

108TH CONGRESS  
1ST SESSION

# H. R. 2741

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

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## IN THE HOUSE OF REPRESENTATIVES

JULY 15, 2003

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

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## A BILL

To 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,*

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

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

4 (b) **TABLE OF CONTENTS.**—The table of contents for  
5 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 House of Representatives concerning investments in cancer research funding.

Sec. 102. Sense of the House of Representatives 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

1 minority, socioeconomic, and ethnic groups dis-  
2 proportionately.

3 (5) Cancer screening can reduce cancer mor-  
4 tality, in some cases by 30 percent or more. While  
5 effective screening tools have yet to be developed for  
6 the majority of cancers, proven screening tools for  
7 early detection do exist for some of the more com-  
8 mon cancers. Screening for some cancers, such as  
9 breast, colorectal, and cervical cancers, has improved  
10 dramatically; however, screening rates are still lower  
11 than optimal. Cancer screening rates vary by cancer  
12 site, population group, and health insurance cov-  
13 erage.

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

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

1           (8) New translational cancer research centers  
2           are needed to provide the preclinical and early clin-  
3           ical trials support required to advance scientific dis-  
4           coveries into new drugs and technologies to prevent,  
5           detect, treat, and diagnose cancer.

6           (9) The quality of cancer care is uneven across  
7           the Nation and can be based on pure coincidence of  
8           where one lives. Many cancer patients do not receive  
9           optimal care.

10          (10) Cancer is a disease of aging and as the  
11          American population ages, cancer incidence will  
12          grow. It is estimated that the number of cancer di-  
13          agnoses in 2010 will increase by 20 percent. The  
14          number of cancer deaths is anticipated to increase  
15          by 20 percent, at an annual cost of over  
16          \$200,000,000,000. With such increases in the inci-  
17          dence of cancer, there will be a serious shortage of  
18          individuals in the workforce to provide cancer care,  
19          particularly in long-term care settings.

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

23          (12) Since 1971, there has been a shift in can-  
24          cer care, such as the administration of chemo-

1 therapy, moving from inpatient to outpatient set-  
2 tings.

3 (13) Since 1971, the conduct of research has  
4 involved more collaboration between the public and  
5 private sectors and more multidisciplinary ap-  
6 proaches. The biotechnology pharmaceutical and de-  
7 vice industry has grown and provided a broad array  
8 of new treatment options and scientific opportunities  
9 for cancer patients, providers, and researchers.

10 (14) Since 1971, technology and communica-  
11 tions have expanded and increased in complexity,  
12 transforming research methodologies and making the  
13 accessing and transmitting of information more  
14 widespread and more readily available.

15 (15) Tobacco use is the leading preventable  
16 cause of disease and premature death in the United  
17 States, resulting in  $\frac{1}{3}$  of all cancer deaths, including  
18 87 percent of lung cancer deaths. Research consist-  
19 ently shows that smoking cessation services can be  
20 1 of the most cost-effective health interventions and  
21 can reduce smoking-related health care costs. Ces-  
22 sation services offered as a combination of tobacco  
23 medication therapy and counseling effectively help  
24 smokers quit successfully and prevent premature  
25 death from tobacco-related cancers.

1 **TITLE I—EXPANSION OF CAN-**  
2 **CER-RELATED RESEARCH,**  
3 **PREVENTION, DETECTION,**  
4 **AND TREATMENT PROGRAMS**

5 **SEC. 101. SENSE OF THE HOUSE OF REPRESENTATIVES**  
6 **CONCERNING INVESTMENTS IN CANCER RE-**  
7 **SEARCH FUNDING.**

8 It is the sense of the House of Representatives that—

9 (1) past investments in cancer research have re-  
10 sulted in better health, an improved quality of life,  
11 and a reduction in national health care expenditures;  
12 and

13 (2) to build on, and sustain, the progress made  
14 over the past 5 years during which Congress doubled  
15 the budget at the National Institutes of Health, the  
16 National Cancer Institute requires continued in-  
17 creases in Federal funding, as outlined in the Na-  
18 tional Cancer Institute Directors Bypass Budget, to  
19 achieve a balanced research portfolio and to develop  
20 more targeted, more effective therapies or drugs and  
21 other cancer treatments and to address those rare,  
22 deadly cancers lacking effective early detection tests  
23 or treatments for a wide range of cancers, commensurable with the National Cancer Institute bypass  
24 budget.  
25

1 **SEC. 102. SENSE OF THE HOUSE OF REPRESENTATIVES**  
2 **CONCERNING INVESTMENTS IN CANCER RE-**  
3 **SEARCH TO DEVELOP TARGETED DRUGS.**

4 (a) FINDINGS.—The House of Representatives finds  
5 that—

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

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

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

15 (b) SENSE OF THE HOUSE OF REPRESENTATIVES.—  
16 It is the sense of the House of Representatives that to  
17 build on the research currently conducted by the National  
18 Institutes of Health, increased funding is necessary to fur-  
19 ther develop this new generation of low toxicity, high effi-  
20 cacy agents which target only the cancer cells leaving in  
21 place the healthy cells.

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

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



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

3           **“CHAPTER I—PURPOSE OF INSTITUTE AND**  
4           **NATIONAL CANCER PROGRAMS”;**

5           and

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

7           **“CHAPTER II—PROGRAMS TO PREVENT AND**  
8           **TREAT CANCER**

9           **“SEC. 417E. STUDY AND STRATEGIC PLANS.**

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

16           “(1) behavioral research associated with caus-  
17 ing and preventing cancer;

18           “(2) research regarding prevention of cancer  
19 other than behavioral interventions;

20           “(3) research to reduce disparities among racial  
21 and ethnic minorities and other disparity popu-  
22 lations;

23           “(4) research regarding palliative care, pain  
24 management;

1           “(5) research regarding preserving and restor-  
2           ing quality-of-life for cancer patients;

3           “(6) research regarding environmental risk fac-  
4           tors for cancer and gene-environment interactions;

5           “(7) research regarding management of symp-  
6           toms;

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

10           “(9) cancer survivorship.

