

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “National Cancer Act of 2003”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 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.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Each year 1,300,000 Americans are diag-
4 nosed with cancer. Each year 560,000 Americans die
5 from cancer. Approximately 40 percent of all Ameri-
6 cans in the United States will be diagnosed with
7 cancer at some point in their lives.

8 (2) Since 1971, when the National Cancer Act
9 was enacted, and the “War on Cancer” was de-
10 clared, the science of cancer has advanced dramati-
11 cally. The revolution in molecular and cellular biol-
12 ogy has created unprecedented opportunities for un-
13 derstanding cancer and the role of genetics, environ-
14 mental risk factors, and lifestyle factors in relation
15 to cancer.

16 (3) Since 1971, mortality rates for some can-
17 cers have decreased, while such rates for other can-
18 cers have not.

19 (4) Since 1971, the Nation’s population has be-
20 come increasingly diverse and cancer affects various
21 minority, socioeconomic, and ethnic groups dis-
22 proportionately.

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

1 early detection do exist for some of the more com-
2 mon cancers. Screening for some cancers, such as
3 breast, colorectal, and cervical cancers, has improved
4 dramatically; however, screening rates are still lower
5 than optimal. Cancer screening rates vary by cancer
6 site, population group, and health insurance cov-
7 erage.

8 (6) Public and private health insurance cov-
9 erage offered in the United States has dramatically
10 changed since 1971. Today, managed care coverage
11 is more typical than the fee-for-service coverage that
12 was more common in the past. This change in the
13 form of coverage has introduced more economic con-
14 siderations into medical decisionmaking, which can
15 affect the quality of all health care provided, includ-
16 ing cancer care.

17 (7) Fewer than 5 percent of adult cancer pa-
18 tients participate in cancer trials.

19 (8) New translational cancer research centers
20 are needed to provide the preclinical and early clin-
21 ical trials support required to advance scientific dis-
22 coveries into new drugs and technologies to prevent,
23 detect, treat, and diagnose cancer.

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

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

3 (10) Cancer is a disease of aging and as the
4 American population ages, cancer incidence will
5 grow. It is estimated that the number of cancer di-
6 agnoses in 2010 will increase by 20 percent. The
7 number of cancer deaths is anticipated to increase
8 by 20 percent, at an annual cost of over
9 \$200,000,000,000. With such increases in the inci-
10 dence of cancer, there will be a serious shortage of
11 individuals in the workforce to provide cancer care,
12 particularly in long-term care settings.

13 (11) The number of medical researchers is de-
14 clining, a decrease which will negatively affect the
15 prevention, detection, and treatment of cancer.

16 (12) Since 1971, there has been a shift in can-
17 cer care, such as the administration of chemo-
18 therapy, moving from inpatient to outpatient set-
19 tings.

20 (13) Since 1971, the conduct of research has
21 involved more collaboration between the public and
22 private sectors and more multidisciplinary ap-
23 proaches. The biotechnology pharmaceutical and de-
24 vice industry has grown and provided a broad array

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

3 (14) Since 1971, technology and communica-
 4 tions have expanded and increased in complexity,
 5 transforming research methodologies and making the
 6 accessing and transmitting of information more
 7 widespread and more readily available.

8 (15) Tobacco use is the leading preventable
 9 cause of disease and premature death in the United
 10 States, resulting in $\frac{1}{3}$ of all cancer deaths, including
 11 87 percent of lung cancer deaths. Research consist-
 12 ently shows that smoking cessation services can be
 13 1 of the most cost-effective health interventions and
 14 can reduce smoking-related health care costs. Ces-
 15 sation services offered as a combination of tobacco
 16 medication therapy and counseling effectively help
 17 smokers quit successfully and prevent premature
 18 death from tobacco-related cancers.

19 **TITLE I—EXPANSION OF CAN-**
 20 **CER-RELATED RESEARCH,**
 21 **PREVENTION, DETECTION,**
 22 **AND TREATMENT PROGRAMS**

23 **SEC. 101. SENSE OF THE SENATE CONCERNING INVEST-**
 24 **MENTS IN CANCER RESEARCH FUNDING.**

25 It is the sense of the Senate that—

1 (1) past investments in cancer research have re-
2 sulted in better health, an improved quality of life,
3 and a reduction in national health care expenditures;
4 and

5 (2) to build on, and sustain, the progress made
6 over the past 5 years during which Congress doubled
7 the budget at the National Institutes of Health, the
8 National Cancer Institute requires continued in-
9 creases in Federal funding, as outlined in the Na-
10 tional Cancer Institute Directors Bypass Budget, to
11 achieve a balanced research portfolio and to develop
12 more targeted, more effective therapies or drugs and
13 other cancer treatments and to address those rare,
14 deadly cancers lacking effective early detection tests
15 or treatments for a wide range of cancers, commen-
16 surable with the National Cancer Institute bypass
17 budget.

18 **SEC. 102. SENSE OF THE SENATE CONCERNING INVEST-**
19 **MENTS IN CANCER RESEARCH TO DEVELOP**
20 **TARGETED DRUGS.**

21 (a) FINDINGS.—The Senate finds that—

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

1 (2) as a normal cell becomes malignant, its sig-
2 nature changes and this change becomes a signal of
3 the presence of cancer; and

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

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

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

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

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

20 **“CHAPTER I—PURPOSE OF INSTITUTE AND**
21 **NATIONAL CANCER PROGRAMS”;**

22 and

23 (2) by adding at the end the following:

1 “(8) research regarding tools for early detec-
2 tion, especially for which there currently are no ade-
3 quate screening technologies; and

4 “(9) cancer survivorship.

5 “(b) PRIORITIES.—The Institute shall determine pri-
6 orities based on scientific opportunities, in consultation
7 with medical, scientific, patient, and provider representa-
8 tives, and prepare 1 or more strategic plans by July 1,
9 2005.

10 **“SEC. 417E-1. GRANTS FOR TRANSLATIONAL CANCER RE-**
11 **SEARCH.**

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

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

17 “(1) award grants to public or nonprofit private
18 entities to plan and operate a national network of at
19 least 20 existing or new translational cancer re-
20 search centers to conduct translational, multidisci-
21 plinary cancer research;

22 “(2) establish networks and partnerships link-
23 ing the translational cancer research centers de-
24 scribed in paragraph (1) to community cancer pro-
25 viders (hospitals, clinics, providers’ practices, par-

1 particularly in underserved areas) and expand opportu-
2 nities for all cancer patients to participate in clinical
3 trials of new agents developed by these centers;

4 “(3) facilitate the process to award grants, con-
5 tracts, and cooperative agreements to private entities
6 to conduct translational cancer research in the fol-
7 lowing areas—

8 “(A) cancer drugs, biologics, and devices;
9 and

10 “(B) cancer detection diagnostic tests,
11 techniques, and technology; and

12 “(4) develop and implement a strategic plan by
13 July 1, 2005, in collaboration with translational cen-
14 ters as authorized in paragraph (7) for intensifying,
15 expanding, and disseminating results of translational
16 research to providers of cancer care.

17 “(c) GRANTS.—

18 “(1) IN GENERAL.—The Director of the Insti-
19 tute shall award grants to public or nonprofit pri-
20 vate entities to establish translational cancer re-
21 search centers to conduct translational, multidisci-
22 plinary cancer research. Funds shall not be used for
23 construction of new facilities.

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

1 vide, to the greatest extent practicable, a broad dis-
2 tribution of such grants among geographic regions
3 of the United States.

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

8 “(4) APPLICATION.—A public or nonprofit enti-
9 ty desiring a grant under this subsection shall sub-
10 mit an application to the Director of the Institute at
11 such time, in such manner, and containing such in-
12 formation as the Director of the Institute may rea-
13 sonably require.

14 “(d) DUTIES OF TRANSLATIONAL RESEARCH CEN-
15 TERS.—The translational research centers shall—

16 “(1) perform research for discovery and pre-
17 clinical evaluation of drugs, biologics, devices, tech-
18 nologies, and strategies with potential to improve the
19 prevention, detection, diagnosis, and treatment of
20 cancer and to improve pain and symptom manage-
21 ment and quality of life of cancer patients;

22 “(2) perform clinical research studies on prom-
23 ising cancer treatments or strategies, in appropriate
24 human populations;

1 “(3) evaluate promising cancer diagnostic tests,
2 techniques, or technologies in individuals being eval-
3 uated for the presence of cancer;

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

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

11 “(6) create systems and external relationships,
12 which do not duplicate capabilities available in the
13 private sector, to accelerate the findings from
14 translational research to a stage that private compa-
15 nies can assume development and commercialization;
16 and

17 “(7) develop and implement a plan expanding
18 and disseminating the efficacious products of
19 translational research to providers of cancer care, in-
20 cluding products approved by the Food and Drug
21 Administration.

22 “(e) DEFINITIONS.—In this section:

23 “(1) CLINICAL TRIAL.—The term ‘clinical trial’
24 means a scientifically-designed clinical investigation
25 in which a patient participates in examining the ef-

1 “(1) award grants and facilitate the process to
2 award grants to public or nonprofit private entities
3 to conduct research to develop a molecularly-ori-
4 ented, knowledge-based approach to cancer drug dis-
5 covery and development; and

6 “(2) not later than July 1, 2005, develop and
7 implement a strategic plan for intensifying and ex-
8 panding research conducted to increase the number
9 of cancer treatments available that are low toxicity,
10 high efficacy agents, and in particular, research to
11 develop treatments that selectively target malignant
12 or cancerous cells.

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

16 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
17 is authorized to be appropriated to carry out this section,
18 \$20,000,000 in fiscal year 2004, and \$20,000,000 for
19 each of the fiscal years 2005, 2006, 2007, and 2008.

20 **“SEC. 417E-3. CLINICAL TRIALS.**

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

24 “(b) PROGRAM.—The program described in sub-
25 section (a) shall include—

1 “(1) an outreach program;

2 “(2) a diversity assurance program;

3 “(3) an assistance program, including recom-
4 mending sources of funding for patients support
5 costs; and

6 “(4) culturally appropriate materials.

7 “(c) OUTREACH PROGRAM.—In carrying out the out-
8 reach program described in subsection (a), the Director
9 of the Institute shall regularly provide information to can-
10 cer care providers, professional and patient organizations,
11 including community-based organizations, and patients to
12 increase provider participation and patient enrollment in
13 clinical trials.

14 “(d) DIVERSITY ASSURANCE PROGRAM.—In carrying
15 out the diversity assurance program described in sub-
16 section (a), the Director of the Institute shall require that
17 all research grant applications include assurances that the
18 applicant will actively recruit a diverse patient population,
19 including disparity populations, to participate in trials,
20 when such recruitment is medically appropriate.

21 **“SEC. 417E-4. CANCER CARE RESEARCHERS.**

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

1 tute, in coordination with the Secretary of Veterans Af-
2 fairs, shall carry out activities to—

3 “(1) increase the number and amount of insti-
4 tutional training grants to institutions supporting
5 cancer research; and

6 “(2) increase the number of career development
7 awards for health professionals, particularly minori-
8 ties, who intend to have, or who expand, careers in
9 basic, clinical, and translational cancer research, in-
10 cluding cancer prevention, cancer information tech-
11 nology, bioinformatics, behavioral research, and re-
12 search on palliative, psychosocial, and end-of-life
13 care.

14 “(b) LOAN REPAYMENT.—

15 “(1) ESTABLISHMENT.—The Director of the
16 Institute, in consultation with the Director of the
17 National Institutes of Health, shall establish a can-
18 cer research loan repayment program.

19 “(2) CONTRACTS.—Under the program estab-
20 lished under paragraph (1), the Director of the In-
21 stitute shall enter into contracts with qualified
22 health professionals under which such professionals
23 will agree to conduct cancer research, in consider-
24 ation of the Federal Government agreeing to repay,
25 for each year of such services, not more than

1 \$35,000 of the principal and interest of the edu-
2 cational loans of such professionals obtained to sup-
3 port training for degrees or licenses, as determined
4 appropriate by the Director of the Institute.

5 “(c) POSTDOCTORAL STIPENDS.—

6 “(1) IN GENERAL.—The Director of the Insti-
7 tute, shall develop and implement, for postdoctoral
8 trainees and fellows, a stipend schedule that by Oc-
9 tober 1, 2004, begins for entry-level positions and
10 individuals with no or limited experience comparable
11 to grade 11 of the Federal general schedule under
12 title 5, United States Code (civil service salary
13 schedule) and that adequately reflects training, edu-
14 cation, experience, and comparable salaries or sti-
15 pends for comparable work in non-Federal settings,
16 and provides for annual cost-of-living adjustments.

17 “(2) AUTHORIZATION OF APPROPRIATIONS.—

18 There is authorized to be appropriated to carry out
19 this subsection, \$79,000,000 for fiscal year 2004,
20 and \$86,000,000 for fiscal year 2005, \$95,000,000
21 for fiscal year 2006, \$105,000,000 for fiscal year
22 2007, and \$115,000,000 for fiscal year 2008.

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

1 \$10,500,000 for fiscal year 2004, and \$10,500,000 for
2 each of fiscal years 2005 through 2008.

3 **“SEC. 417E-5. CANCER CARE WORKFORCE.**

4 “(a) IN GENERAL.—The Secretary shall establish a
5 program to address current and future cancer care work-
6 force needs.

7 “(b) PROGRAM.—The program described in sub-
8 section (a) shall—

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

11 “(2) prepare and implement a plan to provide
12 assistance to individuals based on cancer health pro-
13 fessions with the most severe shortages;

14 “(3) award grants, scholarships, fellowships,
15 and loans to eligible individuals to increase the can-
16 cer care workforce;

17 “(4) make awards to eligible individuals to in-
18 crease cancer care workforce training for all individ-
19 uals to become cancer care providers, especially but
20 not limited to, such individuals who make a commit-
21 ment to serve in underserved communities or areas
22 with disproportionately high cancer incidence or
23 mortality and for health professions for which there
24 are anticipated shortages, including providers, phar-
25 macists, nurses for all settings, allied health profes-

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

3 “(5) be coordinated with existing programs to
4 prevent duplication.

