcare Research and Quality to communities that are underserved and suffer from barriers 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 report 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)).

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 ad-

minister 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 treatment 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) ESTABLISHMENT AND OPERATION OF RESEARCH CENTERS FOR THE STUDY OF BIOMARKERS FOR RISK STRATIFICATION AND EARLY DETECTION OF CANCERS WITH SURVIVAL RATES OF LESS THAN 50 PERCENT.—

(1) IN GENERAL.—The Director of the National Cancer Institute, in consultation with the directors of other relevant institutes and centers of the National Institutes of Health and the Department of Defense, shall enter into cooperative agreements with, or make grants to, public or nonprofit entities to establish and operate centers to conduct research on biomarkers for use in risk stratification for, and

the early detection and screening of, cancer with a five year survival rate of less than 50 percent. Each center shall be known as an Early Detection Biomarker Center of Excellence.

(2) RESEARCH FUNDED.—Federal payments made under a cooperative agreement or grant under paragraph (1) may be used for research on any of the following:

(A) The development and characterization of new biomarkers, and the refinement of existing biomarkers, for cancers with a five-year survival rate of less than 50 percent.

(B) The clinical and laboratory validation of such biomarkers, including technical development, standardization of assay methods, sample preparation, reagents, reproducibility, portability, and other refinements.

(C) The development and implementation of clinical and epidemiological research on the utilization of biomarkers for the early detection and screening of cancers with a five-year survival rate of less than 50 percent.

(D) The development and implementation of new repositories for additional tissue, urine,

serum, and other biological specimens (such as ascites and pleural fluids).

(E) Other areas identified by the Director, in consultation with the research community.

(3) COLLABORATION.—Any center funded under paragraph (1) shall demonstrate their intent to collaborate with current National Cancer Institute funded, sponsored, or funded and sponsored initiatives regarding risk stratification, early detection, and screening of cancer, including but not limited to the early detection research networks, the Cancer Genomic Atlas, and therapeutic biomarker initiatives, where applicable.

(4) AVAILABILITY OF BANKED SPECIMENS.—The Director of the Institute shall make available for research conducted under this section banked serum and tissue specimens from clinical research regarding these cancers that was funded by the Department of Health and Human Services.

(5) REPORT.—Not later than the end of fiscal year 2011, and annually thereafter, the Director of the Institute shall submit a report to the Congress on the cooperative agreements entered into and the grants made under this subsection, the progress of

these grants, and recommendations for any program improvements that would speed discovery.

(6) BIOMARKER CLINICAL TRIAL COMMITTEE.—The Director of the Institute shall establish an Biomarker Clinical Trial Committee (in this section referred to as the ''Committee''), for each cancer with biomarker centers of excellence, to assist the Director to design and implement one or more national clinical trial, in accordance with this subsection, to determine the utility of using biomarkers validated pursuant to the research conducted under this subsection for risk stratification for, and early detection and screening of, cancers with a five-year survival rate of less than 50 percent.

(7) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated $25,000,000 for each of the fiscal years 2011 through 2013, and such sums as may be necessary for each of the fiscal years 2014 through 2020. If for two consecutive years funds are not appropriated to carry out this subsection, this subsection will automatically sunset. Such authorization of appropriations is in addition to any other authorization of appropriations that is available for such purpose.

(f) SENSE OF THE HOUSE OF REPRESENTATIVES.—It is the sense of the House of Representatives 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.

(g) 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. EXTENDING COVERAGE UNDER MEDICAID OF COUNSELING AND PHARMACOTHERAPY FOR CESSATION OF TOBACCO USE.

(a) SERVICES DESCRIBED.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended—

(1) in subsection (a)(4)(D), as inserted by section 4107(a)(1)(B) of the Patient Protection and Affordable Care Act (Public Law 111–148), by striking ''by pregnant women''; and

(2) in subsection (bb), as added by section 4107(a)(2) of the Patient Protection and Affordable Care Act (Public Law 111–148)—

(A) in paragraph (1)—

(i) by striking ''the term 'counseling and pharmacotherapy for cessation of tobacco use by pregnant women'' and inserting ''the term 'counseling and pharmacotherapy for cessation of tobacco use' ''; and

(ii) by striking ''by pregnant women who use tobacco products'' and inserting ''by individuals who use tobacco products''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''with respect to pregnant women''; and

(ii) in subparagraph (B), by striking ''by pregnant women''.

