108TH CONGRESS
1ST SESSION

S. 1101

To provide for a comprehensive Federal effort relating to early detection of, treatments for, and the prevention of cancer, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 21, 2003

Mrs. FEINSTEIN (for herself, Mr. SMITH, Mr. DASCHLE, Mr. JEFFORDS, Mr. KENNEDY, Ms. COLLINS, Ms. LANDRIEU, Mrs. HUTCHISON, Mr. JOHNSON, Mr. CORZINE, Mrs. LINCOLN, Ms. CANTWELL, Mrs. CLINTON, Mr. LAUTENBERG, Mrs. MURRAY, Mr. DODD, Mrs. BOXER, Ms. STABENOW, Mr. NELSON of Florida, Mr. SCHUMER, Mr. HOLLINGS, Mr. REED, Mr. KERRY, Ms. MIKULSKI, and Mr. LEAHY) introduced the following bill; which was read twice and referred to the Committee on Health Education, Labor, and Pensions

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A BILL

To provide for a comprehensive Federal effort relating to early detection of, treatments for, and the prevention of cancer, 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 ''National Cancer Act of 2003''.

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

Sec. 1. Short title; table of contents.
Sec. 2. Findings.

TITLE I—EXPANSION OF CANCER-RELATED RESEARCH, PREVENTION, DETECTION, AND TREATMENT PROGRAMS

Sec. 101. Sense of the Senate concerning investments in cancer research funding.
Sec. 102. Sense of the Senate concerning investments in cancer research to develop targeted drugs.
Sec. 103. Expansion of cancer-related research, prevention, detection, treatment, and survivorship programs.
Sec. 104. National Institute for Environmental Health Sciences.
Sec. 105. Comprehensive cancer control plans.
Sec. 106. Breast, cervical, and colorectal cancer screening.
Sec. 107. IHS grants for model community cancer and chronic disease care and prevention; IHS grants for patient navigators.

TITLE II—EXPANDING ACCESS TO CANCER DRUGS AND TREATMENT

Sec. 201. Acceleration of the drug treatment approval process of the Food and Drug Administration.
Sec. 202. FDA amendment.

TITLE III—CANCER-RELATED HEALTH INSURANCE COVERAGE

Subtitle A—Clinical Trials Coverage

Sec. 301. Coverage for clinical trials under the Public Health Service Act.
Sec. 302. Coverage for clinical trials under the Employee Retirement Income Security Act of 1974.
Sec. 303. Coverage for clinical trials under other public health insurance.

Subtitle B—Cancer Screening and Other Coverage

Sec. 311. Cancer screening coverage.

Subtitle C—Physicians and Quality of Care

Sec. 321. Managing physicians and quality of care for cancer patients under the Public Health Service Act.
Sec. 322. Managing physicians and quality of care for cancer patients under the Employee Retirement Income Security Act of 1974.
Sec. 323. Managing physicians and quality of care for cancer patients under medicare.
Sec. 324. Managing physicians and quality of care for cancer patients under medicaid and SCHIP.

Subtitle D—General Provisions

Sec. 331. Coverage under other public health insurance.

TITLE IV—PATIENT NAVIGATOR AND CANCER CARE WITHIN THE HEALTH RESOURCES AND SERVICES ADMINISTRATION

Sec. 401. HRSA grants for model community cancer and chronic disease care and prevention and grants for patient navigators.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Each year 1,300,000 Americans are diagnosed with cancer. Each year 560,000 Americans die from cancer. Approximately 40 percent of all Americans in the United States will be diagnosed with cancer at some point in their lives.

(2) Since 1971, when the National Cancer Act was enacted, and the ''War on Cancer'' was declared, the science of cancer has advanced dramatically. The revolution in molecular and cellular biology has created unprecedented opportunities for understanding cancer and the role of genetics, environmental risk factors, and lifestyle factors in relation to cancer.

(3) Since 1971, mortality rates for some cancers have decreased, while such rates for other cancers have not.

(4) Since 1971, the Nation's population has become increasingly diverse and cancer affects various minority, socioeconomic, and ethnic groups disproportionately.

(5) Cancer screening can reduce cancer mortality, in some cases by 30 percent or more. While effective screening tools have yet to be developed for the majority of cancers, proven screening tools for

early detection do exist for some of the more common cancers. Screening for some cancers, such as breast, colorectal, and cervical cancers, has improved dramatically; however, screening rates are still lower than optimal. Cancer screening rates vary by cancer site, population group, and health insurance coverage.

(6) Public and private health insurance coverage offered in the United States has dramatically changed since 1971. Today, managed care coverage is more typical than the fee-for-service coverage that was more common in the past. This change in the form of coverage has introduced more economic considerations into medical decisionmaking, which can affect the quality of all health care provided, including cancer care.

(7) Fewer than 5 percent of adult cancer patients participate in cancer trials.

(8) New translational cancer research centers are needed to provide the preclinical and early clinical trials support required to advance scientific discoveries into new drugs and technologies to prevent, detect, treat, and diagnose cancer.

(9) The quality of cancer care is uneven across the Nation and can be based on pure coincidence of

where one lives. Many cancer patients do not receive optimal care.

(10) Cancer is a disease of aging and as the American population ages, cancer incidence will grow. It is estimated that the number of cancer diagnoses in 2010 will increase by 20 percent. The number of cancer deaths is anticipated to increase by 20 percent, at an annual cost of over $200,000,000,000. With such increases in the incidence of cancer, there will be a serious shortage of individuals in the workforce to provide cancer care, particularly in long-term care settings.

(11) The number of medical researchers is declining, a decrease which will negatively affect the prevention, detection, and treatment of cancer.

(12) Since 1971, there has been a shift in cancer care, such as the administration of chemotherapy, moving from inpatient to outpatient settings.

(13) Since 1971, the conduct of research has involved more collaboration between the public and private sectors and more multidisciplinary approaches. The biotechnology pharmaceutical and device industry has grown and provided a broad array

of new treatment options and scientific opportunities for cancer patients, providers, and researchers.

(14) Since 1971, technology and communications have expanded and increased in complexity, transforming research methodologies and making the accessing and transmitting of information more widespread and more readily available.

(15) Tobacco use is the leading preventable cause of disease and premature death in the United States, resulting in ⅓ of all cancer deaths, including 87 percent of lung cancer deaths. Research consistently shows that smoking cessation services can be 1 of the most cost-effective health interventions and can reduce smoking-related health care costs. Cessation services offered as a combination of tobacco medication therapy and counseling effectively help smokers quit successfully and prevent premature death from tobacco-related cancers.

TITLE I—EXPANSION OF CANCER-RELATED RESEARCH, PREVENTION, DETECTION, AND TREATMENT PROGRAMS

SEC. 101. SENSE OF THE SENATE CONCERNING INVESTMENTS IN CANCER RESEARCH FUNDING.

It is the sense of the Senate that—

(1) past investments in cancer research have resulted in better health, an improved quality of life, and a reduction in national health care expenditures; and

(2) to build on, and sustain, the progress made over the past 5 years during which Congress doubled the budget at the National Institutes of Health, the National Cancer Institute requires continued increases in Federal funding, as outlined in the National Cancer Institute Directors Bypass Budget, to achieve a balanced research portfolio and to develop more targeted, more effective therapies or drugs and other cancer treatments and to address those rare, deadly cancers lacking effective early detection tests or treatments for a wide range of cancers, commensurable with the National Cancer Institute bypass budget.

SEC. 102. SENSE OF THE SENATE CONCERNING INVESTMENTS IN CANCER RESEARCH TO DEVELOP TARGETED DRUGS.

(a) FINDINGS.—The Senate finds that—

(1) all cells have molecular signatures, unique identifiable characteristics related to a cells' function in the body;

(2) as a normal cell becomes malignant, its signature changes and this change becomes a signal of the presence of cancer; and

(3) with new technologies, scientists are reading cancer-associated signatures and using this information to devise treatments that target specific cells.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that to build on the research currently conducted by the National Institutes of Health, increased funding is necessary to further develop this new generation of low toxicity, high efficacy agents which target only the cancer cells leaving in place the healthy cells.

SEC. 103. EXPANSION OF CANCER-RELATED RESEARCH, PREVENTION, DETECTION, TREATMENT, AND SURVIVORSHIP PROGRAMS.

Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285) is amended—

(1) by inserting after the subpart heading the following:

"CHAPTER I—PURPOSE OF INSTITUTE AND NATIONAL CANCER PROGRAMS";

and

(2) by adding at the end the following:

"CHAPTER II—PROGRAMS TO PREVENT AND TREAT CANCER

"SEC. 417E. STUDY AND STRATEGIC PLANS.

''(a) IN GENERAL.—Not later than July 1, 2005, the Institute shall prepare 1 or more strategic plans to identify unmet needs and the level of funding in the areas of prevention, treatment, early detection, and quality of life, and to expand and intensify cancer research and cancer-related research by July 1, 2006, for—

''(1) behavioral research associated with causing and preventing cancer;

''(2) research regarding prevention of cancer other than behavioral interventions;

''(3) research to reduce disparities among racial and ethnic minorities and other disparity populations;

''(4) research regarding palliative care, pain management;

''(5) research regarding preserving and restoring quality-of-life for cancer patients;

''(6) research regarding environmental risk factors for cancer and gene-environment interactions;

''(7) research regarding management of symptoms;

''(8) research regarding tools for early detection, especially for which there currently are no adequate screening technologies; and

''(9) cancer survivorship.

''(b) PRIORITIES.—The Institute shall determine priorities based on scientific opportunities, in consultation with medical, scientific, patient, and provider representatives, and prepare 1 or more strategic plans by July 1, 2005.

''SEC. 417E–1. GRANTS FOR TRANSLATIONAL CANCER RESEARCH.

''(a) IN GENERAL.—The Director of the Institute shall carry out a program to establish translational cancer research centers.

''(b) DUTIES OF DIRECTOR.—In carrying out the program, the Director of the Institute shall—

''(1) award grants to public or nonprofit private entities to plan and operate a national network of at least 20 existing or new translational cancer research centers to conduct translational, multidisciplinary cancer research;

''(2) establish networks and partnerships linking the translational cancer research centers described in paragraph (1) to community cancer providers (hospitals, clinics, providers' practices, par-

ticularly in underserved areas) and expand opportunities for all cancer patients to participate in clinical trials of new agents developed by these centers;

''(3) facilitate the process to award grants, contracts, and cooperative agreements to private entities to conduct translational cancer research in the following areas—

''(A) cancer drugs, biologics, and devices; and

''(B) cancer detection diagnostic tests, techniques, and technology; and

''(4) develop and implement a strategic plan by July 1, 2005, in collaboration with translational centers as authorized in paragraph (7) for intensifying, expanding, and disseminating results of translational research to providers of cancer care.

''(c) GRANTS.—

''(1) IN GENERAL.—The Director of the Institute shall award grants to public or nonprofit private entities to establish translational cancer research centers to conduct translational, multidisciplinary cancer research. Funds shall not be used for construction of new facilities.

''(2) EQUITY.—The Director of the Institute shall award grants under subsection (b)(1) to pro-

vide, to the greatest extent practicable, a broad distribution of such grants among geographic regions of the United States.

''(3) DUTIES.—A public or nonprofit entity that receives a grant under subsection (b)(1) shall use funds received through such grant to establish and operate a translational cancer research center.

''(4) APPLICATION.—A public or nonprofit entity desiring a grant under this subsection shall submit an application to the Director of the Institute at such time, in such manner, and containing such information as the Director of the Institute may reasonably require.

''(d) DUTIES OF TRANSLATIONAL RESEARCH CENTERS.—The translational research centers shall—

''(1) perform research for discovery and preclinical evaluation of drugs, biologics, devices, technologies, and strategies with potential to improve the prevention, detection, diagnosis, and treatment of cancer and to improve pain and symptom management and quality of life of cancer patients;

''(2) perform clinical research studies on promising cancer treatments or strategies, in appropriate human populations;

''(3) evaluate promising cancer diagnostic tests, techniques, or technologies in individuals being evaluated for the presence of cancer;

''(4) perform all phases of clinical trials of new drugs, devices, biologics, or other strategies for treating patients with cancer, in collaboration with the existing NCI Cooperative Groups;

''(5) develop and implement a plan to ensure the availability of adequate sources of patients for each type of clinical research study;

''(6) create systems and external relationships, which do not duplicate capabilities available in the private sector, to accelerate the findings from translational research to a stage that private companies can assume development and commercialization; and

''(7) develop and implement a plan expanding and disseminating the efficacious products of translational research to providers of cancer care, including products approved by the Food and Drug Administration.