5 “(c) ELIGIBILITY.—To be eligible to receive a schol-
6 arship, loan, or fellowship under this section, an individual
7 shall submit an application to the Secretary at such time,
8 in such manner, and containing such information as the
9 Secretary reasonably requires. In such application, such
10 individual shall demonstrate the intent to seek training to
11 get a certificate, license, or postsecondary degree in health
12 care, or in the case of licensed health care professionals,
13 the intent to seek professional development to upgrade
14 skills and knowledge or to obtain specialized knowledge ac-
15 cording to criteria developed by the Secretary.

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

20 “(1) care and treatment of cancer patients and
21 survivors;

22 “(2) quality of life and symptom management;

23 “(3) early detection and diagnosis;

24 “(4) cancer prevention;

25 “(5) genetic testing and counseling;

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

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

6 “(5) award grants to public and nonprofit orga-
7 nizations for cancer control and prevention.

8 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
9 is authorized to be appropriated to carry out this section,
10 \$65,000,000 for fiscal year 2004 and such sums as may
11 be necessary for fiscal years 2005, 2006, 2007, and 2008.

12 **“SEC. 417E-7. CANCER SURVIVORSHIP.**

13 “(a) IN GENERAL.—The Secretary, acting through
14 the Director of the Centers for Disease Control and Pre-
15 vention, shall conduct a study of the unique health chal-
16 lenges associated with cancer survivorship and carry out
17 projects and interventions to improve the long-term health
18 status of cancer survivors. Such projects shall be carried
19 out directly or through the awarding of grants or con-
20 tracts.

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

23 “(1) the expansion of current cancer surveil-
24 lance systems to track the health status of cancer
25 survivors and determine whether cancer survivors

1 are at-risk for other chronic and disabling condi-
2 tions;

3 “(2) assess the unique challenges associated
4 with cancer survivorship; and

5 “(3) the development of a national cancer survi-
6 vorship action plan, in partnership with health orga-
7 nizations focused on cancer survivorship, to be car-
8 ried out in coordination with the State-based com-
9 prehensive cancer control program of the Centers for
10 Disease Control and Prevention to—

11 “(A) develop unique and innovative post-
12 treatment programs, services, and demonstra-
13 tions designed to support and advance cancer
14 survivorship through—

15 “(i) promotion of physical activity and
16 healthy lifestyles;

17 “(ii) educational outreach programs
18 for health care providers;

19 “(iii) support for innovative programs
20 to improve the quality of life among cancer
21 survivors;

22 “(iv) home and community-based
23 interventions;

24 “(v) peer support and mentor pro-
25 grams;

1 “(vi) public awareness and outreach
2 campaigns; and

3 “(vii) information dissemination to in-
4 form health care providers and cancer sur-
5 vivors of their health care options and
6 available survivorship programs; and

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

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

16 “(d) REPORT TO CONGRESS.—Not later than Octo-
17 ber 1, 2004, the Secretary shall submit to Congress a re-
18 port describing the results of the study conducted under
19 subsection (a), and as applicable, the strategies developed
20 under such subsection.

21 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
22 is authorized to be appropriated to carry out this section,
23 \$35,000,000 for fiscal year 2004, and such sums as may
24 be necessary for each of fiscal years 2005 through 2008.

1 **“SEC. 417E-8. OFFICE OF CANCER SURVIVORSHIP.**

2 “(a) ESTABLISHMENT.—There is established within
3 the Institute an Office on Cancer Survivorship (in this sec-
4 tion referred to as the ‘Office’), to be headed by an Asso-
5 ciate Director, to implement and direct the expansion and
6 coordination of the activities of the Institute with respect
7 to cancer survivorship research.

8 “(b) COLLABORATION AMONG AGENCIES.—In car-
9 rying out the activities described in subsection (a), the Of-
10 fice shall collaborate with other institutes, centers, and of-
11 fices within the National Institutes of Health that are de-
12 termined appropriate by the Office.

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

18 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
19 are authorized to be appropriated to carry out this section,
20 such sums as may be necessary for each of fiscal years
21 2004 through 2008.

22 **“SEC. 417E-9. MONITORING AND EVALUATING QUALITY**
23 **CANCER CARE AND CANCER SURVIVORSHIP.**

24 “(a) IN GENERAL.—The Secretary, acting through
25 the Director of the Institute and the Director of the Cen-
26 ters for Disease Control and Prevention, shall make grants

1 to eligible entities for the purpose of enabling such entities
2 to monitor and evaluate quality cancer care, develop infor-
3 mation concerning quality cancer care, and monitor cancer
4 survivorship.

5 “(b) ELIGIBLE ENTITIES.—An entity shall be eligible
6 for a grant under this section for a fiscal year if such enti-
7 ty—

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

11 “(2) is certified by the North American Asso-
12 ciation of Central Cancer Registries or another simi-
13 lar certification organization.

14 “(c) CONTRACTING AUTHORITY.—In carrying the
15 purpose described in subsection (a), an eligible entity may
16 expend a grant under such subsection to enter into con-
17 tracts with academic institutions, cancer centers, and
18 other entities, when determined appropriate by the Sec-
19 retary.

20 “(d) APPLICATION.—To be eligible for a grant under
21 subsection (a), an eligible entity shall submit to the Sec-
22 retary an application at such time, in such manner, and
23 containing such agreements, assurances, and information
24 as the Secretary determines to be necessary to carry out
25 this section.

1 “(e) AUTHORITY OF SECRETARY REGARDING USE OF
2 GRANT FUNDS.—The Secretary shall determine the ap-
3 propriate uses of grant funds under subsection (a) to
4 achieve the purpose described in such subsection.

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

9 **“SEC. 417E-10. MODEL COMMUNITY CANCER AND CHRONIC**
10 **DISEASE CARE AND PREVENTION; PATIENT**
11 **NAVIGATORS.**

12 “(a) DEFINITIONS.—In this section:

13 “(1) APPROPRIATE FOLLOW-UP CARE.—The
14 term ‘appropriate follow-up care’ includes palliative
15 and end-of-life care.

16 “(2) CULTURALLY COMPETENT.—The term
17 ‘culturally competent’, with respect to providing
18 health-related services, means services that, in ac-
19 cordance with standards and measures of the Sec-
20 retary, are designed to effectively and efficiently re-
21 spond to the cultural and linguistic needs of pa-
22 tients.

23 “(3) ELIGIBLE ENTITY.—The term ‘eligible en-
24 tity’ means any public or private entity determined
25 to be appropriate by the Director of the Institute

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

6 “(A) A designated cancer center of the In-
7 stitute.

8 “(B) An academic institution.

9 “(C) An Indian Health Service Clinic.

10 “(D) A tribal government.

11 “(E) An urban Indian organization.

12 “(F) A tribal organization.

13 “(G) A hospital.

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

17 “(4) HEALTH DISPARITY POPULATION.—The
18 term ‘health disparity population’ means a popu-
19 lation where there exists a significant disparity in
20 the overall rate of disease incidence, morbidity, mor-
21 tality, or survival rates in the population as com-
22 pared to the health status of the general population.
23 Such term includes—

24 “(A) racial and ethnic minority groups (as
25 defined under section 1707); and

1 “(B) medically underserved groups, such
2 as rural and low-income individuals and individ-
3 uals with low levels of literacy.

4 “(5) PATIENT NAVIGATOR.—

5 “(A) IN GENERAL.—The term ‘patient
6 navigator’ means an individual whose functions
7 include—

8 “(i) assisting and guiding patients
9 with a symptom, abnormal finding, or di-
10 agnosis of cancer or other chronic disease
11 within the health care system to accom-
12 plish the follow-up and diagnosis of an ab-
13 normal finding as well as the treatment
14 and appropriate follow-up care of cancer or
15 other chronic disease, including providing
16 information about clinical trials; and

17 “(ii) identifying, anticipating, and
18 helping patients overcome barriers within
19 the health care system to ensure prompt
20 diagnostic and treatment resolution of an
21 abnormal finding of cancer or other chron-
22 ic disease.

23 “(B) INCLUSIONS.—The term ‘patient nav-
24 igator’ includes representatives of the target
25 health disparity population, such as nurses, so-

1 cial workers, cancer survivors, and patient ad-
2 vocates.

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

5 “(1) IN GENERAL.—The Director of the Insti-
6 tute may make grants to eligible entities for the de-
7 velopment and operation of model programs that—

8 “(A) provide to individuals of health dis-
9 parity populations prevention, early detection,
10 treatment, and appropriate follow-up care serv-
11 ices for cancer and chronic diseases;

12 “(B) ensure that the health services are
13 provided to such individuals in a culturally com-
14 petent manner;

15 “(C) assign patient navigators, in accord-
16 ance with applicable criteria of the Secretary,
17 for managing the care of individuals of health
18 disparity populations to—

19 “(i) accomplish, to the extent possible,
20 the follow-up and diagnosis of an abnormal
21 finding and the treatment and appropriate
22 follow-up care of cancer or other chronic
23 disease; and

24 “(ii) facilitate access to appropriate
25 health care services within the health care

1 system to ensure optimal patient utiliza-
2 tion of such services, including aid in co-
3 ordinating and scheduling appointments
4 and referrals, community outreach, assist-
5 ance with transportation arrangements,
6 and assistance with insurance issues and
7 other barriers to care and providing infor-
8 mation about clinical trials;

9 “(D) require training for patient naviga-
10 tors employed through such model programs to
11 ensure the ability of navigators to perform all
12 of the duties required in this subsection and in
13 subsection (c), including training to ensure that
14 navigators are informed about health insurance
15 systems and are able to aid patients in resolv-
16 ing access issues; and

17 “(E) ensure that consumers have direct ac-
18 cess to patient navigators during regularly
19 scheduled hours of business operation.

20 “(2) APPLICATION FOR GRANT.—An eligible en-
21 tity that desires to receive a grant under paragraph
22 (1) shall submit an application to the Director of the
23 Institute at such time, in such manner, and con-
24 taining such agreements, assurances, and informa-

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

3 “(3) OUTREACH SERVICES.—In order to be eli-
4 gible to receive a grant under paragraph (1), an eli-
5 gible entity shall agree to provide ongoing outreach
6 activities while receiving the grant, in a manner that
7 is culturally competent for the health disparity popu-
8 lation served by the program, to inform the public
9 and the specific community that the program is
10 serving of the services of the model program under
11 the grant. Such activities shall include facilitating
12 access to appropriate health care services and pa-
13 tient navigators within the health care system to en-
14 sure optimal patient utilization of such services.

15 “(4) DATA COLLECTION AND REPORT.—In
16 order to allow for effective program evaluation, an
17 eligible entity that receives a grant under this sub-
18 section shall collect specific patient data recording
19 services provided to each patient served by the pro-
20 gram and shall establish and implement procedures
21 and protocols, consistent with applicable Federal and
22 State laws (including sections 160 and 164 of title
23 45, Code of Federal Regulations) to ensure the con-
24 fidentiality of all information shared by a participant
25 in the program, or their personal representative and

1 their health care providers, group health plans, or
2 health insurance insurers with the program. The
3 program may, consistent with applicable Federal and
4 State confidentiality laws, collect, use, or disclose ag-
5 gregate information that is not individually identifi-
6 able (as defined in sections 160 and 164 of title 45,
7 Code of Federal Regulations). With this data, the
8 grantee shall submit an annual report to the Sec-
9 retary that summarizes and analyzes the data and
10 provides information on needs for navigation serv-
11 ices, types of access difficulties resolved, sources of
12 repeated resolution, and flaws in the system of ac-
13 cess, including insurance barriers.

14 “(5) EVALUATIONS.—

15 “(A) IN GENERAL.—The Director of the
16 Institute, directly or through grants or con-
17 tracts, shall provide for evaluations to deter-
18 mine which outreach activities under paragraph
19 (3) were most effective in informing the public
20 and the specific community that the program is
21 serving of the model program services and to
22 determine the extent to which such programs
23 were effective in providing culturally competent
24 services to the health disparity population
25 served by the programs.

1 “(B) DISSEMINATION OF FINDINGS.—The
2 Director of the Institute shall, as appropriate,
3 disseminate to public and private entities the
4 findings made in evaluations under subpara-
5 graph (A).

6 “(6) COORDINATION WITH OTHER PRO-
7 GRAMS.—The Secretary shall coordinate the pro-
8 gram under this subsection with—

9 “(A) the program under subsection (e);

10 “(B) the program under section 330M;

11 and

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

16 “(c) PROGRAM FOR PATIENT NAVIGATORS.—

17 “(1) IN GENERAL.—The Director of the Insti-
18 tute may make grants to eligible entities for the de-
19 velopment and operation of programs to pay the
20 costs of such entities in—

21 “(A) assigning patient navigators, in ac-
22 cordance with applicable criteria of the Sec-
23 retary, for managing the care of individuals of
24 health disparity populations for the duration of
25 receipt of health services from the health cen-

1 ters, including aid in coordinating and sched-
2 uling appointments and referrals, community
3 outreach, assistance with transportation ar-
4 rangements, assistance with insurance issues
5 and other barriers to care, and providing infor-
6 mation about clinical trials;

7 “(B) ensuring that the services provided by
8 the patient navigators to such individuals in-
9 clude case management and psychosocial as-
10 sessment and care or information and referral
11 to such services;

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

16 “(D) developing model practices for patient
17 navigators, including with respect to—

18 “(i) coordination of health services,
19 including psychosocial assessment and
20 care;

21 “(ii) follow-up services, including psy-
22 chosocial assessment and care;

23 “(iii) determining coverage under
24 health insurance and health plans for all
25 services;

1 “(iv) ensuring the initiation, continu-
2 ation, or sustained access to care pre-
3 scribed by the patients’ health care pro-
4 viders; and

5 “(v) aiding patients with health insur-
6 ance coverage issues;

7 “(E) requiring training for patient naviga-
8 tors to ensure the ability of navigators to per-
9 form all of the duties required in this sub-
10 section and in subsection (b), including train-
11 ing, to ensure that navigators are informed
12 about health insurance systems and are able to
13 aid patients in resolving access issues; and

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

17 “(2) APPLICATION FOR GRANT.—An eligible en-
18 tity that desires to receive a grant under paragraph
19 (1) shall submit an application to the Director of the
20 Institute at such time, in such manner, and con-
21 taining such agreements, assurances, and informa-
22 tion as the Director of the Institute determines to be
23 necessary to carry out this section.