(b) DROPPING EXCEPTION FROM MEDICAID PRESCRIPTION DRUG COVERAGE FOR TOBACCO CESSATION MEDICATIONS.—Section 1927(d)(2)(F) of the Social Security Act (42 U.S.C. 1396r–8(d)(2)(F)), as amended by section 4107(b) of the Patient Protection and Affordable

Care Act (Public Law 111–148), is further amended by striking ''in the case of pregnant women''.

(c) EFFECTIVE DATE.—The amendments made by this section shall 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 such date.

SEC. 9. COMPREHENSIVE CANCER CARE AND COVERAGE UNDER 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) COVERAGE OF CANCER CARE PLANNING SERVICES.—

(1) IN GENERAL.—Section 1861 of the Social Security Act, as amended by section 4103 of the Patient Protection and Affordable Care Act (Public Law 111–148), is amended—

(A) in subsection (s)(2)—

(i) by striking ''and'' at the end of subparagraph (EE);

(ii) by adding ''and'' at the end of subparagraph (FF); and

(iii) by adding at the end the following new subparagraph:

''(GG) comprehensive cancer care planning services (as defined in subsection (iii));''; and

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

''Comprehensive Cancer Care Planning Services

''(iii)(1) 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 furnished in written form 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 appropriately 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 furnished in written form 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 development 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) is furnished in written form 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;

"(iv) 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

"(v) 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 furnished in written form to the individual within a period specified by the Secretary that is as soon as practicable after the date of such revision.

''(2) The Secretary shall establish standards to carry out paragraph (1) in consultation with appropriate organizations representing providers of services related to cancer treatment and organizations representing survivors of cancer. Such standards shall include standards for determining the need and frequency for revisions of the plans of care and follow-up plans based on changes in the condition of the individual and standards for the communication of the plan to the patient.''.

(2) PAYMENT.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)), as amended by section 10501(g)(3)(B) of the Patient Protection and Affordable Care Act (Public Law 111–148), is amended by striking ''and'' before ''(Z)'' and inserting before the semicolon at the end the following: '', and (AA) with respect to comprehensive cancer care planning services described in any of subparagraphs (A) through (D) of section 1861(iii)(1), the amount paid shall be an amount equal to the sum of (i) the national average amount under the physician fee schedule established under section 1848 for

a new patient office consultation of the highest level of service in the non-facility setting, and (ii) the national average amount under such fee schedule for a physician certification described in section 1814(a)(2) for home health services furnished to an individual by a home health agency under a home health plan of care''.

(3) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after the first day of the first calendar year that begins after the date of the enactment of this Act.

(c) MEDICARE COVERAGE OF COMPREHENSIVE CANCER PATIENT TREATMENT EDUCATION SERVICES.—

(1) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by subsection (b)(1), is further amended—

(A) in subsection (s)(2)—

(i) by striking ''and'' at the end of subparagraph (FF);

(ii) by adding ''and'' at the end of subparagraph (GG); and

(iii) by adding at the end the following new subparagraph:

''(HH) comprehensive cancer patient treatment education services (as defined in subsection (jjj)(1));''; and

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

''Comprehensive Cancer Patient Treatment Education Services

''(jjj)(1) The term 'comprehensive cancer patient treatment education services' means—

''(A) in the case of an individual who is diagnosed with cancer, the provision of a one-hour patient treatment education session delivered by a registered nurse that—

''(i) is furnished to the individual and the caregiver (or caregivers) of the individual in advance of the onset of treatment and to the extent practicable, is not furnished on the day of diagnosis or on the first day of treatment;