''(e) DEFINITIONS.—In this section:

''(1) CLINICAL TRIAL.—The term 'clinical trial' means a scientifically-designed clinical investigation in which a patient participates in examining the ef-

fects of a drug, biologic medical treatment, or medical device for the prevention, early detection, or treatment of cancer or the potential side effects of treatment or of the disease.

''(2) TRANSLATIONAL CANCER RESEARCH.—The term 'translational cancer research' means scientific laboratory and clinical research and testing needed to transform scientific discoveries into new approaches and products that can prevent, detect, control, diagnose, and treat cancer, optimize quality of life, and ultimately, cure cancer.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $100,000,000 in fiscal year 2004, and $100,000,000 for each of the fiscal years 2005, 2006, 2007, and 2008.

''SEC. 417E–2. GRANTS FOR DEVELOPMENT OF TARGETED DRUGS.

''(a) IN GENERAL.—The Director of the Institute shall carry out a research grant program to provide funding to projects that seek to develop cancer treatments that target cancer cells.

''(b) DUTIES OF DIRECTOR.—In carrying out the program under subsection (a), the Director of the Institute shall—

''(1) award grants and facilitate the process to award grants to public or nonprofit private entities to conduct research to develop a molecularly-oriented, knowledge-based approach to cancer drug discovery and development; and

''(2) not later than July 1, 2005, develop and implement a strategic plan for intensifying and expanding research conducted to increase the number of cancer treatments available that are low toxicity, high efficacy agents, and in particular, research to develop treatments that selectively target malignant or cancerous cells.

''(c) LIMITATIONS.—Amounts awarded under grants under this section shall not be used for the construction of facilities.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $20,000,000 in fiscal year 2004, and $20,000,000 for each of the fiscal years 2005, 2006, 2007, and 2008.

''SEC. 417E–3. CLINICAL TRIALS.

''(a) IN GENERAL.—The Director of the Institute shall carry out a program to increase patient and provider participation in clinical trials.

''(b) PROGRAM.—The program described in subsection (a) shall include—

''(1) an outreach program;

''(2) a diversity assurance program;

''(3) an assistance program, including recommending sources of funding for patients support costs; and

''(4) culturally appropriate materials.

''(c) OUTREACH PROGRAM.—In carrying out the outreach program described in subsection (a), the Director of the Institute shall regularly provide information to cancer care providers, professional and patient organizations, including community-based organizations, and patients to increase provider participation and patient enrollment in clinical trials.

''(d) DIVERSITY ASSURANCE PROGRAM.—In carrying out the diversity assurance program described in subsection (a), the Director of the Institute shall require that all research grant applications include assurances that the applicant will actively recruit a diverse patient population, including disparity populations, to participate in trials, when such recruitment is medically appropriate.

''SEC. 417E–4. CANCER CARE RESEARCHERS.

''(a) SUPPLY OF CANCER RESEARCHERS.—In order to ensure a sufficient number of researchers trained in the prevention, early detection, diagnosis, cure, and treatment of cancer in future fiscal years, the Director of the Insti-

tute, in coordination with the Secretary of Veterans Affairs, shall carry out activities to—

''(1) increase the number and amount of institutional training grants to institutions supporting cancer research; and

''(2) increase the number of career development awards for health professionals, particularly minorities, who intend to have, or who expand, careers in basic, clinical, and translational cancer research, including cancer prevention, cancer information technology, bioinformatics, behavioral research, and research on palliative, psychosocial, and end-of-life care.

''(b) LOAN REPAYMENT.—

''(1) ESTABLISHMENT.—The Director of the Institute, in consultation with the Director of the National Institutes of Health, shall establish a cancer research loan repayment program.

''(2) CONTRACTS.—Under the program established under paragraph (1), the Director of the Institute shall enter into contracts with qualified health professionals under which such professionals will agree to conduct cancer research, in consideration of the Federal Government agreeing to repay, for each year of such services, not more than

$35,000 of the principal and interest of the educational loans of such professionals obtained to support training for degrees or licenses, as determined appropriate by the Director of the Institute.

''(c) POSTDOCTORAL STIPENDS.—

''(1) IN GENERAL.—The Director of the Institute, shall develop and implement, for postdoctoral trainees and fellows, a stipend schedule that by October 1, 2004, begins for entry-level positions and individuals with no or limited experience comparable to grade 11 of the Federal general schedule under title 5, United States Code (civil service salary schedule) and that adequately reflects training, education, experience, and comparable salaries or stipends for comparable work in non-Federal settings, and provides for annual cost-of-living adjustments.

''(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $79,000,000 for fiscal year 2004, and $86,000,000 for fiscal year 2005, $95,000,000 for fiscal year 2006, $105,000,000 for fiscal year 2007, and $115,000,000 for fiscal year 2008.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section,

$10,500,000 for fiscal year 2004, and $10,500,000 for each of fiscal years 2005 through 2008.

''SEC. 417E–5. CANCER CARE WORKFORCE.

''(a) IN GENERAL.—The Secretary shall establish a program to address current and future cancer care workforce needs.

''(b) PROGRAM.—The program described in subsection (a) shall—

''(1) set annual and long-term training goals to assure an adequate cancer care workforce;

''(2) prepare and implement a plan to provide assistance to individuals based on cancer health professions with the most severe shortages;

''(3) award grants, scholarships, fellowships, and loans to eligible individuals to increase the cancer care workforce;

''(4) make awards to eligible individuals to increase cancer care workforce training for all individuals to become cancer care providers, especially but not limited to, such individuals who make a commitment to serve in underserved communities or areas with disproportionately high cancer incidence or mortality and for health professions for which there are anticipated shortages, including providers, pharmacists, nurses for all settings, allied health profes-

sionals, physicians, specialists, and public health professionals; and

''(5) be coordinated with existing programs to prevent duplication.

''(c) ELIGIBILITY.—To be eligible to receive a scholarship, loan, or fellowship under this section, an individual shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary reasonably requires. In such application, such individual shall demonstrate the intent to seek training to get a certificate, license, or postsecondary degree in health care, or in the case of licensed health care professionals, the intent to seek professional development to upgrade skills and knowledge or to obtain specialized knowledge according to criteria developed by the Secretary.

''(d) USE OF FUNDS.—A recipient of a grant, scholarship, loan, or fellowship under this section may use funds from such grant, scholarship, loan, or fellowship to pay the costs of tuition and fees for training in—

''(1) care and treatment of cancer patients and survivors;

''(2) quality of life and symptom management;

''(3) early detection and diagnosis;

''(4) cancer prevention;

''(5) genetic testing and counseling;

''(6) language and cultural competency in cancer care; and

''(7) palliative and end-of-life care.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $100,000,000 in fiscal year 2004 and such sums as may be necessary in each year for fiscal years 2005, 2006, 2007, and 2008.

"SEC. 417E–6. CENTERS FOR DISEASE CONTROL AND PREVENTION.

''(a) PROGRAM.—The Director of the Centers for Disease Control and Prevention shall—

''(1) expand and update the National Comprehensive Cancer Control Program;

''(2) assist States, territories, tribal organizations, and the District of Columbia in developing and implementing a cancer prevention and control program so that each entity will have an active plan in place and so that States, territories, tribal organizations, and the District of Columbia will conduct activities to prevent and control cancer and so that disparities in specific populations will be addressed;

''(3) establish programs that demonstrate how to prevent and control cancer and improve access to and the quality of cancer care among racial and eth-

nic minority and medically underserved populations with disproportionate incidence of or death from cancer;

''(4) promote cancer education, prevention, and early detection of cancer; and

''(5) award grants to public and nonprofit organizations for cancer control and prevention.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $65,000,000 for fiscal year 2004 and such sums as may be necessary for fiscal years 2005, 2006, 2007, and 2008.

''SEC. 417E–7. CANCER SURVIVORSHIP.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct a study of the unique health challenges associated with cancer survivorship and carry out projects and interventions to improve the long-term health status of cancer survivors. Such projects shall be carried out directly or through the awarding of grants or contracts.

''(b) ACTIVITIES.—Activities that may be carried out under subsection (a) include—

''(1) the expansion of current cancer surveillance systems to track the health status of cancer survivors and determine whether cancer survivors

are at-risk for other chronic and disabling conditions;

''(2) assess the unique challenges associated with cancer survivorship; and

''(3) the development of a national cancer survivorship action plan, in partnership with health organizations focused on cancer survivorship, to be carried out in coordination with the State-based comprehensive cancer control program of the Centers for Disease Control and Prevention to—

''(A) develop unique and innovative post-treatment programs, services, and demonstrations designed to support and advance cancer survivorship through—

''(i) promotion of physical activity and healthy lifestyles;

''(ii) educational outreach programs for health care providers;

''(iii) support for innovative programs to improve the quality of life among cancer survivors;

''(iv) home and community-based interventions;

''(v) peer support and mentor programs;

''(vi) public awareness and outreach campaigns; and

''(vii) information dissemination to inform health care providers and cancer survivors of their health care options and available survivorship programs; and

''(B) develop unique cancer survivorship demonstration programs designed to address the needs of underserved populations, including minorities, children, and individuals residing in rural areas.

''(c) COORDINATION OF ACTIVITIES.—The Secretary shall ensure that activities carried out under this section are coordinated as appropriate with other agencies of the Public Health Service.

''(d) REPORT TO CONGRESS.—Not later than October 1, 2004, the Secretary shall submit to Congress a report describing the results of the study conducted under subsection (a), and as applicable, the strategies developed under such subsection.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $35,000,000 for fiscal year 2004, and such sums as may be necessary for each of fiscal years 2005 through 2008.

"SEC. 417E–8. OFFICE OF CANCER SURVIVORSHIP.

''(a) ESTABLISHMENT.—There is established within the Institute an Office on Cancer Survivorship (in this section referred to as the 'Office'), to be headed by an Associate Director, to implement and direct the expansion and coordination of the activities of the Institute with respect to cancer survivorship research.

''(b) COLLABORATION AMONG AGENCIES.—In carrying out the activities described in subsection (a), the Office shall collaborate with other institutes, centers, and offices within the National Institutes of Health that are determined appropriate by the Office.

''(c) REPORT.—Not later than 1 year after the date of enactment of this section, the Secretary shall prepare and submit to the appropriate committees of Congress a report providing a description of the survivorship activities of the Office and strategies for future activities.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2004 through 2008.

"SEC. 417E–9. MONITORING AND EVALUATING QUALITY CANCER CARE AND CANCER SURVIVORSHIP.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Institute and the Director of the Centers for Disease Control and Prevention, shall make grants

to eligible entities for the purpose of enabling such entities to monitor and evaluate quality cancer care, develop information concerning quality cancer care, and monitor cancer survivorship.

''(b) ELIGIBLE ENTITIES.—An entity shall be eligible for a grant under this section for a fiscal year if such entity—

''(1) operates a statewide cancer registry with funds from a grant made under section 399B for such fiscal year; and

''(2) is certified by the North American Association of Central Cancer Registries or another similar certification organization.

''(c) CONTRACTING AUTHORITY.—In carrying the purpose described in subsection (a), an eligible entity may expend a grant under such subsection to enter into contracts with academic institutions, cancer centers, and other entities, when determined appropriate by the Secretary.

''(d) APPLICATION.—To be eligible for a grant under subsection (a), an eligible entity shall submit to the Secretary an application at such time, in such manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(e) AUTHORITY OF SECRETARY REGARDING USE OF GRANT FUNDS.—The Secretary shall determine the appropriate uses of grant funds under subsection (a) to achieve the purpose described in such subsection.

''(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2004 through 2008.