24 “(3) OUTREACH SERVICES.—In order to be eli-
25 gible to receive a grant under paragraph (1), an eli-

1 gible entity shall agree to provide ongoing outreach
2 activities while receiving the grant, in a manner that
3 is culturally competent for the health disparity popu-
4 lation served by the program, to inform the public
5 and the specific community that the patient navi-
6 gator is serving of the services of the model program
7 under the grant.

8 “(4) DATA COLLECTION AND REPORT.—In
9 order to allow for effective patient navigator pro-
10 gram evaluation, an eligible entity that receives a
11 grant under this subsection shall collect specific pa-
12 tient data recording navigation services provided to
13 each patient served by the program and shall estab-
14 lish and implement procedures and protocols, con-
15 sistent with applicable Federal and State laws (in-
16 cluding sections 160 and 164 of title 45, Code of
17 Federal Regulations) to ensure the confidentiality of
18 all information shared by a participant in the pro-
19 gram, or their personal representative and their
20 health care providers, group health plans, or health
21 insurance insurers with the program. The patient
22 navigator program may, consistent with applicable
23 Federal and State confidentiality laws, collect, use,
24 or disclose aggregate information that is not individ-
25 ually identifiable (as defined in sections 160 and 164

1 of title 45, Code of Federal Regulations). With this
2 data, the grantee shall submit an annual report to
3 the Secretary that summarizes and analyzes the
4 data and provides information on needs for naviga-
5 tion services, types of access difficulties resolved,
6 sources of repeated resolution, and flaws in the sys-
7 tem of access, including insurance barriers.

8 “(5) EVALUATIONS.—

9 “(A) IN GENERAL.—The Director of the
10 Institute, directly or through grants or con-
11 tracts, shall provide for evaluations to deter-
12 mine the effects of the services of patient navi-
13 gators on the health disparity population for
14 whom the services were provided, taking into
15 account the matters referred to in paragraph
16 (1)(C).

17 “(B) DISSEMINATION OF FINDINGS.—The
18 Director of the Institute shall as appropriate
19 disseminate to public and private entities the
20 findings made in evaluations under subpara-
21 graph (A).

22 “(6) COORDINATION WITH OTHER PRO-
23 GRAMS.—The Secretary shall coordinate the pro-
24 gram under this subsection with the programs under
25 subsection (b) and section 330M.

1 “(d) REQUIREMENTS REGARDING FEES.—

2 “(1) IN GENERAL.—In order to be eligible to
3 receive a grant under subsection (b) or (c), the pro-
4 gram for which the grant is made shall have in ef-
5 fect—

6 “(A) a schedule of fees or payments for
7 the provision of such program’s health care
8 services related to the prevention and treatment
9 of disease that is consistent with locally pre-
10 vailing rates or charges and is designed to cover
11 such program’s reasonable costs of operation;
12 and

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

17 “(2) RULE OF CONSTRUCTION.—Nothing in
18 this subsection shall be construed to require pay-
19 ment for navigation services or to require payment
20 for health care services in cases where care is pro-
21 vided free of charge, including the case of services
22 provided through programs of the Indian Health
23 Service.

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

1 shall develop a peer-reviewed model of systems for the
2 services provided by this section. The Director of the Insti-
3 tute shall update such model as may be necessary to en-
4 sure that the best practices are being utilized.

5 “(f) DURATION OF GRANT.—The period during
6 which payments are made to an eligible entity from a
7 grant under subsection (b)(1) or (c)(1) may not exceed
8 5 years. The provision of such payments are subject to
9 annual approval by the Director of the Institute and sub-
10 ject to the availability of appropriations for the fiscal year
11 involved. Nothing in this subsection shall be construed as
12 establishing a limitation on the number of grants under
13 subsections (b) and (c) that may be made to an eligible
14 entity.

15 “(g) AUTHORIZATION OF APPROPRIATIONS.—

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

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

24 “(3) RELATION TO OTHER AUTHORIZATIONS.—
25 Authorizations of appropriations under paragraphs

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

4 **“SEC. 417E-11. CANCER CARE GUIDELINES.**

5 “The Agency for Healthcare Research and Quality
6 shall regularly convene cancer experts, providers, patients,
7 representatives of disparity populations, and other rel-
8 evant experts, including representatives of the Institute,
9 the Health Resources Administration, and the Centers for
10 Disease Control and Prevention, to coordinate the develop-
11 ment and regularly update—

12 “(1) consensus protocols and practice guidelines
13 for optimal cancer treatments and prevention, in-
14 cluding palliation, symptom management, and end-
15 of-life care;

16 “(2) quality of care measures to assist providers
17 and patients in making and evaluating treatment de-
18 cisions; and

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

1 **“SEC. 417E-12. RESEARCH AND OTHER ACTIVITIES OF THE**
2 **AGENCY FOR HEALTHCARE RESEARCH AND**
3 **QUALITY TO IMPROVE THE QUALITY AND**
4 **OUTCOMES OF CANCER CARE.**

5 “(a) IN GENERAL.—

6 “(1) RESEARCH.—The Director for Healthcare
7 Research and Quality shall conduct and support re-
8 search and other activities to build an evidence base
9 regarding effective clinical and organizational inter-
10 vention strategies to improve the quality and out-
11 comes of cancer care, and access to such care, at all
12 stages of the health care continuum and to facilitate
13 the prompt use of that information to improve prac-
14 tice.

15 “(2) FACTORS.—In carrying out paragraph (1),
16 the Director for Healthcare Research and Quality
17 shall take into account the breadth of the continuum
18 of cancer care, from prevention and early detection,
19 through diagnosis and treatment, to rehabilitation,
20 long term survivorship and remission, through psy-
21 chosocial, palliative, and end-of-life care.

22 “(b) SPECIFIC REQUIREMENTS.—The Agency for
23 Healthcare Research and Quality shall—

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

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

3 “(2) regularly assess and synthesize existing
4 scientific evidence on the effectiveness of such inter-
5 ventions;

6 “(3) ensure the targeted dissemination of the
7 most current scientific evidence in appropriate for-
8 mats for use by professional societies and organiza-
9 tions representing clinicians and other caregivers, or-
10 ganizations through which health care and support
11 services are delivered, and organizations rep-
12 resenting cancer patients and their families;

13 “(4) facilitate, as appropriate, the prompt use
14 of existing scientific information by the professional
15 societies and organization listed in paragraph (3) to
16 develop guidance, best practices, quality improve-
17 ment strategies or other initiatives to improve prac-
18 tice;

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

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

1 trends to the quality and outcomes of cancer care;
2 and

3 “(7) assess effective strategies by which an in-
4 dividual physician can provide overall coordination
5 and management of cancer care.

6 “(c) COORDINATION OF FEDERAL QUALITY IM-
7 PROVEMENT ACTIVITIES AND REPORTING OF DATA.—In
8 carrying out subsection (b)—

9 “(1) the Director for Healthcare Research and
10 Quality, working through the Quality Interagency
11 Coordination (QUIC) Task Force, and in collabora-
12 tion with the Director of the Institute, shall facili-
13 tate coordination of Federal research and implemen-
14 tation initiatives to improve the quality and out-
15 comes of cancer care;

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

20 “(3) the Director for Healthcare Research and
21 Quality and the Director of the Institute shall work
22 cooperatively to develop data in order to set bench-
23 marks for, and subsequently measure changes in the
24 quality of cancer care for inclusion, as soon as prac-

1 “(2) FIRST PART.—The first part shall—

2 “(A) examine options for providing medi-
3 care coverage to such individuals;

4 “(B) estimate the cost to the medicare pro-
5 gram and to current and future beneficiaries;
6 and

7 “(C) identify advantages associated with
8 medicare coverage in terms of access to cancer
9 care, improved quality of care and patient out-
10 comes and assess the feasibility of providing
11 medicare coverage to uninsured cancer patients
12 through 5 years of remission and make a rec-
13 ommendation to Congress about whether medi-
14 care should be expanded to this population
15 group.

16 “(3) SECOND PART.—The second part shall—

17 “(A) identify changes in medicare benefits
18 to facilitate the provision of care consistent with
19 quality cancer care standards, including pre-
20 scription drug benefits and benefits to improve
21 home care, symptom management, psychosocial
22 services, and palliative and hospice care;

23 “(B) estimate the cost to the medicare pro-
24 gram and to beneficiaries; and

1 “(C) assess the medical advantages and
2 disadvantages associated with expanding bene-
3 fits.

4 “(4) DEADLINES.—The first part shall be com-
5 pleted by June 30, 2005, and the second part shall
6 be completed by December 31, 2005.

7 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated to carry out this section
9 \$1,000,000 in fiscal year 2004 and \$1,200,000 in fiscal
10 year 2005.”.

11 **SEC. 104. NATIONAL INSTITUTE FOR ENVIRONMENTAL**
12 **HEALTH SCIENCES.**

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

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

1 **SEC. 105. COMPREHENSIVE CANCER CONTROL PLANS.**

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

4 (1) in the first sentence, by inserting “, for sur-
5 vivorship,” after “treatment of cancer”;

6 (2) in paragraph (1)(B), by striking “cancer
7 patients” and all that follows and inserting the fol-
8 lowing: “cancer patients, families of cancer patients,
9 and cancer survivors, and”; and

10 (3) in paragraph (3), by inserting “and con-
11 cerning cancer survivorship programs,” after “con-
12 trol of cancer”.

13 **SEC. 106. BREAST, CERVICAL, AND COLORECTAL CANCER**
14 **SCREENING.**

15 (a) BREAST AND CERVICAL CANCER.—Section
16 1510(a) of the Public Health Service Act (42 U.S.C.
17 300n-5(a)) is amended by striking “\$50,000,000” and all
18 that follows through the period, and inserting
19 “\$250,000,000 for fiscal year 2004, and such sums as
20 may be necessary for fiscal years 2005 through 2008.”.

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

1 **“SEC. 1511. COLORECTAL CANCER SCREENING DEM-**
2 **ONSTRATION PROJECT.**

3 “(a) IN GENERAL.—The Secretary, acting through
4 the Director of the Centers for Disease Control and Pre-
5 vention, shall award competitive grants to public and non-
6 profit private entities to enable such entities to establish
7 demonstration programs pursuant to the general authority
8 of title III to carry out colorectal screening activities in-
9 cluding—

10 “(1) screening asymptomatic individuals for
11 colorectal cancer as a preventive health measure ac-
12 cording to scientific evidence-based screening guide-
13 lines;

14 “(2) providing appropriate referrals for medical
15 treatment of individuals screened pursuant to this
16 section and to ensure, to the extent practicable, the
17 provision of appropriate follow-up services and sup-
18 port services such as case management;

19 “(3) activities to improve the education, train-
20 ing, and skills of health professionals (including al-
21 lied health professionals) in the detection and con-
22 trol of colorectal cancer;

23 “(4) activities to evaluate the programs under
24 this section through appropriate surveillance or pro-
25 gram monitoring activities;

1 “(5) the development and dissemination of find-
2 ings derived through such evaluations through public
3 and professional education; and

4 “(6) activities to promote the benefits of
5 colorectal cancer screening.

6 “(b) PAYMENTS FOR SCREENINGS.—The amount
7 paid by a grantee under this section to an entity on behalf
8 of an individual for the furnishing of services to such indi-
9 vidual shall not exceed the amount that would be paid
10 under part B of title XVIII of the Social Security Act for
11 such services if such payment were made under such part
12 for such services.

13 “(c) REQUIREMENTS.—

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

18 “(A) individual who is at least 50 years of
19 age; or

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

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

1 that grant funds will not be expended to make pay-
2 ments for any item or service to the extent that pay-
3 ment has been made, or can reasonably be expected
4 to be made, with respect to such item or service—

5 “(A) under any State compensation pro-
6 gram, under an insurance policy, or under any
7 Federal or State health benefits program; or

8 “(B) by an entity that provides health
9 service on a prepaid basis.

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

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

17 “(A) establish such fiscal control and fund
18 accounting procedures as may be necessary to
19 ensure proper disbursement of, and accounting for,
20 amounts received under this section; and

21 “(B) provide agreed upon annual reports
22 to the Secretary or the Comptroller of the
23 United States for the purposes of auditing the
24 expenditures by the entity.

1 “(5) REPORTS.—To be eligible for a grant
2 under subsection (a), an entity shall agree to submit
3 to the Secretary such reports as the Secretary deter-
4 mines appropriate.

5 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
6 is authorized to be appropriated to carry out this section,
7 \$50,000,000 for fiscal year 2004, and such sums as may
8 be necessary for each of fiscal years 2005 through 2008.”.

9 **SEC. 107. IHS GRANTS FOR MODEL COMMUNITY CANCER**
10 **AND CHRONIC DISEASE CARE AND PREVEN-**
11 **TION; IHS GRANTS FOR PATIENT NAVIGA-**
12 **TORS.**

13 (a) DEFINITIONS.—In this section:

14 (1) IN GENERAL.—The terms “culturally com-
15 petent”, “appropriate follow-up care”, “health dis-
16 parity population”, and “patient navigator” have the
17 meanings given those terms in section 417E–10 of
18 the Public Health Service Act.

19 (2) SECRETARY.—The term “Secretary” means
20 the Secretary of Health and Human Services.