''(ii) educates the individual and such caregiver (or caregivers) to the greatest extent practicable, about all aspects of the care to be furnished to the individual, informs the individual regarding any potential symptoms, side-effects, or adverse events, and explains ways in which side effects and adverse events can be mini-

mized and health and well-being maximized, and provides guidance regarding those side effects to be reported and to which health care provider the side effects should be reported;

"(iii) includes the provision, in written form, of information about the course of treatment, any responsibilities of the individual with respect to self-dosing, and ways in which to address symptoms and side-effects; and

"(iv) is furnished, to the greatest extent practicable, in an oral, written, or electronic form that appropriately takes into account cultural and linguistic needs of the individual in order to make the information comprehensible to the individual and such caregiver (or caregivers); and

"(B) with respect to an individual for whom a course of cancer treatment or therapy is materially modified, a one-hour patient treatment education session described in subparagraph (A), including updated information on the matters described in such subparagraph should the individual's oncologic health care professional deem it appropriate and necessary.

''(2) In establishing standards to carry out paragraph (1), the Secretary shall consult with appropriate organizations representing providers of oncology patient treatment education services and organizations representing people with cancer.''.

(2) PAYMENT.—Section 1833(a)(1) of such Act (42 U.S.C. 1395l(a)(1)), as amended by subsection (b)(2), is further amended—

(A) by striking ''and'' before ''(AA)''; and

(B) by inserting before the semicolon at the end the following: '', and (BB) with respect to comprehensive cancer patient treatment education service (as defined in section 1861(jjj)(1)), 150 percent of the payment rate established under section 1848 for diabetes outpatient self-management training services (as defined in section 1861(qq)), determined and applied without regard to any coinsurance''.

(3) COVERAGE.—Section 1862(a)(1) of such Act (42 U.S.C. 1395y(a)(1)), as amended by section 4103(d)(1) of the Patient Protection and Affordable Care Act (Public Law 111–148), is amended—

(A) in subparagraph (O), by striking ''and'' at the end;

(B) in subparagraph (P), by striking the semicolon at the end and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(Q) in the case of comprehensive cancer patient treatment education services (as defined in subsection (jjj)(1)) which are performed more frequently than is covered under such section;".

(4) NO IMPACT ON PAYMENT FOR OTHER SERVICES.—Nothing in this section shall be construed to affect or otherwise authorize any reduction or modification, in the Medicare payment amounts otherwise established for chemotherapy infusion or injection codes with respect to the calculation and payment of minutes for chemotherapy teaching or related services.

(5) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after the first day of the first calendar year that begins after the date of the enactment of this Act.

SEC. 10. TARGETED CANCERS PROGRAM.

Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.), as amended by section 14, is further amended by adding at the end the following:

"SEC. 417H. TARGETED CANCERS PROGRAM.

"(a) ESTABLISHMENT.—The Director of the Institute shall establish a targeted cancers program under which the Director may enter into agreements and make grants to conduct and coordinate research activities, with respect to cancers that result in a 5-year survival rate of less than 50 percent, for purposes of increasing such survival rate for such cancers. Such program shall include each of the elements described in subsections (b) through (i).

"(b) STRATEGIC PLAN FOR PROGRESS.—

"(1) IN GENERAL.—Under the targeted cancers program, the Director of the Institute, in coordination with relevant stakeholders and other appropriate Federal agencies, shall develop a comprehensive plan, including budget amounts, for the implementation of the research activities described in this subsection (a) as well as the identification of additional research activities that will be necessary to increase the survival for patients diagnosed with a cancer described in such subsection.

"(2) REPORT.—Not later than 6 months after the date of the enactment of this section, the Director of the Institute shall submit to Congress and make publicly available the comprehensive plan described in paragraph (1).

''(c) DEDICATED FUNDING FOR BASIC RESEARCH.—Under the targeted cancers program, the Director of the Institute shall establish a separate funding mechanism that can be used to fund basic research grants for investigators with a primary interest in one of the cancers described in subsection (a).