"SEC. 417E–10. MODEL COMMUNITY CANCER AND CHRONIC DISEASE CARE AND PREVENTION; PATIENT NAVIGATORS.

''(a) DEFINITIONS.—In this section:

''(1) APPROPRIATE FOLLOW-UP CARE.—The term 'appropriate follow-up care' includes palliative and end-of-life care.

''(2) CULTURALLY COMPETENT.—The term 'culturally competent', with respect to providing health-related services, means services that, in accordance with standards and measures of the Secretary, are designed to effectively and efficiently respond to the cultural and linguistic needs of patients.

''(3) ELIGIBLE ENTITY.—The term 'eligible entity' means any public or private entity determined to be appropriate by the Director of the Institute

that provides services described in subsection (b)(1)(A) for cancer and chronic diseases, or any of the following entities that demonstrates the ability to perform all of the functions outlined in subsections (b) through (d):

"(A) A designated cancer center of the Institute.

"(B) An academic institution.

"(C) An Indian Health Service Clinic.

"(D) A tribal government.

"(E) An urban Indian organization.

"(F) A tribal organization.

"(G) A hospital.

"(H) A qualified nonprofit entity that partners with 1 or more centers providing health care to provide navigation services.

"(4) HEALTH DISPARITY POPULATION.—The term 'health disparity population' means a population where there exists a significant disparity in the overall rate of disease incidence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population. Such term includes—

"(A) racial and ethnic minority groups (as defined under section 1707); and

''(B) medically underserved groups, such as rural and low-income individuals and individuals with low levels of literacy.

''(5) PATIENT NAVIGATOR.—

''(A) IN GENERAL.—The term 'patient navigator' means an individual whose functions include—

''(i) assisting and guiding patients with a symptom, abnormal finding, or diagnosis of cancer or other chronic disease within the health care system to accomplish the follow-up and diagnosis of an abnormal finding as well as the treatment and appropriate follow-up care of cancer or other chronic disease, including providing information about clinical trials; and

''(ii) identifying, anticipating, and helping patients overcome barriers within the health care system to ensure prompt diagnostic and treatment resolution of an abnormal finding of cancer or other chronic disease.

''(B) INCLUSIONS.—The term 'patient navigator' includes representatives of the target health disparity population, such as nurses, so-

cial workers, cancer survivors, and patient advocates.

''(b) MODEL COMMUNITY CANCER AND CHRONIC DISEASE CARE AND PREVENTION.—

''(1) IN GENERAL.—The Director of the Institute may make grants to eligible entities for the development and operation of model programs that—

''(A) provide to individuals of health disparity populations prevention, early detection, treatment, and appropriate follow-up care services for cancer and chronic diseases;

''(B) ensure that the health services are provided to such individuals in a culturally competent manner;

''(C) assign patient navigators, in accordance with applicable criteria of the Secretary, for managing the care of individuals of health disparity populations to—

''(i) accomplish, to the extent possible, the follow-up and diagnosis of an abnormal finding and the treatment and appropriate follow-up care of cancer or other chronic disease; and

''(ii) facilitate access to appropriate health care services within the health care

system to ensure optimal patient utilization of such services, including aid in coordinating and scheduling appointments and referrals, community outreach, assistance with transportation arrangements, and assistance with insurance issues and other barriers to care and providing information about clinical trials;

''(D) require training for patient navigators employed through such model programs to ensure the ability of navigators to perform all of the duties required in this subsection and in subsection (c), including training to ensure that navigators are informed about health insurance systems and are able to aid patients in resolving access issues; and

''(E) ensure that consumers have direct access to patient navigators during regularly scheduled hours of business operation.

''(2) APPLICATION FOR GRANT.—An eligible entity that desires to receive a grant under paragraph (1) shall submit an application to the Director of the Institute at such time, in such manner, and containing such agreements, assurances, and informa-

tion as the Director of the Institute determines to be necessary to carry out this section.

''(3) OUTREACH SERVICES.—In order to be eligible to receive a grant under paragraph (1), an eligible entity shall agree to provide ongoing outreach activities while receiving the grant, in a manner that is culturally competent for the health disparity population served by the program, to inform the public and the specific community that the program is serving of the services of the model program under the grant. Such activities shall include facilitating access to appropriate health care services and patient navigators within the health care system to ensure optimal patient utilization of such services.

''(4) DATA COLLECTION AND REPORT.—In order to allow for effective program evaluation, an eligible entity that receives a grant under this subsection shall collect specific patient data recording services provided to each patient served by the program and shall establish and implement procedures and protocols, consistent with applicable Federal and State laws (including sections 160 and 164 of title 45, Code of Federal Regulations) to ensure the confidentiality of all information shared by a participant in the program, or their personal representative and

their health care providers, group health plans, or health insurance insurers with the program. The program may, consistent with applicable Federal and State confidentiality laws, collect, use, or disclose aggregate information that is not individually identifiable (as defined in sections 160 and 164 of title 45, Code of Federal Regulations). With this data, the grantee shall submit an annual report to the Secretary that summarizes and analyzes the data and provides information on needs for navigation services, types of access difficulties resolved, sources of repeated resolution, and flaws in the system of access, including insurance barriers.

''(5) EVALUATIONS.—

''(A) IN GENERAL.—The Director of the Institute, directly or through grants or contracts, shall provide for evaluations to determine which outreach activities under paragraph (3) were most effective in informing the public and the specific community that the program is serving of the model program services and to determine the extent to which such programs were effective in providing culturally competent services to the health disparity population served by the programs.

''(B) DISSEMINATION OF FINDINGS.—The Director of the Institute shall, as appropriate, disseminate to public and private entities the findings made in evaluations under subparagraph (A).

''(6) COORDINATION WITH OTHER PROGRAMS.—The Secretary shall coordinate the program under this subsection with—

''(A) the program under subsection (c);

''(B) the program under section 330M; and

''(C) to the extent practicable, programs for prevention centers that are carried out by the Director of the Centers for Disease Control and Prevention.

''(c) PROGRAM FOR PATIENT NAVIGATORS.—

''(1) IN GENERAL.—The Director of the Institute may make grants to eligible entities for the development and operation of programs to pay the costs of such entities in—

''(A) assigning patient navigators, in accordance with applicable criteria of the Secretary, for managing the care of individuals of health disparity populations for the duration of receipt of health services from the health cen-

ters, including aid in coordinating and scheduling appointments and referrals, community outreach, assistance with transportation arrangements, assistance with insurance issues and other barriers to care, and providing information about clinical trials;

''(B) ensuring that the services provided by the patient navigators to such individuals include case management and psychosocial assessment and care or information and referral to such services;

''(C) ensuring that the patient navigators with direct knowledge of the communities they serve provide services to such individuals in a culturally competent manner;

''(D) developing model practices for patient navigators, including with respect to—

''(i) coordination of health services, including psychosocial assessment and care;

''(ii) follow-up services, including psychosocial assessment and care;

''(iii) determining coverage under health insurance and health plans for all services;

"(iv) ensuring the initiation, continuation, or sustained access to care prescribed by the patients' health care providers; and

"(v) aiding patients with health insurance coverage issues;

"(E) requiring training for patient navigators to ensure the ability of navigators to perform all of the duties required in this subsection and in subsection (b), including training, to ensure that navigators are informed about health insurance systems and are able to aid patients in resolving access issues; and

"(F) ensuring that consumers have direct access to patient navigators during regularly scheduled hours of business operation.

"(2) APPLICATION FOR GRANT.—An eligible entity that desires to receive a grant under paragraph (1) shall submit an application to the Director of the Institute at such time, in such manner, and containing such agreements, assurances, and information as the Director of the Institute determines to be necessary to carry out this section.

"(3) OUTREACH SERVICES.—In order to be eligible to receive a grant under paragraph (1), an eli-

gible entity shall agree to provide ongoing outreach activities while receiving the grant, in a manner that is culturally competent for the health disparity population served by the program, to inform the public and the specific community that the patient navigator is serving of the services of the model program under the grant.

''(4) DATA COLLECTION AND REPORT.—In order to allow for effective patient navigator program evaluation, an eligible entity that receives a grant under this subsection shall collect specific patient data recording navigation services provided to each patient served by the program and shall establish and implement procedures and protocols, consistent with applicable Federal and State laws (including sections 160 and 164 of title 45, Code of Federal Regulations) to ensure the confidentiality of all information shared by a participant in the program, or their personal representative and their health care providers, group health plans, or health insurance insurers with the program. The patient navigator program may, consistent with applicable Federal and State confidentiality laws, collect, use, or disclose aggregate information that is not individually identifiable (as defined in sections 160 and 164

of title 45, Code of Federal Regulations). With this data, the grantee shall submit an annual report to the Secretary that summarizes and analyzes the data and provides information on needs for navigation services, types of access difficulties resolved, sources of repeated resolution, and flaws in the system of access, including insurance barriers.

''(5) EVALUATIONS.—

''(A) IN GENERAL.—The Director of the Institute, directly or through grants or contracts, shall provide for evaluations to determine the effects of the services of patient navigators on the health disparity population for whom the services were provided, taking into account the matters referred to in paragraph (1)(C).

''(B) DISSEMINATION OF FINDINGS.—The Director of the Institute shall as appropriate disseminate to public and private entities the findings made in evaluations under subparagraph (A).

''(6) COORDINATION WITH OTHER PROGRAMS.—The Secretary shall coordinate the program under this subsection with the programs under subsection (b) and section 330M.

''(d) REQUIREMENTS REGARDING FEES.—

''(1) IN GENERAL.—In order to be eligible to receive a grant under subsection (b) or (c), the program for which the grant is made shall have in effect—

''(A) a schedule of fees or payments for the provision of such program's health care services related to the prevention and treatment of disease that is consistent with locally prevailing rates or charges and is designed to cover such program's reasonable costs of operation; and

''(B) a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the ability of the patient to pay.

''(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require payment for navigation services or to require payment for health care services in cases where care is provided free of charge, including the case of services provided through programs of the Indian Health Service.

''(e) MODEL.—Not later than 5 years after the date of enactment of this section, the Director of the Institute

shall develop a peer-reviewed model of systems for the services provided by this section. The Director of the Institute shall update such model as may be necessary to ensure that the best practices are being utilized.

''(f) DURATION OF GRANT.—The period during which payments are made to an eligible entity from a grant under subsection (b)(1) or (c)(1) may not exceed 5 years. The provision of such payments are subject to annual approval by the Director of the Institute and subject to the availability of appropriations for the fiscal year involved. Nothing in this subsection shall be construed as establishing a limitation on the number of grants under subsections (b) and (c) that may be made to an eligible entity.

''(g) AUTHORIZATION OF APPROPRIATIONS.—

''(1) MODEL PROGRAMS.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

''(2) PATIENT NAVIGATORS.—For the purpose of carrying out subsection (c), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

''(3) RELATION TO OTHER AUTHORIZATIONS.—Authorizations of appropriations under paragraphs

(1) and (2) are in addition to other authorizations of appropriations that are available for the purposes of carrying out subsections (b) and (c).

"SEC. 417E–11. CANCER CARE GUIDELINES.

''The Agency for Healthcare Research and Quality shall regularly convene cancer experts, providers, patients, representatives of disparity populations, and other relevant experts, including representatives of the Institute, the Health Resources Administration, and the Centers for Disease Control and Prevention, to coordinate the development and regularly update—

''(1) consensus protocols and practice guidelines for optimal cancer treatments and prevention, including palliation, symptom management, and end-of-life care;

''(2) quality of care measures to assist providers and patients in making and evaluating treatment decisions; and

''(3) guidelines for providing patients with multi-disciplinary consultation before treatment is initiated and with 1 physician, preferably a specialist when feasible, to provide overall coordination and management of cancer care among all providers of the patient's treatment and services.

"SEC. 417E–12. RESEARCH AND OTHER ACTIVITIES OF THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY TO IMPROVE THE QUALITY AND OUTCOMES OF CANCER CARE.