21 (b) MODEL COMMUNITY CANCER AND CHRONIC DIS-
22 EASE CARE AND PREVENTION.—

23 (1) IN GENERAL.—The Director of the Indian
24 Health Service may make grants, for the develop-
25 ment and operation of model programs that perform

1 the same functions outlined in section 417E–
2 10(b)(1) of the Public Health Service Act, to Indian
3 Health Service Centers, tribal governments, urban
4 Indian organizations, tribal organizations, and quali-
5 fied nonprofit entities demonstrating the ability to
6 perform all of the functions in this subsection and
7 subsections (c) and (d) that partner with providers
8 or centers providing health care services to Native
9 American populations to provide navigation services.

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

16 (3) OUTREACH SERVICES.—In order to be eligi-
17 ble to receive a grant under paragraph (1), an entity
18 shall agree to provide ongoing outreach activities
19 while receiving the grant, in a manner that is cul-
20 turally competent for the health disparity population
21 served by the program, to inform the public and the
22 specific community that the program is serving of
23 the services of the model program under the grant.
24 Such activities shall include facilitating access to ap-
25 propriate health care services and patient navigators

1 within the health care system to ensure optimal pa-
2 tient utilization of such services.

3 (4) DATA COLLECTION AND REPORT.—In order
4 to allow for effective program evaluation, an entity
5 that receives a grant under this subsection shall col-
6 lect specific patient data recording services provided
7 to each patient served by the program and shall es-
8 tablish and implement procedures and protocols,
9 consistent with applicable Federal and State laws
10 (including sections 160 and 164 of title 45, Code of
11 Federal Regulations) to ensure the confidentiality of
12 all information shared by a participant in the pro-
13 gram, or their personal representative and their
14 health care providers, group health plans, or health
15 insurance insurers with the program. The program
16 may, consistent with applicable Federal and State
17 confidentiality laws, collect, use, or disclose aggre-
18 gate information that is not individually identifiable
19 (as defined in sections 160 and 164 of title 45, Code
20 of Federal Regulations). With this data, the grantee
21 shall submit an annual report to the Secretary that
22 summarizes and analyzes the data and provides in-
23 formation on needs for navigation services, types of
24 access difficulties resolved, sources of repeated reso-

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

3 (5) EVALUATIONS.—

4 (A) IN GENERAL.—The Secretary, acting
5 through the Director of the Indian Health Serv-
6 ice, shall, directly or through grants or con-
7 tracts, provide for evaluations to determine
8 which outreach activities under paragraph (3)
9 were most effective in informing the public and
10 the specific community that the program is
11 serving of the model program services and to
12 determine the extent to which such programs
13 were effective in providing culturally competent
14 services to the health disparity population
15 served by the programs.

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

20 (6) COORDINATION WITH OTHER PROGRAMS.—

21 The Secretary shall coordinate the program under
22 this subsection with—

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

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

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

5 (c) PROGRAM FOR PATIENT NAVIGATORS.—

6 (1) IN GENERAL.—The Secretary, acting
7 through the Director of the Indian Health Service,
8 may make grants to Indian Health Service Centers,
9 tribal governments, urban Indian organizations, trib-
10 al organizations, and qualified nonprofit entities
11 demonstrating the ability to perform all of the func-
12 tions in this subsection and subsections (b) and (d)
13 that partner with providers or centers providing
14 health care services to Native American populations
15 to provide navigation services, for the development
16 and operation of model programs to pay the costs of
17 such entities in carrying out the same activities out-
18 lined in section 417E–10(c)(1) of the Public Health
19 Service Act.

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

1 (3) OUTREACH SERVICES.—In order to be eligi-
2 ble to receive a grant under paragraph (1), an entity
3 shall agree to provide ongoing outreach activities
4 while receiving the grant, in a manner that is cul-
5 turally competent for the health disparity population
6 served by the program, to inform the public and the
7 specific community that the patient navigator is
8 serving of the services of the model program under
9 the grant.

10 (4) DATA COLLECTION AND REPORT.—In order
11 to allow for effective patient navigator program eval-
12 uation, an entity that receives a grant under this
13 subsection shall collect specific patient data record-
14 ing navigation services provided to each patient
15 served by the program and shall establish and imple-
16 ment procedures and protocols, consistent with ap-
17 plicable Federal and State laws (including sections
18 160 and 164 of title 45, Code of Federal Regula-
19 tions) to ensure the confidentiality of all information
20 shared by a participant in the program, or their per-
21 sonal representative and their health care providers,
22 group health plans, or health insurance insurers
23 with the program. The patient navigator program
24 may, consistent with applicable Federal and State
25 confidentiality laws, collect, use, or disclose aggre-

1 gate information that is not individually identifiable
2 (as defined in sections 160 and 164 of title 45, Code
3 of Federal Regulations). With this data, the grantee
4 shall submit an annual report to the Secretary that
5 summarizes and analyzes the data and provides in-
6 formation on needs for navigation services, types of
7 access difficulties resolved, sources of repeated reso-
8 lution, and flaws in the system of access, including
9 insurance barriers.

10 (5) EVALUATIONS.—

11 (A) IN GENERAL.—The Secretary, acting
12 through the Director of the Indian Health Serv-
13 ice, shall, directly or through grants or con-
14 tracts, provide for evaluations to determine the
15 effects of the services of patient navigators on
16 the individuals of health disparity populations
17 for whom the services were provided, taking
18 into account the matters referred to in section
19 417E-10(c)(1)(C) of the Public Health Service
20 Act.

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

1 (6) COORDINATION WITH OTHER PROGRAMS.—

2 The Secretary shall coordinate the program under
3 this subsection with the programs under subsection
4 (b) and section 417E–10 of the Public Health Serv-
5 ice Act.

6 (d) REQUIREMENTS REGARDING FEES.—

7 (1) IN GENERAL.—In order to be eligible to re-
8 ceive a grant under subsection (b) or (c), the pro-
9 gram for which the grant is made shall have in ef-
10 fect—

11 (A) a schedule of fees or payments for the
12 provision of such program’s health care services
13 related to the prevention and treatment of dis-
14 ease that is consistent with locally prevailing
15 rates or charges and is designed to cover such
16 program’s reasonable costs of operation; and

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

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

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

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

9 (f) DURATION OF GRANT.—The period during which
10 payments are made to an entity from a grant under sub-
11 section (b)(1) or (c)(1) may not exceed 5 years. The provi-
12 sion of such payments are subject to annual approval by
13 the Secretary and subject to the availability of appropria-
14 tions for the fiscal year involved. Nothing in this sub-
15 section shall be construed as establishing a limitation on
16 the number of grants under subsections (b) and (c) that
17 may be made to an entity.

18 (g) AUTHORIZATION OF APPROPRIATIONS.—

19 (1) IN GENERAL.—

20 (A) MODEL PROGRAMS.—For the purpose
21 of carrying out subsection (b), there are author-
22 ized to be appropriated such sums as may be
23 necessary for each of the fiscal years 2004
24 through 2008.

1 (B) PATIENT NAVIGATORS.—For the pur-
2 pose of carrying out subsection (c), there are
3 authorized to be appropriated such sums as
4 may be necessary for each of the fiscal years
5 2004 through 2008.

6 (C) BUREAU OF PRIMARY HEALTH 13
7 CARE.—Amounts appropriated under subpara-
8 graph (A) or (B) shall be administered through
9 the Bureau of Primary Health Care.

10 (2) PROGRAMS IN RURAL AREAS.—

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

17 (B) PATIENT NAVIGATORS.—For the pur-
18 pose of carrying out subsection (c) in making
19 grants under such subsection for programs in
20 rural areas, there are authorized to be appro-
21 priated such sums as may be necessary for each
22 of the fiscal years 2004 through 2008.

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

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

3 (3) RELATION TO OTHER AUTHORIZATIONS.—

4 Authorizations of appropriations under paragraphs
5 (1) and (2) are in addition to other authorizations
6 of appropriations that are available for the purposes
7 of carrying out subsections (b) and (c).

8 **TITLE II—EXPANDING ACCESS**
9 **TO CANCER DRUGS AND**
10 **TREATMENT**

11 **SEC. 201. ACCELERATION OF THE DRUG TREATMENT AP-**
12 **PROVAL PROCESS OF THE FOOD AND DRUG**
13 **ADMINISTRATION.**

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

19 **SEC. 202. FDA AMENDMENT.**

20 Section 526(a)(2) of the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 360bb(a)(2)) is amended by in-
22 serting “or targets and mechanisms of pathogenesis of dis-
23 eases” after “disease or condition”.

1 **TITLE III—CANCER-RELATED**
2 **HEALTH INSURANCE COVERAGE**
3 **Subtitle A—Clinical Trials**
4 **Coverage**

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

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

10 **“SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING**
11 **IN CLINICAL TRIALS.**

12 “(a) COVERAGE.—

13 “(1) IN GENERAL.—If a group health plan, or
14 health insurance issuer that is providing health in-
15 surance coverage, provides coverage to a qualified in-
16 dividual (as defined in subsection (b)), the plan or
17 issuer—

18 “(A) may not deny the individual partici-
19 pation in the clinical trial referred to in sub-
20 section (b)(2);

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

1 “(C) may not discriminate against the in-
2 dividual on the basis of the enrollee’s partici-
3 pation in such trial.

4 “(2) EXCLUSION OF CERTAIN COSTS.—For pur-
5 poses of paragraph (1)(B), routine patient costs do
6 not include the cost of the tests or measurements
7 conducted primarily for the purpose of the clinical
8 trial involved.

9 “(3) USE OF IN-NETWORK PROVIDERS.—If 1 or
10 more participating providers is participating in a
11 clinical trial, nothing in paragraph (1) shall be con-
12 strued as preventing a plan or issuer from requiring
13 that, if a qualified individual is enrolling in the same
14 clinical trial, the qualified individual participate in
15 the trial through such a participating provider if the
16 provider will accept the individual as a participant in
17 that same trial. If the qualified individual is to enroll
18 in a trial and no acceptable in-network provider is
19 participating in the trial or if a participating pro-
20 vider cannot accept new enrollees, then the qualified
21 individual may enroll in the trial through an out-of-
22 network provider.

23 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
24 poses of subsection (a), the term ‘qualified individual’
25 means an individual who has cancer and is a participant

1 or beneficiary in a group health plan, or who is an enrollee
2 under health insurance coverage, and who meets the fol-
3 lowing conditions:

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

7 “(2) Either the referring physician is author-
8 ized by the plan to treat the patient and has con-
9 cluded that the individual’s participation in such
10 trial would be appropriate based upon the individual
11 meeting the condition described in paragraph (1), or
12 the participant, beneficiary, or enrollee provides
13 medical and scientific information establishing that
14 the individual’s participation in such trial would be
15 appropriate based upon the individual meeting the
16 condition described in paragraph (1).

17 “(c) PAYMENT.—

18 “(1) IN GENERAL.—Under this section a group
19 health plan and a health insurance issuer shall pro-
20 vide for payment for routine patient costs described
21 in subsection (a)(2) but are not required to pay for
22 costs of items and services that are reasonably ex-
23 pected (as determined by the appropriate Secretary)
24 to be paid for by the sponsors of an approved clin-
25 ical trial.

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

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

5 “(B) a nonparticipating provider, the pay-
6 ment rate shall be at the rate the plan or issuer
7 would normally pay for comparable services
8 under subparagraph (A).

9 “(d) APPROVED CLINICAL TRIAL DEFINED.—In this
10 section, the term ‘approved clinical trial’ means a clinical
11 research study or clinical investigation—

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

14 “(A) the National Institutes of Health;

15 “(B) a cooperative group or center of the
16 National Institutes of Health, including a quali-
17 fied nongovernmental research entity to which
18 the National Cancer Institute has awarded a
19 center support grant;

20 “(C) the Department of Veterans Affairs,
21 if the conditions described in subsection (e) are
22 met; or

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

1 “(2) approved by the Food and Drug Adminis-
2 tration; or

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

7 “(A) is registered with the Department of
8 Health and Human Services; and

9 “(B) is associated with an institution that
10 has a Federal assurance approved by the De-
11 partment of Health and Human Services speci-
12 fying compliance with section 46 of title 45,
13 Code of Federal Regulations.

14 “(e) CONDITIONS FOR DEPARTMENTS.—The condi-
15 tions for a study or investigation conducted by a depart-
16 ment, are that the study or investigation has been re-
17 viewed and approved through a system of peer review that
18 the appropriate Secretary determines—

19 “(1) to be comparable to the system of peer re-
20 view of studies and investigations used by the Na-
21 tional Institutes of Health; and

22 “(2) assures unbiased review of the highest eth-
23 ical standards by an institutional review board or
24 other body that meets the standards outlined in sec-

1 tion 46 of title 45, and sections 50 and 56 of title
2 21, Code of Federal Regulations.

3 “(f) CONSTRUCTION.—Nothing in this section shall
4 be construed to limit a plan’s or issuer’s coverage with
5 respect to clinical trials.”.

6 (b) INDIVIDUAL.—Part B of title XXVII of the Pub-
7 lic Health Service Act is amended by inserting after sec-
8 tion 2752 (42 U.S.C. 300gg–52) the following:

9 **“SEC. 2753. PATIENT PROTECTION STANDARDS.**

10 “The provisions of section 2707 shall apply to health
11 insurance coverage offered by a health insurance issuer
12 in the individual market in the same manner as such pro-
13 visions apply to health insurance coverage offered by a
14 health insurance issuer in connection with a group health
15 plan.”.

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

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

23 **“SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
24 **CLINICAL TRIALS.**

25 “(a) COVERAGE.—

1 “(1) IN GENERAL.—If a group health plan, or
2 health insurance issuer that is providing health in-
3 surance coverage, provides coverage to a qualified in-
4 dividual (as defined in subsection (b)), the plan or
5 issuer—

6 “(A) may not deny the individual partici-
7 pation in the clinical trial referred to in sub-
8 section (b)(2);

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

14 “(C) may not discriminate against the in-
15 dividual on the basis of the enrollee’s participa-
16 tion in such trial.