''(d) IMAGING RESEARCH.—Under the targeted cancers program, the Director of the Institute shall provide for research to expand and advance the potential of imaging to assist in early detection, disease management, and drug development.

''(e) INCUBATOR GRANT PROGRAM.—Under the targeted cancers program, the Director of the Institute shall establish a high-risk, high-reward incubator grant program for each cancer described in subsection (a) to allow investigators with a primary interest in such cancer an opportunity to build data for future grants provided by the Institute or the National Institutes of Health.

''(f) GRANT REVIEW BY SCIENTIFIC EXPERTS.—Under the targeted cancers program, the Director of the Institute shall provide for a peer-review process of applications submitted for a grant under this section. Such process shall be conducted by grant peer-review teams that include scientific experts in the specific disease area involved, as well as patient advocates.

''(g) SPECIALIZED TRAINING PROGRAMS.—Under the targeted cancers program, the Director of the Institute shall provide for advanced specialized training and education programs for early career PhD and clinician scientists that ensure sufficient time of such scientists is reserved for research in order to attract and retain a broader pool of investigators for the cancers specified in subsection (a).

''(h) SURVEILLANCE AND SCREENING.—Under the targeted cancers program, the Director of the Institute shall, as prevention, early detection, and treatments are identified for cancers described in subsection (a), develop pilot programs for the surveillance and treatment of such conditions that are precursors to such cancers.

''(i) COOPERATIVE RESEARCH AGREEMENTS.—Under the targeted cancers program, the Director of the Institute may enter into cooperative research agreements with other Federal agencies on programs targeting cancers specified in subsection (a), including other Institutes at the National Institutes of Health, other agencies within the Department of Health and Human Services, the Department of Defense, and the Department of Veterans Affairs.

''(j) IOM REPORT.—

''(1) IN GENERAL.—The Secretary of Health and Human Services shall enter into an arrangement with the Institute of Medicine of the National Academies to provide an independent assessment, with respect to cancers described in subsection (a), of funding of the National Cancer Institute, progress of such Institute, and the additional improvements that should be implemented by the Department of Health and Human Services, by the National Institutes of Health, and by the National Cancer Institute to make sufficient progress on research related to such cancers.

''(2) REPORT.—The agreement entered into under paragraph (1) shall provide for the Institute of Medicine to submit to the Secretary and the Congress, not later than 1 year after the date of the enactment of this section, a report containing a description of the results of the study conducted under such paragraph and the conclusions and recommendations of the Institute of Medicine regarding the issues described in such paragraph.''.

SEC. 11. ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION.

(a) REVIEW, IMPROVEMENT, AND COORDINATION.—The Commissioner of Food and Drugs shall—

(1) conduct a review of the policies, programs, and activities of the Food and Drug Administration relating to oncology products; and

(2) based on the results of such review, improve and coordinate such policies, programs, and activities, including by—

(A) integrating policies, programs, activities, and, if appropriate, organizational units of the Administration to facilitate the concurrent development of oncology products;

(B) considering 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

(C) modernizing the Office of Oncology Drug Products by examining and addressing internal barriers that exist within the Office's organizational structure.

(b) DEFINITIONS.—In this section:

(1) The term ''biological product'' has the meaning given to that term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) The terms ''device'' and ''drug'' have the meanings given to those terms in section 201 of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) The term ''oncology product'' means—

(A) any biological product, drug, or device for cancer diagnosis, prevention, or treatment; or

(B) any other product that is regulated by the Food and Drug Administration and is determined by the Commissioner of Food and Drugs to be relevant to cancer diagnosis, prevention, or treatment.

SEC. 12. CDC CANCER CONTROL PROGRAMS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.), as amended by section 6, is further amended by inserting after section 317U the following:

''SEC. 317V. CANCER CONTROL PROGRAMS.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand and intensify the cancer control programs of the Centers, including programs for conducting surveillance activities or supporting State comprehensive cancer control plans.