''(a) IN GENERAL.—

''(1) RESEARCH.—The Director for Healthcare Research and Quality shall conduct and support research and other activities to build an evidence base regarding effective clinical and organizational intervention strategies to improve the quality and outcomes of cancer care, and access to such care, at all stages of the health care continuum and to facilitate the prompt use of that information to improve practice.

''(2) FACTORS.—In carrying out paragraph (1), the Director for Healthcare Research and Quality shall take into account the breadth of the continuum of cancer care, from prevention and early detection, through diagnosis and treatment, to rehabilitation, long term survivorship and remission, through psychosocial, palliative, and end-of-life care.

''(b) SPECIFIC REQUIREMENTS.—The Agency for Healthcare Research and Quality shall—

''(1) conduct and support research to develop new scientific knowledge regarding the effectiveness and cost-effectiveness of interventions that improve

the quality and outcomes of cancer care, and access to such care;

''(2) regularly assess and synthesize existing scientific evidence on the effectiveness of such interventions;

''(3) ensure the targeted dissemination of the most current scientific evidence in appropriate formats for use by professional societies and organizations representing clinicians and other caregivers, organizations through which health care and support services are delivered, and organizations representing cancer patients and their families;

''(4) facilitate, as appropriate, the prompt use of existing scientific information by the professional societies and organization listed in paragraph (3) to develop guidance, best practices, quality improvement strategies or other initiatives to improve practice;

''(5) develop quality of care measures to assist clinicians and other caregivers, providers and health plans, patients and their families, and purchasers;

''(6) collect information, as appropriate, and conduct and support research on trends in medical care practice patterns and the relationship of such

trends to the quality and outcomes of cancer care; and

''(7) assess effective strategies by which an individual physician can provide overall coordination and management of cancer care.

''(c) COORDINATION OF FEDERAL QUALITY IMPROVEMENT ACTIVITIES AND REPORTING OF DATA.—In carrying out subsection (b)—

''(1) the Director for Healthcare Research and Quality, working through the Quality Interagency Coordination (QUIC) Task Force, and in collaboration with the Director of the Institute, shall facilitate coordination of Federal research and implementation initiatives to improve the quality and outcomes of cancer care;

''(2) the Agency for Healthcare Research and Quality shall serve as a resource for other Federal agencies in the measurement of the quality of cancer care;

''(3) the Director for Healthcare Research and Quality and the Director of the Institute shall work cooperatively to develop data in order to set benchmarks for, and subsequently measure changes in the quality of cancer care for inclusion, as soon as prac-

ticable, in the annual report required by section 913(b)(2); and

''(4) the Director for Healthcare Research and Quality shall ensure coordination of these activities, as appropriate, with his responsibilities for research on health disparities under section 903.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2004 through 2008.

''SEC. 417E–13. INSTITUTE OF MEDICINE STUDY ON CANCER.

''(a) INSTITUTE OF MEDICINE STUDY.—The Secretary shall request the Institute of Medicine of the National Academies of Sciences to initiate a study by January 1, 2004, of the feasibility and costs of providing medicare coverage under title XVIII of the Social Security Act to individuals who are diagnosed with cancer and cancer survivors through 5 years of remission of cancer at any age and who have no other means of purchasing health care or health insurance, as determined under criteria established by the Secretary.

''(b) CONTENT.—

''(1) IN GENERAL.—The study under subsection (a) shall be conducted in 2 parts.

''(2) FIRST PART.—The first part shall—

''(A) examine options for providing medicare coverage to such individuals;

''(B) estimate the cost to the medicare program and to current and future beneficiaries; and

''(C) identify advantages associated with medicare coverage in terms of access to cancer care, improved quality of care and patient outcomes and assess the feasibility of providing medicare coverage to uninsured cancer patients through 5 years of remission and make a recommendation to Congress about whether medicare should be expanded to this population group.

''(3) SECOND PART.—The second part shall—

''(A) identify changes in medicare benefits to facilitate the provision of care consistent with quality cancer care standards, including prescription drug benefits and benefits to improve home care, symptom management, psychosocial services, and palliative and hospice care;

''(B) estimate the cost to the medicare program and to beneficiaries; and

''(C) assess the medical advantages and disadvantages associated with expanding benefits.

''(4) DEADLINES.—The first part shall be completed by June 30, 2005, and the second part shall be completed by December 31, 2005.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $1,000,000 in fiscal year 2004 and $1,200,000 in fiscal year 2005.''.

SEC. 104. NATIONAL INSTITUTE FOR ENVIRONMENTAL HEALTH SCIENCES.

(a) IN GENERAL.—Not later than October 1, 2004, the Director of the National Institute for Environmental Health Sciences shall, in coordination with the National Cancer Institute, prepare and submit to the Secretary of Health and Human Services a strategic plan that identifies the unmet needs regarding research on environmental risk factors for cancer and gene-environment interactions and describes how to increase the amount of such research and resources for such research.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary.

SEC. 105. COMPREHENSIVE CANCER CONTROL PLANS.

Section 412 of the Public Health Service Act (42 U.S.C. 285a-1) is amended—

(1) in the first sentence, by inserting ", for survivorship," after "treatment of cancer";

(2) in paragraph (1)(B), by striking "cancer patients" and all that follows and inserting the following: "cancer patients, families of cancer patients, and cancer survivors, and"; and

(3) in paragraph (3), by inserting "and concerning cancer survivorship programs," after "control of cancer".

SEC. 106. BREAST, CERVICAL, AND COLORECTAL CANCER SCREENING.

(a) BREAST AND CERVICAL CANCER.—Section 1510(a) of the Public Health Service Act (42 U.S.C. 300n–5(a)) is amended by striking "$50,000,000" and all that follows through the period, and inserting "$250,000,000 for fiscal year 2004, and such sums as may be necessary for fiscal years 2005 through 2008.".

(b) COLORECTAL CANCER.—Title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) is amended by adding at the end the following:

"SEC. 1511. COLORECTAL CANCER SCREENING DEMONSTRATION PROJECT.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award competitive grants to public and nonprofit private entities to enable such entities to establish demonstration programs pursuant to the general authority of title III to carry out colorectal screening activities including—

''(1) screening asymptomatic individuals for colorectal cancer as a preventive health measure according to scientific evidence-based screening guidelines;

''(2) providing appropriate referrals for medical treatment of individuals screened pursuant to this section and to ensure, to the extent practicable, the provision of appropriate follow-up services and support services such as case management;

''(3) activities to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of colorectal cancer;

''(4) activities to evaluate the programs under this section through appropriate surveillance or program monitoring activities;

''(5) the development and dissemination of findings derived through such evaluations through public and professional education; and

''(6) activities to promote the benefits of colorectal cancer screening.

''(b) PAYMENTS FOR SCREENINGS.—The amount paid by a grantee under this section to an entity on behalf of an individual for the furnishing of services to such individual shall not exceed the amount that would be paid under part B of title XVIII of the Social Security Act for such services if such payment were made under such part for such services.

''(c) REQUIREMENTS.—

''(1) PRIORITY.—To be eligible for a grant under subsection (a), an entity shall agree to give priority with respect to activities and services under the grant to a low-income—

''(A) individual who is at least 50 years of age; or

''(B) individual at high risk for colorectal cancer (as defined in section 1861(pp)(2) of the Social Security Act (42 U.S.C. 1395x(pp)(2))).

''(2) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—To be eligible for a grant under subsection (a), an entity shall agree

that grant funds will not be expended to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

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

"(B) by an entity that provides health service on a prepaid basis.

"(3) RESTRICTIONS ON USE OF GRANT.—To be eligible for a grant under subsection (a), an entity shall agree that grant funds will not be expended to provide inpatient hospital services for an individual.

"(4) RECORDS AND AUDITS.—To be eligible for a grant under subsection (a), an entity shall agree that the entity will—

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

"(B) provide agreed upon annual reports to the Secretary or the Comptroller of the United States for the purposes of auditing the expenditures by the entity.

''(5) REPORTS.—To be eligible for a grant under subsection (a), an entity shall agree to submit to the Secretary such reports as the Secretary determines appropriate.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2004, and such sums as may be necessary for each of fiscal years 2005 through 2008.''.

SEC. 107. IHS GRANTS FOR MODEL COMMUNITY CANCER AND CHRONIC DISEASE CARE AND PREVENTION; IHS GRANTS FOR PATIENT NAVIGATORS.

(a) DEFINITIONS.—In this section:

(1) IN GENERAL.—The terms ''culturally competent'', ''appropriate follow-up care'', ''health disparity population'', and ''patient navigator'' have the meanings given those terms in section 417E–10 of the Public Health Service Act.

(2) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(b) MODEL COMMUNITY CANCER AND CHRONIC DISEASE CARE AND PREVENTION.—

(1) IN GENERAL.—The Director of the Indian Health Service may make grants, for the development and operation of model programs that perform

the same functions outlined in section 417E–10(b)(1) of the Public Health Service Act, to Indian Health Service Centers, tribal governments, urban Indian organizations, tribal organizations, and qualified nonprofit entities demonstrating the ability to perform all of the functions in this subsection and subsections (c) and (d) that partner with providers or centers providing health care services to Native American populations to provide navigation services.

(2) APPLICATION FOR GRANT.—An entity that desires to receive a grant under paragraph (1) shall submit an application to the Secretary at such time, in such manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(3) OUTREACH SERVICES.—In order to be eligible to receive a grant under paragraph (1), an entity shall agree to provide ongoing outreach activities while receiving the grant, in a manner that is culturally competent for the health disparity population served by the program, to inform the public and the specific community that the program is serving of the services of the model program under the grant. Such activities shall include facilitating access to appropriate health care services and patient navigators

within the health care system to ensure optimal patient utilization of such services.

(4) DATA COLLECTION AND REPORT.—In order to allow for effective program evaluation, an entity that receives a grant under this subsection shall collect specific patient data recording services provided to each patient served by the program and shall establish and implement procedures and protocols, consistent with applicable Federal and State laws (including sections 160 and 164 of title 45, Code of Federal Regulations) to ensure the confidentiality of all information shared by a participant in the program, or their personal representative and their health care providers, group health plans, or health insurance insurers with the program. The program may, consistent with applicable Federal and State confidentiality laws, collect, use, or disclose aggregate information that is not individually identifiable (as defined in sections 160 and 164 of title 45, Code of Federal Regulations). With this data, the grantee shall submit an annual report to the Secretary that summarizes and analyzes the data and provides information on needs for navigation services, types of access difficulties resolved, sources of repeated reso-

lution, and flaws in the system of access, including insurance barriers.

(5) EVALUATIONS.—

(A) IN GENERAL.—The Secretary, acting through the Director of the Indian Health Service, shall, directly or through grants or contracts, provide for evaluations to determine which outreach activities under paragraph (3) were most effective in informing the public and the specific community that the program is serving of the model program services and to determine the extent to which such programs were effective in providing culturally competent services to the health disparity population served by the programs.

(B) DISSEMINATION OF FINDINGS.—The Secretary shall as appropriate disseminate to public and private entities the findings made in evaluations under subparagraph (A).

(6) COORDINATION WITH OTHER PROGRAMS.—The Secretary shall coordinate the program under this subsection with—

(A) the program under subsection (c);

(B) the program under section 417E–10 of the Public Health Service Act; and

(C) to the extent practicable, programs for prevention centers that are carried out by the Director of the Centers for Disease Control and Prevention.

(c) PROGRAM FOR PATIENT NAVIGATORS.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Indian Health Service, may make grants to Indian Health Service Centers, tribal governments, urban Indian organizations, tribal organizations, and qualified nonprofit entities demonstrating the ability to perform all of the functions in this subsection and subsections (b) and (d) that partner with providers or centers providing health care services to Native American populations to provide navigation services, for the development and operation of model programs to pay the costs of such entities in carrying out the same activities outlined in section 417E–10(c)(1) of the Public Health Service Act.

(2) APPLICATION FOR GRANT.—An entity that desires to receive a grant under paragraph (1) shall submit an application to the Secretary at such time, in such manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(3) OUTREACH SERVICES.—In order to be eligible to receive a grant under paragraph (1), an entity shall agree to provide ongoing outreach activities while receiving the grant, in a manner that is culturally competent for the health disparity population served by the program, to inform the public and the specific community that the patient navigator is serving of the services of the model program under the grant.