17 “(2) EXCLUSION OF CERTAIN COSTS.—For pur-
18 poses of paragraph (1)(B), routine patient costs do
19 not include the cost of the tests or measurements
20 conducted primarily for the purpose of the clinical
21 trial involved.

22 “(3) USE OF IN-NETWORK PROVIDERS.—If 1 or
23 more participating providers is participating in a
24 clinical trial, nothing in paragraph (1) shall be con-
25 strued as preventing a plan or issuer from requiring

1 that, if a qualified individual is enrolling in the same
2 clinical trial, the qualified individual participate in
3 the trial through such a participating provider if the
4 provider will accept the individual as a participant in
5 that same trial. If the qualified individual is to enroll
6 in a trial and no acceptable in-network provider is
7 participating in the trial or if a participating pro-
8 vider cannot accept new enrollees, then the qualified
9 individual may enroll in the trial through an out-of-
10 network provider.

11 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
12 poses of subsection (a), the term ‘qualified individual’
13 means an individual who has cancer and is a participant
14 or beneficiary in a group health plan, or who is an enrollee
15 under health insurance coverage, and who meets the fol-
16 lowing conditions:

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

20 “(2) Either the referring physician is author-
21 ized by the plan to treat the patient and has con-
22 cluded that the individual’s participation in such
23 trial would be appropriate based upon the individual
24 meeting the condition described in paragraph (1), or
25 the participant, beneficiary, or enrollee provides

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

5 “(c) PAYMENT.—

6 “(1) IN GENERAL.—Under this section a group
7 health plan and a health insurance issuer shall pro-
8 vide for payment for routine patient costs described
9 in subsection (a)(2) but are not required to pay for
10 costs of items and services that are reasonably ex-
11 pected (as determined by the appropriate Secretary)
12 to be paid for by the sponsors of an approved clin-
13 ical trial.

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

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

18 “(B) a nonparticipating provider, the pay-
19 ment rate shall be at the rate the plan or issuer
20 would normally pay for comparable services
21 under subparagraph (A).

22 “(d) APPROVED CLINICAL TRIAL DEFINED.—In this
23 section, the term ‘approved clinical trial’ means a clinical
24 research study or clinical investigation—

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

3 “(A) the National Institutes of Health;

4 “(B) a cooperative group or center of the
5 National Institutes of Health, including a quali-
6 fied nongovernmental research entity to which
7 the National Cancer Institute has awarded a
8 center support grant;

9 “(C) the Department of Veterans Affairs,
10 if the conditions described in subsection (e) are
11 met; or

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

14 “(2) approved by the Food and Drug Adminis-
15 tration; or

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

20 “(A) is registered with the Department of
21 Health and Human Services; and

22 “(B) is associated with an institution that
23 has a Federal assurance approved by the De-
24 partment of Health and Human Services speci-

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

3 “(e) CONDITIONS FOR DEPARTMENTS.—The condi-
4 tions for a study or investigation conducted by a depart-
5 ment, are that the study or investigation has been re-
6 viewed and approved through a system of peer review that
7 the appropriate Secretary determines—

8 “(1) to be comparable to the system of peer re-
9 view of studies and investigations used by the Na-
10 tional Institutes of Health; and

11 “(2) assures unbiased review of the highest eth-
12 ical standards by an institutional review board or
13 other body that meets the standards outlined in sec-
14 tion 46 of title 45, and sections 50 and 56 of title
15 21, Code of Federal Regulations.

16 “(f) CONSTRUCTION.—Nothing in this section shall
17 be construed to limit a plan’s or issuer’s coverage with
18 respect to clinical trials.”.

19 (b) CONFORMING AMENDMENT.—The table of con-
20 tents in section 1 of the Employee Retirement Income Se-
21 curity Act of 1974 is amended by inserting after the item
22 relating to section 713 the following new item:

“Sec. 714. Coverage for individuals participating in clinical trials.”.

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

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

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

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

12 (3) the State Children’s Health Insurance Pro-
 13 gram under title XXI of the Social Security Act (42
 14 U.S.C. 1398 et seq.);

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

17 (5) programs offered by the Department of De-
 18 fense;

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

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

23 **Subtitle B—Cancer Screening and**
 24 **Other Coverage**

25 **SEC. 311. CANCER SCREENING COVERAGE.**

26 (a) GROUP HEALTH PLANS.—

1 (1) PUBLIC HEALTH SERVICE ACT AMEND-
2 MENTS.—

3 (A) IN GENERAL.—Subpart 2 of part A of
4 title XXVII of the Public Health Service Act
5 (42 U.S.C. 300gg–4 et seq.), as amended by
6 section 301(a), is further amended by adding at
7 the end the following:

8 **“SEC. 2708. COVERAGE OF CANCER SCREENING.**

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

16 “(1) MAMMOGRAMS.—In the case of a female
17 participant or beneficiary who is 40 years of age or
18 older, or is under 40 years of age but is at high risk
19 (as defined in subsection (e)) of developing breast
20 cancer, an annual mammography (as defined in sec-
21 tion 1861(jj) of the Social Security Act) conducted
22 by a facility that has a certificate (or provisional cer-
23 tificate) issued under section 354.

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

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

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

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

13 “(A) an annual diagnostic laboratory test
 14 (popularly known as a ‘pap smear’) consisting
 15 of a routine exfoliative cytology test (Papani-
 16 colaou test) provided to a woman for the pur-
 17 pose of early detection of cervical or vaginal
 18 cancer and including an interpretation by a
 19 qualified health professional of the results of
 20 the test; and

21 “(B) an annual pelvic examination.

22 “(4) COLORECTAL CANCER SCREENING PROCE-
 23 DURES.—

24 “(A) IN GENERAL.—In the case of a par-
 25 ticipant or beneficiary who is 50 years of age or

1 older, or who is under 50 years of age and is
2 an individual at high risk for colorectal cancer,
3 the group health plan or health insurance issuer
4 shall cover methods of colorectal cancer screen-
5 ing that—

6 “(i) are deemed appropriate by a phy-
7 sician (as defined in section 1861(r) of the
8 Social Security Act (42 U.S.C. 1395x(r)))
9 treating the participant or beneficiary, in
10 consultation with the participant or bene-
11 ficiary;

12 “(ii) are—

13 “(I) described in section
14 1861(pp)(1) of the Social Security Act
15 (42 U.S.C. 1395x(pp)(1)) or section
16 410.37 of title 42, Code of Federal
17 Regulations; or

18 “(II) specified by the Secretary
19 based upon the recommendations of
20 appropriate organizations with special
21 expertise in the field of colorectal can-
22 cer; and

23 “(iii) are performed at a frequency
24 not greater than that—

1 “(I) described for such method in
2 section 1834(d) of the Social Security
3 Act (42 U.S.C. 1395m(d)) or section
4 410.37 of title 42, Code of Federal
5 Regulations; or

6 “(II) specified by the Secretary
7 for such method if the Secretary
8 finds, based upon new scientific
9 knowledge and consistent with the
10 recommendations of appropriate orga-
11 nizations with special expertise in the
12 field of colorectal cancer, that a dif-
13 ferent frequency would not adversely
14 affect the effectiveness of such screen-
15 ing.

16 “(B) DEFINITION OF HIGH RISK.—In this
17 paragraph, the term ‘individual at high risk for
18 colorectal cancer’ has the meaning given the
19 term in section 1861(pp)(2) of the Social Secu-
20 rity Act (42 U.S.C. 1395x(pp)(2)).

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

1 a history of prostate cancer in a first degree family
2 member), the procedures described in section
3 1861(oo)(2) of Social Security Act (42 U.S.C.
4 1395x(oo)(2)) shall be furnished to the individual
5 for the early detection of prostate cancer. The group
6 health plan or health insurance issuer shall provide
7 coverage for the method and frequency of prostate
8 cancer screening determined to be appropriate by a
9 health care provider treating such participant or
10 beneficiary, in consultation with the participant or
11 beneficiary.

12 “(6) TOBACCO THERAPY AND COUNSELING.—

13 “(A) IN GENERAL.—Therapy and coun-
14 seling for cessation of tobacco use for individ-
15 uals who use tobacco products or who are being
16 treated for tobacco use that is furnished—

17 “(i) by or under the supervision of a
18 physician; or

19 “(ii) by any other health care profes-
20 sional—

21 “(I) who is legally authorized to
22 furnish such services under State law
23 (or the State regulatory mechanism
24 provided by State law) of the State in
25 which the services are furnished; and

1 “(II) who, for medicare bene-
2 ficiaries, is authorized to receive pay-
3 ment for other services under this title
4 or is designated by the Secretary for
5 this purpose.

6 “(B) LIMITATION.—Subject to subpara-
7 graph (C), such therapy and counseling are lim-
8 ited to—

9 “(i) therapy and counseling services
10 recommended in ‘Treating Tobacco Use
11 and Dependence: A Clinical Practice
12 Guideline’, published by the Public Health
13 Service in June 2000, or any subsequent
14 modification of such Guideline; and

15 “(ii) such other therapy and coun-
16 seling services that the Secretary recog-
17 nizes to be effective.

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

22 “(7) MEDICAL NUTRITION THERAPY SERV-
23 ICES.—Medical nutrition therapy services, as defined
24 in section 1861(vv) of the Social Security Act (42
25 U.S.C. 1395x(vv)) for the purpose of improving the

1 health of cancer patients and preventing cancer in
2 other beneficiaries.

3 “(8) GENETIC TESTS AND GENETIC SERV-
4 ICES.—

5 “(A) IN GENERAL.—Genetic tests and ge-
6 netic services provided by a licensed health care
7 professional to obtain predictive genetic infor-
8 mation about an individual at risk of cancer for
9 purposes of a health assessment, cancer man-
10 agement, cancer prevention, other diagnostic or
11 therapeutic purposes, or genetic education and
12 counseling.

13 “(B) DEFINITIONS.—In this paragraph:

14 “(i) FAMILY MEMBER.—The term
15 ‘family member’ means with respect to an
16 individual—

17 “(I) the spouse of the individual;

18 “(II) a dependent child of the in-
19 dividual, including a child who is born
20 to or placed for adoption with the in-
21 dividual; and

22 “(III) all other individuals re-
23 lated by blood to the individual or the
24 spouse or child described in subclause
25 (I) or (II).

1 “(ii) GENETIC INFORMATION.—The
2 term ‘genetic information’ means informa-
3 tion about genes, gene products, or inher-
4 ited characteristics that may derive from
5 an individual or a family member of such
6 individual (including information about a
7 request for or the receipt of genetic serv-
8 ices by such individual or family member
9 of such individual).

10 “(iii) GENETIC SERVICES.—The term
11 ‘genetic services’ means health services, in-
12 cluding genetic tests, provided to obtain,
13 assess, or interpret genetic information for
14 diagnostic and therapeutic purposes, and
15 for genetic education and counseling.

16 “(iv) GENETIC TEST.—The term ‘ge-
17 netic test’ means the analysis of human
18 DNA, RNA, chromosomes, proteins, and
19 certain metabolites in order to detect
20 genotypes, mutations, or chromosomal
21 changes.

22 “(v) PREDICTIVE GENETIC INFORMA-
23 TION.—

1 “(I) IN GENERAL.—The term
2 ‘predictive genetic information’
3 means—

4 “(aa) information about an
5 individual’s genetic tests;

6 “(bb) information about ge-
7 netic tests of family members of
8 the individual; or

9 “(cc) information about the
10 occurrence of a disease or dis-
11 order in family members.

12 “(II) LIMITATIONS.—The term
13 ‘predictive genetic information’ shall
14 not include—

15 “(aa) information about the
16 sex or age of the individual;

17 “(bb) information about
18 chemical, blood, or urine analyses
19 of the individual, unless these
20 analyses are genetic tests; or

21 “(cc) information about
22 physical exams of the individual,
23 and other information relevant to
24 determining the current health
25 status of the individual.

1 “(9) OTHER TESTS AND PROCEDURES.—Such
2 other tests or procedures for the detection of cancer,
3 and modifications to the tests and procedures, with
4 such frequency, as the Secretary determines to be
5 appropriate, in consultation with appropriate organi-
6 zations and agencies, for the diagnosis or detection
7 of cancer.

8 “(b) PROHIBITIONS.—A group health plan, and a
9 health insurance issuer offering group health insurance
10 coverage in connection with a group health plan, shall
11 not—

12 “(1) deny to an individual eligibility, or contin-
13 ued eligibility, to enroll or to renew coverage under
14 the terms of the plan, solely for the purpose of
15 avoiding the requirements of this section;

16 “(2) provide monetary payments or rebates to
17 individuals to encourage such individuals to accept
18 less than the minimum protections available under
19 this section;

20 “(3) penalize or otherwise reduce or limit the
21 reimbursement of a provider because such provider
22 provided care to an individual participant or bene-
23 ficiary in accordance with this section; or

24 “(4) provide incentives (monetary or otherwise)
25 to a provider to induce such provider to provide care

1 to an individual participant or beneficiary in a man-
2 ner inconsistent with this section.

3 “(c) RULES OF CONSTRUCTION.—

4 “(1) Nothing in this section shall be construed
5 to require an individual who is a participant or bene-
6 ficiary to undergo a procedure, examination, or test
7 described in subsection (a).

8 “(2) Nothing in this section shall be construed
9 as preventing a group health plan or issuer from im-
10 posing deductibles, coinsurance, or other cost-shar-
11 ing in relation to benefits described in subsection (a)
12 consistent with such subsection, except that such co-
13 insurance or other cost-sharing shall not discrimi-
14 nate on any basis related to the coverage required
15 under this section.

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

19 “(d) NOTICE.—A group health plan under this part
20 shall comply with the notice requirement under section
21 714(d) of the Employee Retirement Income Security Act
22 of 1974 with respect to the requirements of this section
23 as if such section applied to such plan.