''(b) CERTAIN ACTIVITIES.—In carrying out subsection (a), the Secretary shall—

''(1) in collaboration with the Director of the National Cancer Institute, provide guidance to States on projects and interventions that may be incorporated into State comprehensive cancer control programs to improve the long-term health status of childhood cancer survivors, including childhood cancer survivors in minority and other medically underserved populations;

''(2) encourage States to incorporate strategies for improving systems of care for childhood cancer survivors and their families into State comprehensive cancer plans; and

''(3) collaborate with the Director of the National Cancer Institute to improve existing surveillance systems or develop appropriate new systems for tracking cancer survivors and assessing their health status and risk for other chronic and disabling conditions.

''(c) CHILDHOOD CANCER SURVIVORSHIP.—

''(1) FOCUS ON CHILDHOOD CANCER SURVIVORSHIP.—In conducting or supporting national, State, and local comprehensive cancer control programs through the Centers for Disease Control and Prevention, the Secretary shall enhance such programs—

''(A) to include a focus on childhood cancer survivorship, including survivorship in minority and other medically underserved populations; and

''(B) to include childhood cancer survivorship initiatives for improving—

''(i) the monitoring of survivors of all forms of cancer; and

''(ii) follow-up treatment for childhood cancer survivors.

''(2) RELIANCE ON GUIDELINES.—In carrying out this subsection, the Secretary shall rely, where appropriate, on existing guidelines for care of childhood cancer survivors.''.

SEC. 13. NIH CANCER SURVIVORSHIP PROGRAMS.

(a) 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 In-

vestment and Education Act of 2002 (Public Law 107–172; 116 Stat. 541).

(b) CANCER SURVIVORSHIP PROGRAMS.—Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.), is amended by adding at the end the following:

"SEC. 417G. 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 and its treatment, including physical, neu-rocognitive, 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 patients and families, including studies focusing on—

''(A) preventive interventions during treatment;

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

''(C) rehabilitative or remediative interventions;

''(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) childhood cancer survivors within minority 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 childhood cancer survivors within minority populations, the Director of NIH shall ensure that such research addresses both the physical and the psychosocial 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) 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.

"SEC. 417G–1. IMPROVING THE QUALITY OF FOLLOW-UP CARE FOR SURVIVORS OF CHILDHOOD CANCERS AND THEIR FAMILIES.

''(a) IN GENERAL.—The Secretary, in consultation with the Director of NIH, shall make grants to eligible entities to establish or improve training programs for

health care professionals (including physicians, nurses, physician assistants, and mental health professionals)—

''(1) to improve the quality of immediate and long-term follow-up care for survivors of childhood cancers and their families; and

''(2) to ensure that such care is linguistically and culturally competent.

''(b) ELIGIBLE ENTITIES.—In this section, the term 'eligible entity' means—

''(1) a medical school;

''(2) a children's hospital;

''(3) a cancer center;

''(4) a hospital with one or more residency programs that serve a significant number of childhood cancer patients;

''(5) a graduate training program for health professionals described in subsection (a) who will treat survivors of childhood cancers; or

''(6) any other entity with significant experience and expertise in treating survivors of childhood cancers.

''(c) DURATION.—Each grant under this section shall be for a period of 2 years.

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appro-

priated $5,000,000 for each of fiscal years 2012 through 2016.

"SEC. 417G–2. STUDY OF PILOT PROGRAMS TO EXPLORE MODEL SYSTEMS OF CARE.

"(a) IN GENERAL.—The Director of NIH, in consultation with the Administrator of the Health Resources and Services Administration, shall make grants to eligible entities to establish pilot programs to develop, study, or evaluate model systems for monitoring and caring for childhood cancer survivors.

"(b) ELIGIBLE ENTITIES.—In this section, the term 'eligible entity' means—

"(1) a medical school;

"(2) a children's hospital;

"(3) a cancer center; or

"(4) any other entity with significant experience and expertise in treating survivors of childhood cancers.

"(c) USE OF FUNDS.—The Director of NIH may make a grant under this section to an eligible entity only if the entity agrees—

"(1) to use the grant to establish a pilot program to develop, study, or evaluate one or more model systems for monitoring and caring for cancer survivors; and

''(2) in developing, studying, and evaluating such systems, to give special emphasis to the following:

''(A) Design of protocols for follow-up care, monitoring, and other survivorship programs (including peer support and mentoring programs).