(4) DATA COLLECTION AND REPORT.—In order to allow for effective patient navigator program evaluation, an entity that receives a grant under this subsection shall collect specific patient data recording navigation services provided to each patient served by the program and shall establish and implement procedures and protocols, consistent with applicable Federal and State laws (including sections 160 and 164 of title 45, Code of Federal Regulations) to ensure the confidentiality of all information shared by a participant in the program, or their personal representative and their health care providers, group health plans, or health insurance insurers with the program. The patient navigator program may, consistent with applicable Federal and State confidentiality laws, collect, use, or disclose aggre-

gate information that is not individually identifiable (as defined in sections 160 and 164 of title 45, Code of Federal Regulations). With this data, the grantee shall submit an annual report to the Secretary that summarizes and analyzes the data and provides information on needs for navigation services, types of access difficulties resolved, sources of repeated resolution, and flaws in the system of access, including insurance barriers.

(5) EVALUATIONS.—

(A) IN GENERAL.—The Secretary, acting through the Director of the Indian Health Service, shall, directly or through grants or contracts, provide for evaluations to determine the effects of the services of patient navigators on the individuals of health disparity populations for whom the services were provided, taking into account the matters referred to in section 417E-10(c)(1)(C) of the Public Health Service Act.

(B) DISSEMINATION OF FINDINGS.—The Secretary shall as appropriate disseminate to public and private entities the findings made in evaluations under subparagraph (A).

(6) COORDINATION WITH OTHER PROGRAMS.—The Secretary shall coordinate the program under this subsection with the programs under subsection (b) and section 417E–10 of the Public Health Service Act.

(d) REQUIREMENTS REGARDING FEES.—

(1) IN GENERAL.—In order to be eligible to receive a grant under subsection (b) or (c), the program for which the grant is made shall have in effect—

(A) a schedule of fees or payments for the provision of such program's health care services related to the prevention and treatment of disease that is consistent with locally prevailing rates or charges and is designed to cover such program's reasonable costs of operation; and

(B) a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the ability of the patient to pay.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require payment for navigation services or to require payment for health care services in cases where care is provided free of

charge, including the case of services provided through programs of the Indian Health Service.

(e) MODEL.—Not later than 5 years after the date of enactment of this section, the Secretary shall develop a peer-reviewed model of systems for the services provided by this section. The Secretary shall update such model as may be necessary to ensure that the best practices are being utilized.

(f) DURATION OF GRANT.—The period during which payments are made to an entity from a grant under subsection (b)(1) or (c)(1) may not exceed 5 years. The provision of such payments are subject to annual approval by the Secretary and subject to the availability of appropriations for the fiscal year involved. Nothing in this subsection shall be construed as establishing a limitation on the number of grants under subsections (b) and (c) that may be made to an entity.

(g) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—

(A) MODEL PROGRAMS.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

(B) PATIENT NAVIGATORS.—For the purpose of carrying out subsection (c), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

(C) BUREAU OF PRIMARY HEALTH CARE.—Amounts appropriated under subparagraph (A) or (B) shall be administered through the Bureau of Primary Health Care.

(2) PROGRAMS IN RURAL AREAS.—

(A) MODEL PROGRAMS.—For the purpose of carrying out subsection (b) in making grants under such subsection for model programs in rural areas, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

(B) PATIENT NAVIGATORS.—For the purpose of carrying out subsection (c) in making grants under such subsection for programs in rural areas, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

(C) OFFICE OF RURAL HEALTH POLICY.—Amounts appropriated under subparagraph (A)

or (B) shall be administered through the Office of Rural Health Policy.

(3) RELATION TO OTHER AUTHORIZATIONS.—Authorizations of appropriations under paragraphs (1) and (2) are in addition to other authorizations of appropriations that are available for the purposes of carrying out subsections (b) and (c).

TITLE II—EXPANDING ACCESS TO CANCER DRUGS AND TREATMENT

SEC. 201. ACCELERATION OF THE DRUG TREATMENT APPROVAL PROCESS OF THE FOOD AND DRUG ADMINISTRATION.

Not later than July 1, 2004, the Commissioner of Food and Drugs shall prepare and submit to Congress a strategic plan that outlines the steps that the Commissioner is taking to accelerate the process for reviewing and approving new cancer drugs and treatments.

SEC. 202. FDA AMENDMENT.

Section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)) is amended by inserting ''or targets and mechanisms of pathogenesis of diseases'' after ''disease or condition''.

TITLE III—CANCER-RELATED HEALTH INSURANCE COVERAGE

Subtitle A—Clinical Trials Coverage

SEC. 301. COVERAGE FOR CLINICAL TRIALS UNDER THE PUBLIC HEALTH SERVICE ACT.

(a) GROUP.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–4 et seq.) is amended by adding at the end the following:

"SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING IN CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan, or health insurance issuer that is providing health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

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

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

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

"(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

"(3) USE OF IN-NETWORK PROVIDERS.—If 1 or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that, if a qualified individual is enrolling in the same clinical trial, the qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in that same trial. If the qualified individual is to enroll in a trial and no acceptable in-network provider is participating in the trial or if a participating provider cannot accept new enrollees, then the qualified individual may enroll in the trial through an out-of-network provider.

"(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who has cancer and is a participant

or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who meets the following conditions:

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

''(2) Either the referring physician is authorized by the plan to treat the patient and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the condition described in paragraph (1), or the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the condition described in paragraph (1).

''(c) PAYMENT.—

''(1) IN GENERAL.—Under this section a group health plan and a health insurance issuer shall provide for payment for routine patient costs described in subsection (a)(2) but are not required to pay for costs of items and services that are reasonably expected (as determined by the appropriate Secretary) to be paid for by the sponsors of an approved clinical trial.

''(2) PAYMENT RATE.—In the case of covered items and services provided by—

''(A) a participating provider, the payment rate shall be at the agreed upon rate; or

''(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

''(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation—

''(1) approved and funded (which may include funding through in-kind contributions) by—

''(A) the National Institutes of Health;

''(B) a cooperative group or center of the National Institutes of Health, including a qualified nongovernmental research entity to which the National Cancer Institute has awarded a center support grant;

''(C) the Department of Veterans Affairs, if the conditions described in subsection (e) are met; or

''(D) the Department of Defense, if the conditions described in subsection (e) are met;

''(2) approved by the Food and Drug Administration; or

''(3) approved by a qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants or an institutional review board that—

''(A) is registered with the Department of Health and Human Services; and

''(B) is associated with an institution that has a Federal assurance approved by the Department of Health and Human Services specifying compliance with section 46 of title 45, Code of Federal Regulations.

''(e) CONDITIONS FOR DEPARTMENTS.—The conditions for a study or investigation conducted by a department, are that the study or investigation has been reviewed and approved through a system of peer review that the appropriate Secretary determines—

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

''(2) assures unbiased review of the highest ethical standards by an institutional review board or other body that meets the standards outlined in sec-

tion 46 of title 45, and sections 50 and 56 of title 21, Code of Federal Regulations.

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

(b) INDIVIDUAL.—Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 (42 U.S.C. 300gg–52) the following:

''SEC. 2753. PATIENT PROTECTION STANDARDS.

''The provisions of section 2707 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan.''.

SEC. 302. COVERAGE FOR CLINICAL TRIALS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

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

''SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan, or health insurance issuer that is providing health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

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

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

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

''(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

''(3) USE OF IN-NETWORK PROVIDERS.—If 1 or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring

that, if a qualified individual is enrolling in the same clinical trial, the qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in that same trial. If the qualified individual is to enroll in a trial and no acceptable in-network provider is participating in the trial or if a participating provider cannot accept new enrollees, then the qualified individual may enroll in the trial through an out-of-network provider.

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

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

''(2) Either the referring physician is authorized by the plan to treat the patient and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the condition described in paragraph (1), or the participant, beneficiary, or enrollee provides

medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the condition described in paragraph (1).

''(c) PAYMENT.—

''(1) IN GENERAL.—Under this section a group health plan and a health insurance issuer shall provide for payment for routine patient costs described in subsection (a)(2) but are not required to pay for costs of items and services that are reasonably expected (as determined by the appropriate Secretary) to be paid for by the sponsors of an approved clinical trial.

''(2) PAYMENT RATE.—In the case of covered items and services provided by—

''(A) a participating provider, the payment rate shall be at the agreed upon rate; or

''(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

''(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation—

''(1) approved and funded (which may include funding through in-kind contributions) by—

''(A) the National Institutes of Health;

''(B) a cooperative group or center of the National Institutes of Health, including a qualified nongovernmental research entity to which the National Cancer Institute has awarded a center support grant;

''(C) the Department of Veterans Affairs, if the conditions described in subsection (e) are met; or

''(D) the Department of Defense, if the conditions described in subsection (e) are met;

''(2) approved by the Food and Drug Administration; or

''(3) approved by a qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants or an institutional review board that—

''(A) is registered with the Department of Health and Human Services; and

''(B) is associated with an institution that has a Federal assurance approved by the Department of Health and Human Services speci-

fying compliance with section 46 of title 45, Code of Federal Regulations.

''(e) CONDITIONS FOR DEPARTMENTS.—The conditions for a study or investigation conducted by a department, are that the study or investigation has been reviewed and approved through a system of peer review that the appropriate Secretary determines—

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

''(2) assures unbiased review of the highest ethical standards by an institutional review board or other body that meets the standards outlined in section 46 of title 45, and sections 50 and 56 of title 21, Code of Federal Regulations.

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

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 713 the following new item:

''Sec. 714. Coverage for individuals participating in clinical trials.''.

SEC. 303. COVERAGE FOR CLINICAL TRIALS UNDER OTHER PUBLIC HEALTH INSURANCE.

Coverage for individuals participating in clinical trials, as described in section 2707 and 2753 of the Public Health Service Act (as added under section 301), shall be provided for any individual, participant, or beneficiary who have coverage under—

(1) the medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.);

(2) the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.);

(3) the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1398 et seq.);

(4) a health plan offered under chapter 89 of title 5, United States Code;

(5) programs offered by the Department of Defense;

(6) a medical care program of the Indian Health Service or of a tribal organization; and

(7) a health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Subtitle B—Cancer Screening and Other Coverage

SEC. 311. CANCER SCREENING COVERAGE.

(a) GROUP HEALTH PLANS.—

(1) PUBLIC HEALTH SERVICE ACT AMENDMENTS.—

(A) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–4 et seq.), as amended by section 301(a), is further amended by adding at the end the following:

"SEC. 2708. COVERAGE OF CANCER SCREENING.

''(a) REQUIREMENT.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide coverage and payment under the plan or coverage for the following items and services under terms and conditions that are no less favorable than the terms and conditions applicable to other screening benefits otherwise provided under the plan or coverage:

''(1) MAMMOGRAMS.—In the case of a female participant or beneficiary who is 40 years of age or older, or is under 40 years of age but is at high risk (as defined in subsection (e)) of developing breast cancer, an annual mammography (as defined in section 1861(jj) of the Social Security Act) conducted by a facility that has a certificate (or provisional certificate) issued under section 354.

''(2) CLINICAL BREAST EXAMINATIONS.—In the case of a female participant or beneficiary who—

"(A)(i) is 40 years of age or older or (ii) is at least 20 (but less than 40) years of age and is at high risk of developing breast cancer, an annual clinical breast examination; or

"(B) is at least 20, but less than 40, years of age and who is not at high risk of developing breast cancer, a clinical breast examination each 3 years.

"(3) PAP TESTS AND PELVIC EXAMINATIONS.—In the case of a female participant or beneficiary who is 18 years of age or older, or who is under 18 years of age and is or has been sexually active—

"(A) an annual diagnostic laboratory test (popularly known as a 'pap smear') consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and including an interpretation by a qualified health professional of the results of the test; and

"(B) an annual pelvic examination.