24 “(e) RISK DEFINED.—For purposes of this section,
25 an individual is considered to be at ‘risk’ of developing

1 a particular type of cancer if, under guidelines developed
2 or recognized by the Secretary based upon scientific evi-
3 dence, the individual—

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

6 “(2) has previously had that type of cancer;

7 “(3) has the presence of an appropriate recog-
8 nized gene marker that is identified as putting the
9 individual at a higher risk of developing that type of
10 cancer; or

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

14 For purposes of this subsection, the term ‘type of cancer’
15 includes other types of cancer that the Secretary recog-
16 nizes as closely related for purposes of establishing risk.

17 **“SEC. 2709. PATIENT ACCESS TO INFORMATION.**

18 “(a) DISCLOSURE REQUIREMENT.—A group health
19 plan, and health insurance issuer offering group health in-
20 surance coverage shall—

21 “(1) provide to participants and beneficiaries at
22 the time of initial coverage under the plan (or the
23 effective date of this section, in the case of individ-
24 uals who are participants or beneficiaries as of such

1 date), and at least annually thereafter, the informa-
2 tion described in subsection (b) in printed form;

3 “(2) provide to participants and beneficiaries,
4 within a reasonable period (as specified by the ap-
5 propriate Secretary) before or after the date of sig-
6 nificant changes in the information described in sub-
7 section (b), information in printed form regarding
8 such significant changes; and

9 “(3) upon request, make available to partici-
10 pants and beneficiaries, the applicable authority, and
11 prospective participants and beneficiaries, the infor-
12 mation described in subsection (b) in printed form.

13 “(b) INFORMATION PROVIDED.—The information de-
14 scribed in subsection (a) that shall be disclosed includes
15 the following, as such relates to cancer screening required
16 under section 2708(a):

17 “(1) BENEFITS.—Benefits offered under the
18 plan or coverage, including—

19 “(A) covered benefits, including benefit
20 limits and coverage exclusions;

21 “(B) cost-sharing, such as deductibles, co-
22 insurance, and copayment amounts, including
23 any liability for balance billing, any maximum
24 limitations on out of pocket expenses, and the
25 maximum out of pocket costs for services that

1 are provided by nonparticipating providers or
2 that are furnished without meeting the applica-
3 ble utilization review requirements;

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

6 “(D) the extent to which a participant,
7 beneficiary, or enrollee may select from among
8 participating providers and the types of pro-
9 viders participating in the plan or issuer net-
10 work.

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

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

14 “(B) Out-of-network coverage (if any) pro-
15 vided by the plan or coverage.

16 “(C) Any point-of-service option (including
17 any supplemental premium or cost-sharing for
18 such option).

19 “(D) The procedures for participants,
20 beneficiaries, and enrollees to select, access, and
21 change participating primary and specialty pro-
22 viders.

23 “(E) The rights and procedures for obtain-
24 ing referrals (including standing referrals) to
25 participating and nonparticipating providers.

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

5 “(G) How the plan or issuer addresses the
6 needs of participants, beneficiaries, and enroll-
7 ees and others who do not speak English or
8 who have other special communications needs in
9 accessing providers under the plan or coverage,
10 including the provision of information under
11 this subsection.”.

12 (B) TECHNICAL AMENDMENT.—Section
13 2723(c) of the Public Health Service Act (42
14 U.S.C. 300gg–23(c)) is amended by striking
15 “section 2704” and inserting “sections 2704
16 and 2708”.

17 (2) ERISA AMENDMENTS.—

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

1 **“SEC. 715. COVERAGE OF CANCER SCREENING.**

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

9 “(1) MAMMOGRAMS.—In the case of a female
10 participant or beneficiary who is 40 years of age or
11 older, or is under 40 years of age but is at high risk
12 (as defined in subsection (e)) of developing breast
13 cancer, an annual mammography (as defined in sec-
14 tion 1861(jj) of the Social Security Act) conducted
15 by a facility that has a certificate (or provisional cer-
16 tificate) issued under section 354 of the Public
17 Health Service Act.

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

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

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

1 breast cancer, a clinical breast examination
2 each 3 years.

3 “(3) PAP TESTS AND PELVIC EXAMINATIONS.—

4 In the case of a female participant or beneficiary
5 who is 18 years of age or older, or who is under 18
6 years of age and is or has been sexually active—

7 “(A) an annual diagnostic laboratory test
8 (popularly known as a ‘pap smear’) consisting
9 of a routine exfoliative cytology test (Papani-
10 colaou test) provided to a woman for the pur-
11 pose of early detection of cervical or vaginal
12 cancer and including an interpretation by a
13 qualified health professional of the results of
14 the test; and

15 “(B) an annual pelvic examination.

16 “(4) COLORECTAL CANCER SCREENING PROCE-
17 DURES.—

18 “(A) IN GENERAL.—In the case of a par-
19 ticipant or beneficiary who is 50 years of age or
20 older, or who is under 50 years of age and is
21 an individual at high risk for colorectal cancer,
22 the group health plan or health insurance issuer
23 shall cover methods of colorectal cancer screen-
24 ing that—

1 “(i) are deemed appropriate by a phy-
2 sician (as defined in section 1861(r) of the
3 Social Security Act (42 U.S.C. 1395x(r)))
4 treating the participant or beneficiary, in
5 consultation with the participant or bene-
6 ficiary;

7 “(ii) are—

8 “(I) described in section
9 1861(pp)(1) of the Social Security Act
10 (42 U.S.C. 1395x(pp)(1)) or section
11 410.37 of title 42, Code of Federal
12 Regulations; or

13 “(II) specified by the Secretary
14 based upon the recommendations of
15 appropriate organizations with special
16 expertise in the field of colorectal can-
17 cer; and

18 “(iii) are performed at a frequency
19 not greater than that—

20 “(I) described for such method in
21 section 1834(d) of the Social Security
22 Act (42 U.S.C. 1395m(d)) or section
23 410.37 of title 42, Code of Federal
24 Regulations; or

1 “(II) specified by the Secretary
2 for such method if the Secretary
3 finds, based upon new scientific
4 knowledge and consistent with the
5 recommendations of appropriate orga-
6 nizations with special expertise in the
7 field of colorectal cancer, that a dif-
8 ferent frequency would not adversely
9 affect the effectiveness of such screen-
10 ing.

11 “(B) DEFINITION OF HIGH RISK.—In this
12 paragraph, the term ‘individual at high risk for
13 colorectal cancer’ has the meaning given the
14 term in section 1861(pp)(2) of the Social Secu-
15 rity Act (42 U.S.C. 1395x(pp)(2)).

16 “(5) PROSTATE CANCER SCREENING.—In the
17 case of a male participant or beneficiary who is 50
18 years of age or older, or who is younger than 50
19 years of age and is at high risk for prostate cancer
20 (including African American men or a male who has
21 a history of prostate cancer in a first degree family
22 member), the procedures described in section
23 1861(oo)(2) of the Social Security Act (42 U.S.C.
24 1395x(oo)(2)) shall be furnished to the individual
25 for the early detection of prostate cancer. The group

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

7 “(6) TOBACCO THERAPY AND COUNSELING.—

8 “(A) IN GENERAL.—Therapy and coun-
9 seling for cessation of tobacco use for individ-
10 uals who use tobacco products or who are being
11 treated for tobacco use that is furnished—

12 “(i) by or under the supervision of a
13 physician; or

14 “(ii) by any other health care profes-
15 sional who—

16 “(I) is legally authorized to fur-
17 nish such services under State law (or
18 the State regulatory mechanism pro-
19 vided by State law) of the State in
20 which the services are furnished; and

21 “(II) for medicare beneficiaries,
22 is authorized to receive payment for
23 other services under this title or is
24 designated by the Secretary for this
25 purpose.

1 “(B) LIMITATION.—Subject to subpara-
2 graph (C), such therapy and counseling are lim-
3 ited to—

4 “(i) therapy and counseling services
5 recommended in ‘Treating Tobacco Use
6 and Dependence: A Clinical Practice
7 Guideline’, published by the Public Health
8 Service in June 2000, or any subsequent
9 modification of such Guideline; and

10 “(ii) such other therapy and coun-
11 seling services that the Secretary recog-
12 nizes to be effective.

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

17 “(7) MEDICAL NUTRITION THERAPY SERV-
18 ICES.—Medical nutrition therapy services, as defined
19 in section 1861(vv) of the Social Security Act (42
20 U.S.C. 1395x(vv)) for the purpose of improving the
21 health of cancer patients and preventing cancer in
22 other beneficiaries.

23 “(8) GENETIC TESTS AND GENETIC SERV-
24 ICES.—

1 “(A) IN GENERAL.—Genetic tests and ge-
2 netic services provided by a licensed health care
3 professional to obtain predictive genetic infor-
4 mation about an individual at risk of cancer for
5 purposes of a health assessment, cancer man-
6 agement, cancer prevention, other diagnostic or
7 therapeutic purposes, or genetic education and
8 counseling.

9 “(B) DEFINITIONS.—In this paragraph:

10 “(i) FAMILY MEMBER.—The term
11 ‘family member’ means with respect to an
12 individual—

13 “(I) the spouse of the individual;

14 “(II) a dependent child of the in-
15 dividual, including a child who is born
16 to or placed for adoption with the in-
17 dividual; and

18 “(III) all other individuals re-
19 lated by blood to the individual or the
20 spouse or child described in subclause
21 (I) or (II).

22 “(ii) GENETIC INFORMATION.—The
23 term ‘genetic information’ means informa-
24 tion about genes, gene products, or inher-
25 ited characteristics that may derive from

1 an individual or a family member of such
2 individual (including information about a
3 request for or the receipt of genetic serv-
4 ices by such individual or family member
5 of such individual).

6 “(iii) GENETIC SERVICES.—The term
7 ‘genetic services’ means health services, in-
8 cluding genetic tests, provided to obtain,
9 assess, or interpret genetic information for
10 diagnostic and therapeutic purposes, and
11 for genetic education and counseling.

12 “(iv) GENETIC TEST.—The term ‘ge-
13 netic test’ means the analysis of human
14 DNA, RNA, chromosomes, proteins, and
15 certain metabolites in order to detect
16 genotypes, mutations, or chromosomal
17 changes.

18 “(v) PREDICTIVE GENETIC INFORMA-
19 TION.—

20 “(I) IN GENERAL.—The term
21 ‘predictive genetic information’
22 means—

23 “(aa) information about an
24 individual’s genetic tests;

1 “(bb) information about ge-
2 netic tests of family members of
3 the individual; or

4 “(cc) information about the
5 occurrence of a disease or dis-
6 order in family members.

7 “(II) LIMITATIONS.—The term
8 ‘predictive genetic information’ shall
9 not include—

10 “(aa) information about the
11 sex or age of the individual;

12 “(bb) information about
13 chemical, blood, or urine analyses
14 of the individual, unless these
15 analyses are genetic tests; or

16 “(cc) information about
17 physical exams of the individual,
18 and other information relevant to
19 determining the current health
20 status of the individual.

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

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

3 “(b) PROHIBITIONS.—A group health plan, and a
4 health insurance issuer offering group health insurance
5 coverage in connection with a group health plan, may
6 not—

7 “(1) deny to an individual eligibility, or contin-
8 ued eligibility, to enroll or to renew coverage under
9 the terms of the plan, solely for the purpose of
10 avoiding the requirements of this section;

11 “(2) provide monetary payments or rebates to
12 individuals to encourage such individuals to accept
13 less than the minimum protections available under
14 this section;

15 “(3) penalize or otherwise reduce or limit the
16 reimbursement of a provider because such provider
17 provided care to an individual participant or bene-
18 ficiary in accordance with this section; or

19 “(4) provide incentives (monetary or otherwise)
20 to a provider to induce such provider to provide care
21 to an individual participant or beneficiary in a man-
22 ner inconsistent with this section.

23 “(c) RULES OF CONSTRUCTION.—

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

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

3 “(2) Nothing in this section shall be construed
4 as preventing a group health plan or issuer from im-
5 posing deductibles, coinsurance, or other cost-shar-
6 ing in relation to benefits described in subsection (a)
7 consistent with such subsection, except that such co-
8 insurance or other cost-sharing shall not discrimi-
9 nate on any basis related to the coverage required
10 under this section.

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

14 “(d) NOTICE UNDER GROUP HEALTH PLAN.—The
15 imposition of the requirement of this section shall be treat-
16 ed as a material modification in the terms of the plan de-
17 scribed in section 102(a), for purposes of assuring notice
18 of such requirements under the plan; except that the sum-
19 mary description required to be provided under the last
20 sentence of section 104(b)(1) with respect to such modi-
21 fication shall be provided by not later than 60 days after
22 the first day of the first plan year in which such require-
23 ment apply.

24 “(e) RISK DEFINED.—For purposes of this section,
25 an individual is considered to be at ‘risk’ of developing

1 a particular type of cancer if, under guidelines developed
2 or recognized by the Secretary based upon scientific evi-
3 dence, the individual—

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

6 “(2) has previously had that type of cancer;

7 “(3) has the presence of an appropriate recog-
8 nized gene marker that is identified as putting the
9 individual at a higher risk of developing that type of
10 cancer; or

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

14 For purposes of this subsection, the term ‘type of cancer’
15 includes other types of cancer that the Secretary recog-
16 nizes as closely related for purposes of establishing risk.

17 **“SEC. 716. PATIENT ACCESS TO INFORMATION.**

18 “(a) DISCLOSURE REQUIREMENT.—A group health
19 plan, and health insurance issuer offering group health in-
20 surance coverage shall—

21 “(1) provide to participants and beneficiaries at
22 the time of initial coverage under the plan (or the
23 effective date of this section, in the case of individ-
24 uals who are participants or beneficiaries as of such

1 date), and at least annually thereafter, the informa-
2 tion described in subsection (b) in printed form;

3 “(2) provide to participants and beneficiaries,
4 within a reasonable period (as specified by the ap-
5 propriate Secretary) before or after the date of sig-
6 nificant changes in the information described in sub-
7 section (b), information in printed form regarding
8 such significant changes; and

9 “(3) upon request, make available to partici-
10 pants and beneficiaries, the applicable authority, and
11 prospective participants and beneficiaries, the infor-
12 mation described in subsection (b) in printed form.