''(B) Dissemination of information to health care providers about how to provide linguistically and culturally competent follow-up care and monitoring to cancer survivors and their families.

''(C) Dissemination of other information, as appropriate, to health care providers and to cancer survivors and their families.

''(D) Development of support programs to improve the quality of life of cancer survivors.

''(E) Design of systems for the effective transfer of treatment information from cancer care providers to other health care providers (including family practice physicians and internists) and to cancer survivors and their families, where appropriate.

''(F) Development of various models for providing multidisciplinary care.

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2012 through 2016.''.

(c) 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 recom-

mending revisions to the relevant oversight organizations.

SEC. 14. CLINICS FOR COMPREHENSIVE LONG-TERM FOLLOW-UP SERVICES FOR CHILDHOOD CANCER SURVIVORS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.), as amended by sections 6 and 13, is further amended by inserting after section 317V the following:

"SEC. 317W. CLINICS FOR COMPREHENSIVE LONG-TERM FOLLOW-UP SERVICES FOR CHILDHOOD CANCER SURVIVORS.

''(a) IN GENERAL.—The Secretary shall make grants to eligible entities to pay all or a portion of the costs incurred during the first 4 years of establishing and operating a clinic for comprehensive long-term follow-up services for childhood cancer survivors.

''(b) ELIGIBLE ENTITIES.—In this section, the term 'eligible entity' means—

''(1) a school of medicine;

''(2) a children's hospital;

''(3) a cancer center; or

''(4) any other entity with significant experience and expertise in treating survivors of childhood cancers.

''(c) PRIORITY.—In making grants under this section, the Secretary shall give priority to any eligible entity that demonstrates an expertise in improving access to care for minority and other medically underserved populations.

''(d) USE OF FUNDS.—The Secretary may make a grant under this section to an eligible entity only if the entity agrees to use the grant to pay costs incurred during the first 4 years of establishing and operating a clinic for comprehensive long-term follow-up services for childhood cancer survivors. Such costs may include the costs of—

''(1) purchasing or leasing facilities;

''(2) providing medical and psychosocial follow-up services, including coordination with the patient's primary care provider and oncologist in order to ensure that the unique medical needs of survivors are addressed;

''(3) conducting research to improve care for childhood cancer survivors;

''(4) providing linguistically and culturally competent information to childhood cancer survivors and their families; and

''(5) improving access by minority or other medically underserved populations to the best practices and care for childhood cancer survivors.

''(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $15,000,000 for each of fiscal years 2012 through 2016.''.

SEC. 15. GRANTS TO IMPROVE ACCESS TO CARE FOR CHILDHOOD CANCER SURVIVORS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.), as amended by sections 6, 13, and 15, is further amended by inserting after section 317W the following:

''SEC. 317X. GRANTS TO IMPROVE ACCESS TO CARE FOR CHILDHOOD CANCER SURVIVORS.

''(a) GRANTS.—The Secretary shall make grants to recognized childhood cancer professional and advocacy organizations to improve physical and psychosocial care for childhood cancer survivors, especially childhood cancer survivors in minority or other medically underserved populations.

''(b) USE OF FUNDS.—The Secretary may make a grant under this section to an organization only if the organization agrees to use the grant to improve physical and psychosocial care for childhood cancer survivors, especially childhood cancer survivors in minority or other medically underserved populations. Such care may include—

''(1) patient navigator programs;

''(2) peer support programs;

''(3) education and outreach for survivors and their families, including developing bilingual materials;

''(4) follow-up care for uninsured and underinsured survivors—

''(A) to identify, prevent, or control side effects associated with cancer and its treatment; and

''(B) to screen for cancer recurrence; and

''(5) assistance with transportation necessary to receive medical care for survivors and their families who lack adequate transportation resources.

''(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2012 through 2016.''.

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