"(4) COLORECTAL CANCER SCREENING PROCEDURES.—

"(A) IN GENERAL.—In the case of a participant or beneficiary who is 50 years of age or

older, or who is under 50 years of age and is an individual at high risk for colorectal cancer, the group health plan or health insurance issuer shall cover methods of colorectal cancer screening that—

''(i) are deemed appropriate by a physician (as defined in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r))) treating the participant or beneficiary, in consultation with the participant or beneficiary;

''(ii) are—

''(I) described in section 1861(pp)(1) of the Social Security Act (42 U.S.C. 1395x(pp)(1)) or section 410.37 of title 42, Code of Federal Regulations; or

''(II) specified by the Secretary based upon the recommendations of appropriate organizations with special expertise in the field of colorectal cancer; and

''(iii) are performed at a frequency not greater than that—

"(I) described for such method in section 1834(d) of the Social Security Act (42 U.S.C. 1395m(d)) or section 410.37 of title 42, Code of Federal Regulations; or

"(II) specified by the Secretary for such method if the Secretary finds, based upon new scientific knowledge and consistent with the recommendations of appropriate organizations with special expertise in the field of colorectal cancer, that a different frequency would not adversely affect the effectiveness of such screening.

"(B) DEFINITION OF HIGH RISK.—In this paragraph, the term 'individual at high risk for colorectal cancer' has the meaning given the term in section 1861(pp)(2) of the Social Security Act (42 U.S.C. 1395x(pp)(2)).

"(5) PROSTATE CANCER SCREENING.—In the case of a male participant or beneficiary who is 50 years of age or older, or who is younger than 50 years of age and is at high risk for prostate cancer (including African American men or a male who has

a history of prostate cancer in a first degree family member), the procedures described in section 1861(oo)(2) of Social Security Act (42 U.S.C. 1395x(oo)(2)) shall be furnished to the individual for the early detection of prostate cancer. The group health plan or health insurance issuer shall provide coverage for the method and frequency of prostate cancer screening determined to be appropriate by a health care provider treating such participant or beneficiary, in consultation with the participant or beneficiary.

''(6) TOBACCO THERAPY AND COUNSELING.—

''(A) IN GENERAL.—Therapy and counseling for cessation of tobacco use for individuals who use tobacco products or who are being treated for tobacco use that is furnished—

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

''(ii) by any other health care professional—

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

"(II) who, for medicare beneficiaries, is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose.

"(B) LIMITATION.—Subject to subparagraph (C), such therapy and counseling are limited to—

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

"(ii) such other therapy and counseling services that the Secretary recognizes to be effective.

"(C) EXCLUSION.—Such therapy and counseling shall not include coverage for drugs or biologicals that are not otherwise covered under the plan or coverage.

"(7) MEDICAL NUTRITION THERAPY SERVICES.—Medical nutrition therapy services, as defined in section 1861(vv) of the Social Security Act (42 U.S.C. 1395x(vv)) for the purpose of improving the

health of cancer patients and preventing cancer in other beneficiaries.

''(8) GENETIC TESTS AND GENETIC SERVICES.—

''(A) IN GENERAL.—Genetic tests and genetic services provided by a licensed health care professional to obtain predictive genetic information about an individual at risk of cancer for purposes of a health assessment, cancer management, cancer prevention, other diagnostic or therapeutic purposes, or genetic education and counseling.

''(B) DEFINITIONS.—In this paragraph:

''(i) FAMILY MEMBER.—The term 'family member' means with respect to an individual—

''(I) the spouse of the individual;

''(II) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

''(III) all other individuals related by blood to the individual or the spouse or child described in subclause (I) or (II).

''(ii) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of such individual (including information about a request for or the receipt of genetic services by such individual or family member of such individual).

''(iii) GENETIC SERVICES.—The term 'genetic services' means health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

''(iv) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect genotypes, mutations, or chromosomal changes.

''(v) PREDICTIVE GENETIC INFORMATION.—

"(I) IN GENERAL.—The term 'predictive genetic information' means—

"(aa) information about an individual's genetic tests;

"(bb) information about genetic tests of family members of the individual; or

"(cc) information about the occurrence of a disease or disorder in family members.

"(II) LIMITATIONS.—The term 'predictive genetic information' shall not include—

"(aa) information about the sex or age of the individual;

"(bb) information about chemical, blood, or urine analyses of the individual, unless these analyses are genetic tests; or

"(cc) information about physical exams of the individual, and other information relevant to determining the current health status of the individual.

''(9) OTHER TESTS AND PROCEDURES.—Such other tests or procedures for the detection of cancer, and modifications to the tests and procedures, with such frequency, as the Secretary determines to be appropriate, in consultation with appropriate organizations and agencies, for the diagnosis or detection of cancer.

''(b) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not—

''(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

''(2) provide monetary payments or rebates to individuals to encourage such individuals to accept less than the minimum protections available under this section;

''(3) penalize or otherwise reduce or limit the reimbursement of a provider because such provider provided care to an individual participant or beneficiary in accordance with this section; or

''(4) provide incentives (monetary or otherwise) to a provider to induce such provider to provide care

to an individual participant or beneficiary in a manner inconsistent with this section.

''(c) RULES OF CONSTRUCTION.—

''(1) Nothing in this section shall be construed to require an individual who is a participant or beneficiary to undergo a procedure, examination, or test described in subsection (a).

''(2) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits described in subsection (a) consistent with such subsection, except that such coinsurance or other cost-sharing shall not discriminate on any basis related to the coverage required under this section.

''(3) Nothing in this section shall be construed to result in a reduction, diminishment, or change in coverage resulting in less coverage.

''(d) NOTICE.—A group health plan under this part shall comply with the notice requirement under section 714(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.

''(e) RISK DEFINED.—For purposes of this section, an individual is considered to be at 'risk' of developing

a particular type of cancer if, under guidelines developed or recognized by the Secretary based upon scientific evidence, the individual—

''(1) has 1 or more first degree family members who have developed that type of cancer;

''(2) has previously had that type of cancer;

''(3) has the presence of an appropriate recognized gene marker that is identified as putting the individual at a higher risk of developing that type of cancer; or

''(4) has other predisposing or environmental risk factors that significantly increases the risk of the individual contracting that type of cancer.

For purposes of this subsection, the term 'type of cancer' includes other types of cancer that the Secretary recognizes as closely related for purposes of establishing risk.

''SEC. 2709. PATIENT ACCESS TO INFORMATION.

''(a) DISCLOSURE REQUIREMENT.—A group health plan, and health insurance issuer offering group health insurance coverage shall—

''(1) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such

date), and at least annually thereafter, the information described in subsection (b) in printed form;

''(2) provide to participants and beneficiaries, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form regarding such significant changes; and

''(3) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsection (b) in printed form.

''(b) INFORMATION PROVIDED.—The information described in subsection (a) that shall be disclosed includes the following, as such relates to cancer screening required under section 2708(a):

''(1) BENEFITS.—Benefits offered under the plan or coverage, including—

''(A) covered benefits, including benefit limits and coverage exclusions;

''(B) cost-sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that

are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;

''(C) the extent to which benefits may be obtained from nonparticipating providers; and

''(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network.

''(2) ACCESS.—A description of the following:

''(A) The number, mix, and distribution of providers under the plan or coverage.

''(B) Out-of-network coverage (if any) provided by the plan or coverage.

''(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

''(D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.

''(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.

''(F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.

''(G) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information under this subsection.''.

(B) TECHNICAL AMENDMENT.—Section 2723(c) of the Public Health Service Act (42 U.S.C. 300gg–23(c)) is amended by striking ''section 2704'' and inserting ''sections 2704 and 2708''.

(2) ERISA AMENDMENTS.—

(A) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.), as amended by section 302, is further amended by adding at the end the following new section:

"SEC. 715. COVERAGE OF CANCER SCREENING.

''(a) REQUIREMENT.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide coverage and payment under the plan or coverage for the following items and services under terms and conditions that are no less favorable than the terms and conditions applicable to other screening benefits otherwise provided under the plan or coverage:

''(1) MAMMOGRAMS.—In the case of a female participant or beneficiary who is 40 years of age or older, or is under 40 years of age but is at high risk (as defined in subsection (e)) of developing breast cancer, an annual mammography (as defined in section 1861(jj) of the Social Security Act) conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act.

''(2) CLINICAL BREAST EXAMINATIONS.—In the case of a female participant or beneficiary who—

''(A)(i) is 40 years of age or older or (ii) is at least 20 (but less than 40) years of age and is at high risk of developing breast cancer, an annual clinical breast examination; or

''(B) is at least 20, but less than 40, years of age and who is not at high risk of developing

breast cancer, a clinical breast examination each 3 years.

''(3) PAP TESTS AND PELVIC EXAMINATIONS.—In the case of a female participant or beneficiary who is 18 years of age or older, or who is under 18 years of age and is or has been sexually active—

''(A) an annual diagnostic laboratory test (popularly known as a 'pap smear') consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and including an interpretation by a qualified health professional of the results of the test; and

''(B) an annual pelvic examination.

''(4) COLORECTAL CANCER SCREENING PROCEDURES.—

''(A) IN GENERAL.—In the case of a participant or beneficiary who is 50 years of age or older, or who is under 50 years of age and is an individual at high risk for colorectal cancer, the group health plan or health insurance issuer shall cover methods of colorectal cancer screening that—

"(i) are deemed appropriate by a physician (as defined in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r))) treating the participant or beneficiary, in consultation with the participant or beneficiary;

"(ii) are—

"(I) described in section 1861(pp)(1) of the Social Security Act (42 U.S.C. 1395x(pp)(1)) or section 410.37 of title 42, Code of Federal Regulations; or

"(II) specified by the Secretary based upon the recommendations of appropriate organizations with special expertise in the field of colorectal cancer; and

"(iii) are performed at a frequency not greater than that—

"(I) described for such method in section 1834(d) of the Social Security Act (42 U.S.C. 1395m(d)) or section 410.37 of title 42, Code of Federal Regulations; or

''(II) specified by the Secretary for such method if the Secretary finds, based upon new scientific knowledge and consistent with the recommendations of appropriate organizations with special expertise in the field of colorectal cancer, that a different frequency would not adversely affect the effectiveness of such screening.

''(B) DEFINITION OF HIGH RISK.—In this paragraph, the term 'individual at high risk for colorectal cancer' has the meaning given the term in section 1861(pp)(2) of the Social Security Act (42 U.S.C. 1395x(pp)(2)).

''(5) PROSTATE CANCER SCREENING.—In the case of a male participant or beneficiary who is 50 years of age or older, or who is younger than 50 years of age and is at high risk for prostate cancer (including African American men or a male who has a history of prostate cancer in a first degree family member), the procedures described in section 1861(oo)(2) of the Social Security Act (42 U.S.C. 1395x(oo)(2)) shall be furnished to the individual for the early detection of prostate cancer. The group

health plan or health insurance issuer shall provide coverage for the method and frequency of prostate cancer screening determined to be appropriate by a health care provider treating such participant or beneficiary, in consultation with the participant or beneficiary.

''(6) TOBACCO THERAPY AND COUNSELING.—

''(A) IN GENERAL.—Therapy and counseling for cessation of tobacco use for individuals who use tobacco products or who are being treated for tobacco use that is furnished—

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

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

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

''(II) for medicare beneficiaries, is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose.

"(B) LIMITATION.—Subject to subparagraph (C), such therapy and counseling are limited to—

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

"(ii) such other therapy and counseling services that the Secretary recognizes to be effective.

"(C) EXCLUSION.—Such therapy and counseling shall not include coverage for drugs or biologicals that are not otherwise covered under the plan or coverage.

"(7) MEDICAL NUTRITION THERAPY SERVICES.—Medical nutrition therapy services, as defined in section 1861(vv) of the Social Security Act (42 U.S.C. 1395x(vv)) for the purpose of improving the health of cancer patients and preventing cancer in other beneficiaries.

"(8) GENETIC TESTS AND GENETIC SERVICES.—

''(A) IN GENERAL.—Genetic tests and genetic services provided by a licensed health care professional to obtain predictive genetic information about an individual at risk of cancer for purposes of a health assessment, cancer management, cancer prevention, other diagnostic or therapeutic purposes, or genetic education and counseling.