13 “(b) INFORMATION PROVIDED.—The information de-
14 scribed in subsection (a) that shall be disclosed includes
15 the following, as such relates to cancer screening required
16 under section 715(a):

17 “(1) BENEFITS.—Benefits offered under the
18 plan or coverage, including—

19 “(A) covered benefits, including benefit
20 limits and coverage exclusions;

21 “(B) cost-sharing, such as deductibles, co-
22 insurance, and copayment amounts, including
23 any liability for balance billing, any maximum
24 limitations on out of pocket expenses, and the
25 maximum out of pocket costs for services that

1 are provided by nonparticipating providers or
2 that are furnished without meeting the applica-
3 ble utilization review requirements;

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

6 “(D) the extent to which a participant,
7 beneficiary, or enrollee may select from among
8 participating providers and the types of pro-
9 viders participating in the plan or issuer net-
10 work.

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

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

14 “(B) Out-of-network coverage (if any) pro-
15 vided by the plan or coverage.

16 “(C) Any point-of-service option (including
17 any supplemental premium or cost-sharing for
18 such option).

19 “(D) The procedures for participants,
20 beneficiaries, and enrollees to select, access, and
21 change participating primary and specialty pro-
22 viders.

23 “(E) The rights and procedures for obtain-
24 ing referrals (including standing referrals) to
25 participating and nonparticipating providers.

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

5 “(G) How the plan or issuer addresses the
6 needs of participants, beneficiaries, and enroll-
7 ees and others who do not speak English or
8 who have other special communications needs in
9 accessing providers under the plan or coverage,
10 including the provision of information under
11 this subsection.”.

12 (B) TECHNICAL AMENDMENTS.—

13 (i) Section 731(c) of the Employee
14 Retirement Income Security Act of 1974
15 (29 U.S.C. 1191(c)) is amended by strik-
16 ing “section 711” and inserting “sections
17 711 and 715”.

18 (ii) Section 732(a) of the Employee
19 Retirement Income Security Act of 1974
20 (29 U.S.C. 1191a(a)) is amended by strik-
21 ing “section 711” and inserting “sections
22 711 and 715”.

23 (iii) The table of contents in section 1
24 of the Employee Retirement Income Secu-
25 rity Act of 1974, as amended by section

1 302, is further amended by inserting after
 2 the item relating to section 714 the fol-
 3 lowing new items:

“Sec. 715. Coverage of cancer screening.

“Sec. 716. Patient access to information.”.

4 (b) INDIVIDUAL HEALTH INSURANCE.—

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

9 **“SEC. 2754. STANDARD RELATING PATIENT FREEDOM OF**
 10 **CHOICE.**

11 “(a) IN GENERAL.—The provisions of section 2708
 12 (other than subsection (d)) shall apply to health insurance
 13 coverage offered by a health insurance issuer in the indi-
 14 vidual market with respect to an enrollee under such cov-
 15 erage in the same manner as they apply to health insur-
 16 ance coverage offered by a health insurance issuer in con-
 17 nection with a group health plan in the small or large
 18 group market to a participant or beneficiary in such plan.

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

1 **“SEC. 2755. PATIENT ACCESS TO INFORMATION.**

2 “The provisions of section 2709 shall apply health in-
3 surance coverage offered by a health insurance issuer in
4 the individual market with respect to an enrollee under
5 such coverage in the same manner as they apply to health
6 insurance coverage offered by a health insurance issuer
7 in connection with a group health plan in the small or
8 large group market to a participant or beneficiary in such
9 plan.”.

10 (2) TECHNICAL AMENDMENT.—Section
11 2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2))
12 is amended by striking “section 2751” and inserting
13 “sections 2751 and 2754”.

14 (c) EFFECTIVE DATES.—

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

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

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

1 tween employee representatives and 1 or more em-
2 ployers ratified before the date of enactment of this
3 Act, the amendments made to subsection (a) shall
4 not apply to plan years beginning before the later
5 of—

6 (A) the date on which the last collective
7 bargaining agreements relating to the plan ter-
8 minates (determined without regard to any ex-
9 tension thereof agreed to after the date of en-
10 actment of this Act), or

11 (B) January 1, 2004.

12 For purposes of subparagraph (A), any plan amend-
13 ment made pursuant to a collective bargaining
14 agreement relating to the plan which amends the
15 plan solely to conform to any requirement added by
16 subsection (a) shall not be treated as a termination
17 of such collective bargaining agreement.

18 (d) COORDINATED REGULATIONS.—Section 104(1)
19 of the Health Insurance Portability and Accountability
20 Act of 1996 (Public Law 104–191) is amended by striking
21 “this subtitle (and the amendments made by this subtitle
22 and section 401)” and inserting “the provisions of part
23 7 of subtitle B of title I of the Employee Retirement In-
24 come Security Act of 1974, the provisions of parts A and

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

3 (e) MODIFICATION OF COVERAGE.—

4 (1) IN GENERAL.—The Secretary of Health and
5 Human Services may modify the coverage require-
6 ments for the amendments under this subtitle to
7 allow such requirements to incorporate and reflect
8 new scientific and technological advances regarding
9 cancer screening, practice pattern changes in such
10 screening, or other updated medical practices re-
11 garding such screening, such as the use of new tests
12 or other emerging technologies. Such modifications
13 shall not in any way diminish the coverage require-
14 ments listed under this subtitle. Such modifications
15 may be made on the Secretary’s own initiative or
16 upon petition to the Secretary by an individual or
17 organization.

18 (2) CONSULTATION.—In modifying coverage re-
19 quirements under paragraph (1), the Secretary of
20 Health and Human Services shall consult with ap-
21 propriate organizations, experts, and agencies.

22 (3) PETITIONS.—The Secretary of Health and
23 Human Services may issue requirements for the pe-
24 titioning process under paragraph (1), including re-
25 quirements that the petition be in writing and in-

1 clude scientific or medical bases for the modification
 2 sought. Upon receipt of such a petition, the Sec-
 3 retary shall respond to the petitioner and decide
 4 whether to propose a regulation proposing a change
 5 within 90 days of such receipt. If a regulation is re-
 6 quired, the Secretary shall propose such regulation
 7 within 6 months of such determination. The Sec-
 8 retary shall provide the petitioner the reasons for
 9 the decision of the Secretary. The Secretary may
 10 make changes requested by a petitioner in whole or
 11 in part.

12 **Subtitle C—Physicians and Quality**
 13 **of Care**

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

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

21 **“SEC. 2710. MANAGING PHYSICIANS AND QUALITY OF CARE**
 22 **FOR CANCER PATIENTS.**

23 “(a) MANAGING PHYSICIAN.—A group health plan,
 24 or health insurance issuer that is providing health insur-
 25 ance coverage, shall ensure that with respect to items or

1 services provided under the plan or coverage relating to
2 the treatment of cancer, a lead managing physician be des-
3 igned at the time of diagnosis by the provider and paid
4 a bonus by the plan, in consultation with the participant
5 or beneficiary, and other providers involved to provide for
6 the overall coordination and management of the cancer
7 care of the participant or beneficiary among all providers
8 who provide items or services to the participant or bene-
9 ficiary and paid for overall coordination of services.

10 “(b) QUALITY OF CARE.—A group health plan, or
11 health insurance issuer that is providing health insurance
12 coverage, shall require that all participating health care
13 professionals who provide primary care cancer services fol-
14 low the most current quality-of-care cancer care guide-
15 lines, as developed by medical professionals with expertise
16 in the field of medicine for which the guidelines are de-
17 signed and widely recognized as medically necessary and
18 appropriate.

19 “(c) PROHIBITIONS.—A group health plan, and a
20 health insurance issuer offering group health insurance
21 coverage in connection with a group health plan, shall
22 not—

23 “(1) deny to an individual eligibility, or contin-
24 ued eligibility, to enroll or to renew coverage under

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

3 “(2) provide monetary payments or rebates to
4 individuals to encourage such individuals to accept
5 less than the minimum protections available under
6 this section;

7 “(3) penalize or otherwise reduce or limit the
8 reimbursement of a provider because such provider
9 provided care to an individual participant or bene-
10 ficiary in accordance with this section; or

11 “(4) provide incentives (monetary or otherwise)
12 to a provider to induce such provider to provide care
13 to an individual participant or beneficiary in a man-
14 ner inconsistent with this section.

15 “(d) RULES OF CONSTRUCTION.—Nothing in this
16 section shall be construed as preventing a group health
17 plan or issuer from imposing deductibles, coinsurance, or
18 other cost-sharing in relation to benefits described in sub-
19 sections (a) or (b) consistent with such subsections, except
20 that such coinsurance or other cost-sharing shall not dis-
21 criminate on any basis related to the coverage required
22 under this section.

23 “(e) NOTICE.—A group health plan under this part
24 shall comply with the notice requirement under section
25 714(d) of the Employee Retirement Income Security Act

1 of 1974 with respect to the requirements of this section
 2 as if such section applied to such plan.”.

3 (b) INDIVIDUAL.—Part B of title XXVII of the Pub-
 4 lic Health Service Act is amended by inserting after sec-
 5 tion 2755, as added by section 311, the following:

6 **“SEC. 2756. MANAGING PHYSICIANS AND QUALITY OF CARE**
 7 **FOR CANCER PATIENTS.**

8 “The provisions of section 2710 shall apply to health
 9 insurance coverage offered by a health insurance issuer
 10 in the individual market in the same manner as such pro-
 11 visions apply to health insurance coverage offered by a
 12 health insurance issuer in connection with a group health
 13 plan.”.

14 **SEC. 322. MANAGING PHYSICIANS AND QUALITY OF CARE**
 15 **FOR CANCER PATIENTS UNDER THE EM-**
 16 **PLOYEE RETIREMENT INCOME SECURITY**
 17 **ACT OF 1974.**

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

1 **“SEC. 717. MANAGING PHYSICIANS AND QUALITY OF CARE**
2 **FOR CANCER PATIENTS.**

3 “(a) **MANAGING PHYSICIAN.**—A group health plan,
4 or health insurance issuer that is providing health insur-
5 ance coverage, shall ensure that with respect to items or
6 services provided under the plan or coverage relating to
7 the treatment of cancer, a lead managing physician be des-
8 ignated at the time of diagnosis by the participant or bene-
9 ficiary involved to provide for the overall coordination and
10 management of the cancer care of the participant or bene-
11 ficiary among all providers who provide items or services
12 to the participant or beneficiary and paid for overall co-
13 ordination of services.

14 “(b) **QUALITY OF CARE.**—A group health plan, or
15 health insurance issuer that is providing health insurance
16 coverage, shall require that all participating health care
17 professionals who provide primary care cancer services fol-
18 low the most current quality-of-care cancer care guide-
19 lines, as developed by medical professionals with expertise
20 in the field of medicine for which the guidelines are de-
21 signed and widely recognized as medically necessary and
22 appropriate.

23 “(c) **PROHIBITIONS.**—A group health plan, and a
24 health insurance issuer offering group health insurance
25 coverage in connection with a group health plan, shall
26 not—

1 “(1) deny to an individual eligibility, or contin-
2 ued eligibility, to enroll or to renew coverage under
3 the terms of the plan, solely for the purpose of
4 avoiding the requirements of this section;

5 “(2) provide monetary payments or rebates to
6 individuals to encourage such individuals to accept
7 less than the minimum protections available under
8 this section;

9 “(3) penalize or otherwise reduce or limit the
10 reimbursement of a provider because such provider
11 provided care to an individual participant or bene-
12 ficiary in accordance with this section; or

13 “(4) provide incentives (monetary or otherwise)
14 to a provider to induce such provider to provide care
15 to an individual participant or beneficiary in a man-
16 ner inconsistent with this section.

17 “(d) RULES OF CONSTRUCTION.—Nothing in this
18 section shall be construed as preventing a group health
19 plan or issuer from imposing deductibles, coinsurance, or
20 other cost-sharing in relation to benefits described in sub-
21 sections (a) or (b) consistent with such subsections, except
22 that such coinsurance or other cost-sharing shall not dis-
23 criminate on any basis related to the coverage required
24 under this section.

1 “(e) NOTICE.—A group health plan under this part
2 shall comply with the notice requirement under section
3 714(d) of the Employee Retirement Income Security Act
4 of 1974 with respect to the requirements of this section
5 as if such section applied to such plan.”.

6 (b) CONFORMING AMENDMENT.—The table of con-
7 tents in section 1 of the Employee Retirement Income Se-
8 curity Act of 1974, as amended by sections 302 and 311,
9 is further amended by inserting after the item relating to
10 section 716 the following new item:

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

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

13 (a) APPLICATION OF CANCER COVERAGE REQUIRE-
14 MENTS.—Part B of title XVIII of the Social Security Act
15 (42 U.S.C. 1395j et seq.) is amended by adding at the
16 end the following:

17 “APPLICATION OF CANCER COVERAGE REQUIREMENTS

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

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

25 (1) by inserting “(1)” after “(m)”; and

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

3 “(2) In the case of physicians’ services furnished to
4 an individual who has been diagnosed with cancer, who
5 is covered under the insurance program established under
6 this part who receives care for such cancer from a team
7 of physicians, and who incurs expenses for physicians’
8 services that are related to that diagnosis, there shall be
9 paid to the physician designated by such team of physi-
10 cians at the time of diagnosis of the individual as the phy-
11 sician responsible for the overall coordination and manage-
12 ment of the medical and other health services provided to
13 that individual during the period in which that individual
14 is undergoing treatment for such cancer (or to an em-
15 ployer or facility in the cases described in subparagraph
16 (A) of section 1842(b)(6)) (on a monthly or quarterly
17 basis) from the Federal Supplementary Medical Insurance
18 Trust Fund a separate and additional payment amount
19 for the services under this part in addition to any amount
20 otherwise paid under this part.”.