''(B) DEFINITIONS.—In this paragraph:

''(i) FAMILY MEMBER.—The term 'family member' means with respect to an individual—

''(I) the spouse of the individual;

''(II) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

''(III) all other individuals related by blood to the individual or the spouse or child described in subclause (I) or (II).

''(ii) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from

an individual or a family member of such individual (including information about a request for or the receipt of genetic services by such individual or family member of such individual).

''(iii) GENETIC SERVICES.—The term 'genetic services' means health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

''(iv) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect genotypes, mutations, or chromosomal changes.

''(v) PREDICTIVE GENETIC INFORMATION.—

''(I) IN GENERAL.—The term 'predictive genetic information' means—

''(aa) information about an individual's genetic tests;

''(bb) information about genetic tests of family members of the individual; or

''(cc) information about the occurrence of a disease or disorder in family members.

''(II) LIMITATIONS.—The term 'predictive genetic information' shall not include—

''(aa) information about the sex or age of the individual;

''(bb) information about chemical, blood, or urine analyses of the individual, unless these analyses are genetic tests; or

''(cc) information about physical exams of the individual, and other information relevant to determining the current health status of the individual.

''(9) OTHER TESTS AND PROCEDURES.—Such other tests or procedures for the detection of cancer, and modifications to the tests and procedures, with such frequency, as the Secretary determines to be appropriate, in consultation with appropriate organi-

zations and agencies, for the diagnosis or detection of cancer.

''(b) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not—

''(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

''(2) provide monetary payments or rebates to individuals to encourage such individuals to accept less than the minimum protections available under this section;

''(3) penalize or otherwise reduce or limit the reimbursement of a provider because such provider provided care to an individual participant or beneficiary in accordance with this section; or

''(4) provide incentives (monetary or otherwise) to a provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section.

''(c) RULES OF CONSTRUCTION.—

''(1) Nothing in this section shall be construed to require an individual who is a participant or bene-

ficiary to undergo a procedure, examination, or test described in subsection (a).

''(2) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits described in subsection (a) consistent with such subsection, except that such coinsurance or other cost-sharing shall not discriminate on any basis related to the coverage required under this section.

''(3) Nothing in this section shall be construed to result in a reduction, diminishment, or change in coverage resulting in less coverage.

''(d) NOTICE UNDER GROUP HEALTH PLAN.—The imposition of the requirement of this section shall be treated as a material modification in the terms of the plan described in section 102(a), for purposes of assuring notice of such requirements under the plan; except that the summary description required to be provided under the last sentence of section 104(b)(1) with respect to such modification shall be provided by not later than 60 days after the first day of the first plan year in which such requirement apply.

''(e) RISK DEFINED.—For purposes of this section, an individual is considered to be at 'risk' of developing

a particular type of cancer if, under guidelines developed or recognized by the Secretary based upon scientific evidence, the individual—

''(1) has 1 or more first degree family members who have developed that type of cancer;

''(2) has previously had that type of cancer;

''(3) has the presence of an appropriate recognized gene marker that is identified as putting the individual at a higher risk of developing that type of cancer; or

''(4) has other predisposing or environmental risk factors that significantly increases the risk of the individual contracting that type of cancer.

For purposes of this subsection, the term 'type of cancer' includes other types of cancer that the Secretary recognizes as closely related for purposes of establishing risk.

''SEC. 716. PATIENT ACCESS TO INFORMATION.

''(a) DISCLOSURE REQUIREMENT.—A group health plan, and health insurance issuer offering group health insurance coverage shall—

''(1) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such

date), and at least annually thereafter, the information described in subsection (b) in printed form;

''(2) provide to participants and beneficiaries, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form regarding such significant changes; and

''(3) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsection (b) in printed form.

''(b) INFORMATION PROVIDED.—The information described in subsection (a) that shall be disclosed includes the following, as such relates to cancer screening required under section 715(a):

''(1) BENEFITS.—Benefits offered under the plan or coverage, including—

''(A) covered benefits, including benefit limits and coverage exclusions;

''(B) cost-sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that

are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;

''(C) the extent to which benefits may be obtained from nonparticipating providers; and

''(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network.

''(2) ACCESS.—A description of the following:

''(A) The number, mix, and distribution of providers under the plan or coverage.

''(B) Out-of-network coverage (if any) provided by the plan or coverage.

''(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

''(D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.

''(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.

''(F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.

''(G) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information under this subsection.''.

(B) TECHNICAL AMENDMENTS.—

(i) Section 731(c) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191(c)) is amended by striking ''section 711'' and inserting ''sections 711 and 715''.

(ii) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 715''.

(iii) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by section

302, is further amended by inserting after the item relating to section 714 the following new items:

''Sec. 715. Coverage of cancer screening.
''Sec. 716. Patient access to information.''.

(b) INDIVIDUAL HEALTH INSURANCE.—

(1) IN GENERAL.—Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2753, as added by section 301(b), the following new section:

''SEC. 2754. STANDARD RELATING PATIENT FREEDOM OF CHOICE.

''(a) IN GENERAL.—The provisions of section 2708 (other than subsection (d)) shall apply to health insurance coverage offered by a health insurance issuer in the individual market with respect to an enrollee under such coverage in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market to a participant or beneficiary in such plan.

''(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 715(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.

"SEC. 2755. PATIENT ACCESS TO INFORMATION.

''The provisions of section 2709 shall apply health insurance coverage offered by a health insurance issuer in the individual market with respect to an enrollee under such coverage in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market to a participant or beneficiary in such plan.''.

(2) TECHNICAL AMENDMENT.—Section 2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2)) is amended by striking ''section 2751'' and inserting ''sections 2751 and 2754''.

(c) EFFECTIVE DATES.—

(1) GROUP HEALTH PLANS.—Subject to paragraph (3), the amendments made by subsection (a) shall apply with respect to group health plans for plan years beginning on or after January 1, 2004.

(2) INDIVIDUAL PLANS.—The amendment made by subsection (b) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after such date.

(3) COLLECTIVE BARGAINING AGREEMENT.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements be-

tween employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made to subsection (a) shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act), or

(B) January 1, 2004.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by subsection (a) shall not be treated as a termination of such collective bargaining agreement.

(d) COORDINATED REGULATIONS.—Section 104(1) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191) is amended by striking ''this subtitle (and the amendments made by this subtitle and section 401)'' and inserting ''the provisions of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, the provisions of parts A and

C of title XXVII of the Public Health Service Act, and chapter 100 of the Internal Revenue Code of 1986''.

(e) MODIFICATION OF COVERAGE.—

(1) IN GENERAL.—The Secretary of Health and Human Services may modify the coverage requirements for the amendments under this subtitle to allow such requirements to incorporate and reflect new scientific and technological advances regarding cancer screening, practice pattern changes in such screening, or other updated medical practices regarding such screening, such as the use of new tests or other emerging technologies. Such modifications shall not in any way diminish the coverage requirements listed under this subtitle. Such modifications may be made on the Secretary's own initiative or upon petition to the Secretary by an individual or organization.

(2) CONSULTATION.—In modifying coverage requirements under paragraph (1), the Secretary of Health and Human Services shall consult with appropriate organizations, experts, and agencies.

(3) PETITIONS.—The Secretary of Health and Human Services may issue requirements for the petitioning process under paragraph (1), including requirements that the petition be in writing and in-

clude scientific or medical bases for the modification sought. Upon receipt of such a petition, the Secretary shall respond to the petitioner and decide whether to propose a regulation proposing a change within 90 days of such receipt. If a regulation is required, the Secretary shall propose such regulation within 6 months of such determination. The Secretary shall provide the petitioner the reasons for the decision of the Secretary. The Secretary may make changes requested by a petitioner in whole or in part.

Subtitle C—Physicians and Quality of Care

SEC. 321. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS UNDER THE PUBLIC HEALTH SERVICE ACT.

(a) GROUP.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–4 et seq.), as amended by sections 301 and 311, is further amended by adding at the end the following:

"SEC. 2710. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS.

''(a) MANAGING PHYSICIAN.—A group health plan, or health insurance issuer that is providing health insurance coverage, shall ensure that with respect to items or

services provided under the plan or coverage relating to the treatment of cancer, a lead managing physician be designated at the time of diagnosis by the provider and paid a bonus by the plan, in consultation with the participant or beneficiary, and other providers involved to provide for the overall coordination and management of the cancer care of the participant or beneficiary among all providers who provide items or services to the participant or beneficiary and paid for overall coordination of services.

''(b) QUALITY OF CARE.—A group health plan, or health insurance issuer that is providing health insurance coverage, shall require that all participating health care professionals who provide primary care cancer services follow the most current quality-of-care cancer care guidelines, as developed by medical professionals with expertise in the field of medicine for which the guidelines are designed and widely recognized as medically necessary and appropriate.

''(c) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not—

''(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under

the terms of the plan, solely for the purpose of avoiding the requirements of this section;

''(2) provide monetary payments or rebates to individuals to encourage such individuals to accept less than the minimum protections available under this section;

''(3) penalize or otherwise reduce or limit the reimbursement of a provider because such provider provided care to an individual participant or beneficiary in accordance with this section; or

''(4) provide incentives (monetary or otherwise) to a provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section.

''(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits described in subsections (a) or (b) consistent with such subsections, except that such coinsurance or other cost-sharing shall not discriminate on any basis related to the coverage required under this section.

''(e) NOTICE.—A group health plan under this part shall comply with the notice requirement under section 714(d) of the Employee Retirement Income Security Act

of 1974 with respect to the requirements of this section as if such section applied to such plan.''.

(b) INDIVIDUAL.—Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2755, as added by section 311, the following:

''SEC. 2756. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS.

''The provisions of section 2710 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan.''.

SEC. 322. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.), as amended by sections 302 and 311, is further amended by adding at the end the following:

"SEC. 717. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS.

"(a) MANAGING PHYSICIAN.—A group health plan, or health insurance issuer that is providing health insurance coverage, shall ensure that with respect to items or services provided under the plan or coverage relating to the treatment of cancer, a lead managing physician be designated at the time of diagnosis by the participant or beneficiary involved to provide for the overall coordination and management of the cancer care of the participant or beneficiary among all providers who provide items or services to the participant or beneficiary and paid for overall coordination of services.

"(b) QUALITY OF CARE.—A group health plan, or health insurance issuer that is providing health insurance coverage, shall require that all participating health care professionals who provide primary care cancer services follow the most current quality-of-care cancer care guidelines, as developed by medical professionals with expertise in the field of medicine for which the guidelines are designed and widely recognized as medically necessary and appropriate.

"(c) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not—

''(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

''(2) provide monetary payments or rebates to individuals to encourage such individuals to accept less than the minimum protections available under this section;

''(3) penalize or otherwise reduce or limit the reimbursement of a provider because such provider provided care to an individual participant or beneficiary in accordance with this section; or

''(4) provide incentives (monetary or otherwise) to a provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section.

''(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits described in subsections (a) or (b) consistent with such subsections, except that such coinsurance or other cost-sharing shall not discriminate on any basis related to the coverage required under this section.

''(e) NOTICE.—A group health plan under this part shall comply with the notice requirement under section 714(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.''.

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by sections 302 and 311, is further amended by inserting after the item relating to section 716 the following new item:

''Sec. 717. Managing physicians and quality of care for cancer patients.''.

SEC. 323. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS UNDER MEDICARE.

(a) APPLICATION OF CANCER COVERAGE REQUIREMENTS.—Part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) is amended by adding at the end the following:

''APPLICATION OF CANCER COVERAGE REQUIREMENTS

''SEC. 1849. The provisions of sections 2707, 2708, and 2710 of the Public Health Service Act shall apply to an individual who has been diagnosed with cancer and who is covered under the insurance program established under this part.''.

(b) ADDITIONAL PAYMENT.—Section 1833(m) of the Social Security Act (42 U.S.C. 1395*l*(m)) is amended—

(1) by inserting ''(1)'' after ''(m)''; and

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

''(2) In the case of physicians' services furnished to an individual who has been diagnosed with cancer, who is covered under the insurance program established under this part who receives care for such cancer from a team of physicians, and who incurs expenses for physicians' services that are related to that diagnosis, there shall be paid to the physician designated by such team of physicians at the time of diagnosis of the individual as the physician responsible for the overall coordination and management of the medical and other health services provided to that individual during the period in which that individual is undergoing treatment for such cancer (or to an employer or facility in the cases described in subparagraph (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund a separate and additional payment amount for the services under this part in addition to any amount otherwise paid under this part.''.

SEC. 324. MANAGING PHYSICIANS AND QUALITY OF CARE FOR CANCER PATIENTS UNDER MEDICAID AND SCHIP.

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

(1) in paragraph (64), by striking ''and'' at the end;

(2) in paragraph (65), by striking the period and inserting ''; and''; and

(3) by inserting after paragraph (65) the following:

''(66) provide—

''(A) that the provisions of sections 2707, 2708, and 2710 of the Public Health Service Act shall apply to individuals eligible for medical assistance under the State plan who have been diagnosed with cancer; and

''(B) that, in the case of an individual who has been diagnosed with cancer, who is eligible for medical assistance under this title, and who receives care for such cancer from a team of physicians, and who incurs expenses for physicians' services that are related to that diagnosis, that there shall be paid to the physician designated by such team of physicians at the time of diagnosis of the individual as the physician responsible for the overall coordination and management of the medical and other health services provided to that individual during the period in which that individual is undergoing

treatment for such cancer, a separate and additional payment amount for the services provided in addition to any amount otherwise paid under the State plan.''.

(b) SCHIP.—Section 2103(f) of the Social Security Act (42 U.S.C. 1397cc(f)) is amended by adding at the end the following:

''(3) APPLICATION OF CANCER COVERAGE PROVISIONS.—

''(A) IN GENERAL.—The provisions of sections 2707, 2708, and 2710 of the Public Health Service Act shall apply to the coverage offered under the State child health plan.

''(B) ADDITIONAL PAYMENT.—The State child health plan shall provide in the case of an individual who has been diagnosed with cancer, who is eligible for child health assistance under this title, and who receives care for such cancer from a team of physicians, and who incurs expenses for physicians' services that are related to that diagnosis, that there shall be paid to the physician designated by such team of physicians at the time of diagnosis of the individual as the physician responsible for the overall coordination and management of the medical and other

health services provided to that individual during the period in which that individual is undergoing treatment for such cancer, a separate and additional payment amount for the services provided in addition to any amount otherwise paid under the State child health plan.''.

Subtitle D—General Provisions

SEC. 331. COVERAGE UNDER OTHER PUBLIC HEALTH INSURANCE.

(a) IN GENERAL.—The coverage described in subsection (b) shall be provided for any individual, participant, or beneficiary who has coverage under—

(1) the medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.);

(2) the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.);

(3) the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1398 et seq.);

(4) a health plan offered under chapter 89 of title 5, United States Code;

(5) programs offered by the Department of Defense;

(6) a medical care program of the Indian Health Service or of a tribal organization; and

(7) a health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

(b) COVERAGE DESCRIBED.—The coverage described in this subsection is—

(1) the coverage described in section 2708 of the Public Health Service Act (as added by section 311) for individuals participating in cancer screening activities; and

(2) the coverage described in section 2710 of the Public Health Service Act (as added by section 321) for individuals receiving cancer-related items or services.

(c) APPLICATION TO OTHER HEALTH CARE COVERAGE.—Chapter 89 of title 5, United States Code, is amended by adding at the end the following:

"§ 8915. Standards relating to coverage of cancer-related activities

''(a) The provisions of sections 2707, 2708, 2709, and 2710 of the Public Health Service Act shall apply to the provision of items and services under this chapter.

''(b) Nothing in this section or section 2707, 2708, 2709, or 2710 of the Public Health Service Act shall be construed as authorizing a health insurance issuer or entity to impose cost-sharing with respect to the coverage or benefits required to be provided under such sections that

is inconsistent with the cost-sharing that is otherwise permitted under this chapter.''.

TITLE IV—PATIENT NAVIGATOR AND CANCER CARE WITHIN THE HEALTH RESOURCES AND SERVICES ADMINISTRATION

SEC. 401. HRSA GRANTS FOR MODEL COMMUNITY CANCER AND CHRONIC DISEASE CARE AND PREVENTION AND GRANTS FOR PATIENT NAVIGATORS.

Subpart I of part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following:

''SEC. 330M. MODEL COMMUNITY CANCER AND CHRONIC DISEASE CARE AND PREVENTION; PATIENT NAVIGATORS.

''(a) DEFINITIONS.—In this section, the terms ''culturally competent'', ''appropriate follow-up care'', ''health disparity population'', and ''patient navigator'' have the meanings given those terms in section 417E–10.

''(b) MODEL COMMUNITY CANCER AND CHRONIC DISEASE CARE AND PREVENTION.—

''(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources

and Services Administration, may make grants to public and nonprofit private health centers (including health centers under section 330, Indian Health Service Centers, tribal governments, urban Indian organizations, tribal organizations, clinics serving Asian Americans and Pacific Islanders and Alaskan Natives, rural health clinics, and qualified nonprofit entities that partner with 1 or more centers providing health care services to provide navigation services that demonstrate the ability to perform all of the functions outlined in this subsection and subsections (c) and (d)) for the development and operation of model programs that perform the same functions outlined in section 417E–10(b)(1).

''(2) APPLICATION FOR GRANT.—An entity that desires to receive a grant under paragraph (1) shall submit an application to the Secretary at such time, in such manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(3) OUTREACH SERVICES.—In order to be eligible to receive a grant under paragraph (1), an entity shall agree to provide ongoing outreach activities while receiving the grant, in a manner that is culturally competent for the health disparity population

served by the program, to inform the public and the specific community that the program is serving of the services of the model program under the grant. Such activities shall include facilitating access to appropriate health care services and patient navigators within the health care system to ensure optimal patient utilization of such services.

''(4) DATA COLLECTION AND REPORT.—In order to allow for effective program evaluation, an entity that receives a grant under this subsection shall collect specific patient data recording services provided to each patient served by the program and shall establish and implement procedures and protocols, consistent with applicable Federal and State laws (including sections 160 and 164 of title 45, Code of Federal Regulations) to ensure the confidentiality of all information shared by a participant in the program, or their personal representative and their health care providers, group health plans, or health insurance insurers with the program. The program may, consistent with applicable Federal and State confidentiality laws, collect, use, or disclose aggregate information that is not individually identifiable (as defined in sections 160 and 164 of title 45, Code of Federal Regulations). With this data, the

grantee shall submit an annual report to the Secretary that summarizes and analyzes the data and provides information on needs for navigation services, types of access difficulties resolved, sources of repeated resolution, and flaws in the system of access, including insurance barriers.

''(5) EVALUATIONS.—

''(A) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall, directly or through grants or contracts, provide for evaluations to determine which outreach activities under paragraph (3) were most effective in informing the public and the specific community that the program is serving of the model program services and to determine the extent to which such programs were effective in providing culturally competent services to the health disparity population served by the programs.

''(B) DISSEMINATION OF FINDINGS.—The Secretary shall as appropriate disseminate to public and private entities the findings made in evaluations under subparagraph (A).

''(6) COORDINATION WITH OTHER PROGRAMS.—The Secretary shall coordinate the program under this subsection with—

''(A) the program under subsection (c);

''(B) the program under section 417E–10 of the Public Health Service Act; and

''(C) to the extent practicable, programs for prevention centers that are carried out by the Director of the Centers for Disease Control and Prevention.

''(c) PROGRAM FOR PATIENT NAVIGATORS.—

''(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to public and nonprofit private health centers (including health centers under section 330, Indian Health Service Centers, tribal governments, urban Indian organizations, tribal organizations, clinics serving Asian Americans and Pacific Islanders and Alaskan Natives, rural health clinics, and qualified nonprofit entities that partner with 1 or more centers providing health care to provide navigation services, that demonstrate the ability to perform all of the functions outlined in this subsection and subsections (b) and (d)) for the development and operation of

programs to pay the costs of such health centers in carrying out the same activities outlined in section 417E–10(c)(1).

''(2) APPLICATION FOR GRANT.—An entity that desires to receive a grant under paragraph (1) shall submit an application to the Secretary at such time, in such manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(3) OUTREACH SERVICES.—In order to be eligible to receive a grant under paragraph (1), an entity shall agree to provide ongoing outreach activities while receiving the grant, in a manner that is culturally competent for the health disparity population served by the program, to inform the public and the specific community that the patient navigator is serving of the services of the model program under the grant.

''(4) DATA COLLECTION AND REPORT.—In order to allow for effective patient navigator program evaluation, an entity that receives a grant under this subsection shall collect specific patient data recording navigation services provided to each patient served by the program and shall establish and implement procedures and protocols, consistent

with applicable Federal and State laws (including sections 160 and 164 of title 45, Code of Federal Regulations) to ensure the confidentiality of all information shared by a participant in the program, or their personal representative and their health care providers, group health plans, or health insurance insurers with the program. The patient navigator program may, consistent with applicable Federal and State confidentiality laws, collect, use, or disclose aggregate information that is not individually identifiable (as defined in sections 160 and 164 of title 45, Code of Federal Regulations). With this data, the grantee shall submit an annual report to the Secretary that summarizes and analyzes the data and provides information on needs for navigation services, types of access difficulties resolved, sources of repeated resolution, and flaws in the system of access, including insurance barriers.

''(5) EVALUATIONS.—

''(A) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall, directly or through grants or contracts, provide for evaluations to determine the effects of the services of patient navigators on the individuals

of health disparity populations for whom the services were provided, taking into account the matters referred to in section 417E–10(c)(1)(C).

''(B) DISSEMINATION OF FINDINGS.—The Secretary shall, as appropriate, disseminate to public and private entities the findings made in evaluations under subparagraph (A).

''(6) COORDINATION WITH OTHER PROGRAMS.—The Secretary shall coordinate the program under this subsection with the programs under subsection (b) and section 417E–10.

''(d) REQUIREMENTS REGARDING FEES.—

''(1) IN GENERAL.—In order to be eligible to receive a grant under subsection (b) or (c), the program for which the grant is made shall have in effect—

''(A) a schedule of fees or payments for the provision of such program's health care services related to the prevention and treatment of disease that is consistent with locally prevailing rates or charges and is designed to cover such program's reasonable costs of operation; and

''(B) a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the ability of the patient to pay.

''(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require payment for navigation services or to require payment for health care services in cases where care is provided free of charge, including the case of services provided through programs of the Indian Health Service.

''(e) MODEL.—Not later than 5 years after the date of enactment of this section, the Secretary shall develop a peer-reviewed model of systems for the services provided by this section. The Secretary shall update such model as may be necessary to ensure that the best practices are being utilized.

''(f) DURATION OF GRANT.—The period during which payments are made to an entity from a grant under subsection (b)(1) or (c)(1) may not exceed 5 years. The provision of such payments are subject to annual approval by the Secretary and subject to the availability of appropriations for the fiscal year involved. Nothing in this subsection shall be construed as establishing a limitation on

the number of grants under subsections (b) and (c) that may be made to an entity.

''(g) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—

''(A) MODEL PROGRAMS.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

''(B) PATIENT NAVIGATORS.—For the purpose of carrying out subsection (c), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

''(C) BUREAU OF PRIMARY HEALTH CARE.—Amounts appropriated under subparagraph (A) or (B) shall be administered through the Bureau of Primary Health Care.

''(2) PROGRAMS IN RURAL AREAS.—

''(A) MODEL PROGRAMS.—For the purpose of carrying out subsection (b) in making grants under such subsection for model programs in rural areas, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

''(B) PATIENT NAVIGATORS.—For the purpose of carrying out subsection (c) in making grants under such subsection for programs in rural areas, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.

''(C) OFFICE OF RURAL HEALTH POLICY.—Amounts appropriated under subparagraph (A) or (B) shall be administered through the Office of Rural Health Policy.

''(3) RELATION TO OTHER AUTHORIZATIONS.—Authorizations of appropriations under paragraphs (1) and (2) are in addition to other authorizations of appropriations that are available for the purposes of carrying out subsections (b) and (c).''.

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