21 **SEC. 324. MANAGING PHYSICIANS AND QUALITY OF CARE**
22 **FOR CANCER PATIENTS UNDER MEDICAID**
23 **AND SCHIP.**

24 (a) MEDICAID.—Section 1902(a) of the Social Secu-
25 rity Act (42 U.S.C. 1396a(a)) is amended—

1 (1) in paragraph (64), by striking “and” at the
2 end;

3 (2) in paragraph (65), by striking the period
4 and inserting “; and”; and

5 (3) by inserting after paragraph (65) the fol-
6 lowing:

7 “(66) provide—

8 “(A) that the provisions of sections 2707,
9 2708, and 2710 of the Public Health Service
10 Act shall apply to individuals eligible for med-
11 ical assistance under the State plan who have
12 been diagnosed with cancer; and

13 “(B) that, in the case of an individual who
14 has been diagnosed with cancer, who is eligible
15 for medical assistance under this title, and who
16 receives care for such cancer from a team of
17 physicians, and who incurs expenses for physi-
18 cians’ services that are related to that diag-
19 nosis, that there shall be paid to the physician
20 designated by such team of physicians at the
21 time of diagnosis of the individual as the physi-
22 cian responsible for the overall coordination and
23 management of the medical and other health
24 services provided to that individual during the
25 period in which that individual is undergoing

1 treatment for such cancer, a separate and addi-
2 tional payment amount for the services provided
3 in addition to any amount otherwise paid under
4 the State plan.”.

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

8 “(3) APPLICATION OF CANCER COVERAGE PRO-
9 VISIONS.—

10 “(A) IN GENERAL.—The provisions of sec-
11 tions 2707, 2708, and 2710 of the Public
12 Health Service Act shall apply to the coverage
13 offered under the State child health plan.

14 “(B) ADDITIONAL PAYMENT.—The State
15 child health plan shall provide in the case of an
16 individual who has been diagnosed with cancer,
17 who is eligible for child health assistance under
18 this title, and who receives care for such cancer
19 from a team of physicians, and who incurs ex-
20 penses for physicians’ services that are related
21 to that diagnosis, that there shall be paid to the
22 physician designated by such team of physicians
23 at the time of diagnosis of the individual as the
24 physician responsible for the overall coordina-
25 tion and management of the medical and other

1 health services provided to that individual dur-
 2 ing the period in which that individual is under-
 3 going treatment for such cancer, a separate and
 4 additional payment amount for the services pro-
 5 vided in addition to any amount otherwise paid
 6 under the State child health plan.”.

7 **Subtitle D—General Provisions**

8 **SEC. 331. COVERAGE UNDER OTHER PUBLIC HEALTH IN-** 9 **SURANCE.**

10 (a) IN GENERAL.—The coverage described in sub-
 11 section (b) shall be provided for any individual, partici-
 12 pant, or beneficiary who has coverage under—

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

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

17 (3) the State Children’s Health Insurance Pro-
 18 gram under title XXI of the Social Security Act (42
 19 U.S.C. 1398 et seq.);

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

22 (5) programs offered by the Department of De-
 23 fense;

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

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

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

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

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

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

16 **“§ 8915. Standards relating to coverage of cancer-re-**
17 **lated activities**

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

21 “(b) Nothing in this section or section 2707, 2708,
22 2709, or 2710 of the Public Health Service Act shall be
23 construed as authorizing a health insurance issuer or enti-
24 ty to impose cost-sharing with respect to the coverage or
25 benefits required to be provided under such sections that

1 is inconsistent with the cost-sharing that is otherwise per-
 2 mitted under this chapter.”.

3 **TITLE IV—PATIENT NAVIGATOR**
 4 **AND CANCER CARE WITHIN**
 5 **THE HEALTH RESOURCES**
 6 **AND SERVICES ADMINISTRA-**
 7 **TION**

8 **SEC. 401. HRSA GRANTS FOR MODEL COMMUNITY CANCER**
 9 **AND CHRONIC DISEASE CARE AND PREVEN-**
 10 **TION AND GRANTS FOR PATIENT NAVIGA-**
 11 **TORS.**

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

15 **“SEC. 330M. MODEL COMMUNITY CANCER AND CHRONIC**
 16 **DISEASE CARE AND PREVENTION; PATIENT**
 17 **NAVIGATORS.**

18 “(a) DEFINITIONS.—In this section, the terms “cul-
 19 turally competent”, “appropriate follow-up care”, “health
 20 disparity population”, and “patient navigator” have the
 21 meanings given those terms in section 417E–10.

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

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

1 and Services Administration, may make grants to
2 public and nonprofit private health centers (includ-
3 ing health centers under section 330, Indian Health
4 Service Centers, tribal governments, urban Indian
5 organizations, tribal organizations, clinics serving
6 Asian Americans and Pacific Islanders and Alaskan
7 Natives, rural health clinics, and qualified nonprofit
8 entities that partner with 1 or more centers pro-
9 viding health care services to provide navigation
10 services that demonstrate the ability to perform all
11 of the functions outlined in this subsection and sub-
12 sections (c) and (d)) for the development and oper-
13 ation of model programs that perform the same
14 functions outlined in section 417E–10(b)(1).

15 “(2) APPLICATION FOR GRANT.—An entity that
16 desires to receive a grant under paragraph (1) shall
17 submit an application to the Secretary at such time,
18 in such manner, and containing such agreements,
19 assurances, and information as the Secretary deter-
20 mines to be necessary to carry out this section.

21 “(3) OUTREACH SERVICES.—In order to be eli-
22 gible to receive a grant under paragraph (1), an en-
23 tity shall agree to provide ongoing outreach activities
24 while receiving the grant, in a manner that is cul-
25 turally competent for the health disparity population

1 served by the program, to inform the public and the
2 specific community that the program is serving of
3 the services of the model program under the grant.
4 Such activities shall include facilitating access to ap-
5 propriate health care services and patient navigators
6 within the health care system to ensure optimal pa-
7 tient utilization of such services.

8 “(4) DATA COLLECTION AND REPORT.—In
9 order to allow for effective program evaluation, an
10 entity that receives a grant under this subsection
11 shall collect specific patient data recording services
12 provided to each patient served by the program and
13 shall establish and implement procedures and proto-
14 cols, consistent with applicable Federal and State
15 laws (including sections 160 and 164 of title 45,
16 Code of Federal Regulations) to ensure the confiden-
17 tiality of all information shared by a participant in
18 the program, or their personal representative and
19 their health care providers, group health plans, or
20 health insurance insurers with the program. The
21 program may, consistent with applicable Federal and
22 State confidentiality laws, collect, use, or disclose ag-
23 gregate information that is not individually identifi-
24 able (as defined in sections 160 and 164 of title 45,
25 Code of Federal Regulations). With this data, the

1 grantee shall submit an annual report to the Sec-
2 retary that summarizes and analyzes the data and
3 provides information on needs for navigation serv-
4 ices, types of access difficulties resolved, sources of
5 repeated resolution, and flaws in the system of ac-
6 cess, including insurance barriers.

7 “(5) EVALUATIONS.—

8 “(A) IN GENERAL.—The Secretary, acting
9 through the Administrator of the Health Re-
10 sources and Services Administration, shall, di-
11 rectly or through grants or contracts, provide
12 for evaluations to determine which outreach ac-
13 tivities under paragraph (3) were most effective
14 in informing the public and the specific commu-
15 nity that the program is serving of the model
16 program services and to determine the extent to
17 which such programs were effective in providing
18 culturally competent services to the health dis-
19 parity population served by the programs.

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

1 “(6) COORDINATION WITH OTHER PRO-
2 GRAMS.—The Secretary shall coordinate the pro-
3 gram under this subsection with—

4 “(A) the program under subsection (c);

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

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

11 “(c) PROGRAM FOR PATIENT NAVIGATORS.—

12 “(1) IN GENERAL.—The Secretary, acting
13 through the Administrator of the Health Resources
14 and Services Administration, may make grants to
15 public and nonprofit private health centers (includ-
16 ing health centers under section 330, Indian Health
17 Service Centers, tribal governments, urban Indian
18 organizations, tribal organizations, clinics serving
19 Asian Americans and Pacific Islanders and Alaskan
20 Natives, rural health clinics, and qualified nonprofit
21 entities that partner with 1 or more centers pro-
22 viding health care to provide navigation services,
23 that demonstrate the ability to perform all of the
24 functions outlined in this subsection and subsections
25 (b) and (d)) for the development and operation of

1 programs to pay the costs of such health centers in
2 carrying out the same activities outlined in section
3 417E–10(c)(1).

4 “(2) APPLICATION FOR GRANT.—An entity that
5 desires to receive a grant under paragraph (1) shall
6 submit an application to the Secretary at such time,
7 in such manner, and containing such agreements,
8 assurances, and information as the Secretary deter-
9 mines to be necessary to carry out this section.

10 “(3) OUTREACH SERVICES.—In order to be eli-
11 gible to receive a grant under paragraph (1), an en-
12 tity shall agree to provide ongoing outreach activities
13 while receiving the grant, in a manner that is cul-
14 turally competent for the health disparity population
15 served by the program, to inform the public and the
16 specific community that the patient navigator is
17 serving of the services of the model program under
18 the grant.

19 “(4) DATA COLLECTION AND REPORT.—In
20 order to allow for effective patient navigator pro-
21 gram evaluation, an entity that receives a grant
22 under this subsection shall collect specific patient
23 data recording navigation services provided to each
24 patient served by the program and shall establish
25 and implement procedures and protocols, consistent

1 with applicable Federal and State laws (including
2 sections 160 and 164 of title 45, Code of Federal
3 Regulations) to ensure the confidentiality of all in-
4 formation shared by a participant in the program, or
5 their personal representative and their health care
6 providers, group health plans, or health insurance
7 insurers with the program. The patient navigator
8 program may, consistent with applicable Federal and
9 State confidentiality laws, collect, use, or disclose ag-
10 gregate information that is not individually identifi-
11 able (as defined in sections 160 and 164 of title 45,
12 Code of Federal Regulations). With this data, the
13 grantee shall submit an annual report to the Sec-
14 retary that summarizes and analyzes the data and
15 provides information on needs for navigation serv-
16 ices, types of access difficulties resolved, sources of
17 repeated resolution, and flaws in the system of ac-
18 cess, including insurance barriers.

19 “(5) EVALUATIONS.—

20 “(A) IN GENERAL.—The Secretary, acting
21 through the Administrator of the Health Re-
22 sources and Services Administration, shall, di-
23 rectly or through grants or contracts, provide
24 for evaluations to determine the effects of the
25 services of patient navigators on the individuals

1 of health disparity populations for whom the
2 services were provided, taking into account the
3 matters referred to in section 417E–
4 10(c)(1)(C).

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

9 “(6) COORDINATION WITH OTHER PRO-
10 GRAMS.—The Secretary shall coordinate the pro-
11 gram under this subsection with the programs under
12 subsection (b) and section 417E–10.

13 “(d) REQUIREMENTS REGARDING FEES.—

14 “(1) IN GENERAL.—In order to be eligible to
15 receive a grant under subsection (b) or (c), the pro-
16 gram for which the grant is made shall have in ef-
17 fect—

18 “(A) a schedule of fees or payments for
19 the provision of such program’s health care
20 services related to the prevention and treatment
21 of disease that is consistent with locally pre-
22 vailing rates or charges and is designed to cover
23 such program’s reasonable costs of operation;
24 and

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

5 “(2) RULE OF CONSTRUCTION.—Nothing in
6 this subsection shall be construed to require pay-
7 ment for navigation services or to require payment
8 for health care services in cases where care is pro-
9 vided free of charge, including the case of services
10 provided through programs of the Indian Health
11 Service.

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

18 “(f) DURATION OF GRANT.—The period during
19 which payments are made to an entity from a grant under
20 subsection (b)(1) or (c)(1) may not exceed 5 years. The
21 provision of such payments are subject to annual approval
22 by the Secretary and subject to the availability of appro-
23 priations for the fiscal year involved. Nothing in this sub-
24 section shall be construed as establishing a limitation on

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

3 “(g) AUTHORIZATION OF APPROPRIATIONS.—

4 “(1) IN GENERAL.—

5 “(A) MODEL PROGRAMS.—For the purpose
6 of carrying out subsection (b), there are author-
7 ized to be appropriated such sums as may be
8 necessary for each of the fiscal years 2004
9 through 2008.

10 “(B) PATIENT NAVIGATORS.—For the pur-
11 pose of carrying out subsection (c), there are
12 authorized to be appropriated such sums as
13 may be necessary for each of the fiscal years
14 2004 through 2008.

15 “(C) BUREAU OF PRIMARY HEALTH
16 CARE.—Amounts appropriated under subpara-
17 graph (A) or (B) shall be administered through
18 the Bureau of Primary Health Care.

19 “(2) PROGRAMS IN RURAL AREAS.—

20 “(A) MODEL PROGRAMS.—For the purpose
21 of carrying out subsection (b) in making grants
22 under such subsection for model programs in
23 rural areas, there are authorized to be appro-
24 priated such sums as may be necessary for each
25 of the fiscal years 2004 through 2008.

1 “(B) PATIENT NAVIGATORS.—For the pur-
2 pose of carrying out subsection (c) in making
3 grants under such subsection for programs in
4 rural areas, there are authorized to be appro-
5 priated such sums as may be necessary for each
6 of the fiscal years 2004 through 2008.

7 “(C) OFFICE OF RURAL HEALTH POL-
8 ICY.—Amounts appropriated under subpara-
9 graph (A) or (B) shall be administered through
10 the Office of Rural Health Policy.

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

○