11           “(b) PRIORITIES.—The Institute shall determine pri-  
12           orities based on scientific opportunities, in consultation  
13           with medical, scientific, patient, and provider representa-  
14           tives, and prepare 1 or more strategic plans by July 1,  
15           2005.

16           **“SEC. 417E-1. GRANTS FOR TRANSLATIONAL CANCER RE-**  
17           **SEARCH.**

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

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

23           “(1) award grants to public or nonprofit private  
24           entities to plan and operate a national network of at  
25           least 20 existing or new translational cancer re-

1 search centers to conduct translational, multidisci-  
2 plinary cancer research;

3 “(2) establish networks and partnerships link-  
4 ing the translational cancer research centers de-  
5 scribed in paragraph (1) to community cancer pro-  
6 viders (hospitals, clinics, providers’ practices, par-  
7 ticularly in underserved areas) and expand opportu-  
8 nities for all cancer patients to participate in clinical  
9 trials of new agents developed by these centers;

10 “(3) facilitate the process to award grants, con-  
11 tracts, and cooperative agreements to private entities  
12 to conduct translational cancer research in the fol-  
13 lowing areas—

14 “(A) cancer drugs, biologics, and devices;  
15 and

16 “(B) cancer detection diagnostic tests,  
17 techniques, and technology; and

18 “(4) develop and implement a strategic plan by  
19 July 1, 2005, in collaboration with translational cen-  
20 ters as authorized in paragraph (7) for intensifying,  
21 expanding, and disseminating results of translational  
22 research to providers of cancer care.

23 “(c) GRANTS.—

24 “(1) IN GENERAL.—The Director of the Insti-  
25 tute shall award grants to public or nonprofit pri-

1 vate entities to establish translational cancer re-  
2 search centers to conduct translational, multidisci-  
3 plinary cancer research. Funds shall not be used for  
4 construction of new facilities.

5 “(2) EQUITY.—The Director of the Institute  
6 shall award grants under subsection (b)(1) to pro-  
7 vide, to the greatest extent practicable, a broad dis-  
8 tribution of such grants among geographic regions  
9 of the United States.

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

14 “(4) APPLICATION.—A public or nonprofit enti-  
15 ty desiring a grant under this subsection shall sub-  
16 mit an application to the Director of the Institute at  
17 such time, in such manner, and containing such in-  
18 formation as the Director of the Institute may rea-  
19 sonably require.

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

22 “(1) perform research for discovery and pre-  
23 clinical evaluation of drugs, biologics, devices, tech-  
24 nologies, and strategies with potential to improve the  
25 prevention, detection, diagnosis, and treatment of

1 cancer and to improve pain and symptom manage-  
2 ment and quality of life of cancer patients;

3 “(2) perform clinical research studies on prom-  
4 ising cancer treatments or strategies, in appropriate  
5 human populations;

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

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

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

16 “(6) create systems and external relationships,  
17 which do not duplicate capabilities available in the  
18 private sector, to accelerate the findings from  
19 translational research to a stage that private compa-  
20 nies can assume development and commercialization;  
21 and

22 “(7) develop and implement a plan expanding  
23 and disseminating the efficacious products of  
24 translational research to providers of cancer care, in-

1 including products approved by the Food and Drug  
2 Administration.

3 “(e) DEFINITIONS.—In this section:

4 “(1) CLINICAL TRIAL.—The term ‘clinical trial’  
5 means a scientifically-designed clinical investigation  
6 in which a patient participates in examining the ef-  
7 fects of a drug, biologic medical treatment, or med-  
8 ical device for the prevention, early detection, or  
9 treatment of cancer or the potential side effects of  
10 treatment or of the disease.

11 “(2) TRANSLATIONAL CANCER RESEARCH.—  
12 The term ‘translational cancer research’ means sci-  
13 entific laboratory and clinical research and testing  
14 needed to transform scientific discoveries into new  
15 approaches and products that can prevent, detect,  
16 control, diagnose, and treat cancer, optimize quality  
17 of life, and ultimately, cure cancer.

18 “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
19 is authorized to be appropriated to carry out this section,  
20 \$100,000,000 in fiscal year 2004, and \$100,000,000 for  
21 each of the fiscal years 2005, 2006, 2007, and 2008.

22 **“SEC. 417E-2. GRANTS FOR DEVELOPMENT OF TARGETED**  
23 **DRUGS.**

24 “(a) IN GENERAL.—The Director of the Institute  
25 shall carry out a research grant program to provide fund-

1 ing to projects that seek to develop cancer treatments that  
2 target cancer cells.

3 “(b) DUTIES OF DIRECTOR.—In carrying out the  
4 program under subsection (a), the Director of the Insti-  
5 tute shall—

6 “(1) award grants and facilitate the process to  
7 award grants to public or nonprofit private entities  
8 to conduct research to develop a molecularly-ori-  
9 ented, knowledge-based approach to cancer drug dis-  
10 covery and development; and

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

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

21 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
22 is authorized to be appropriated to carry out this section,  
23 \$20,000,000 in fiscal year 2004, and \$20,000,000 for  
24 each of the fiscal years 2005, 2006, 2007, and 2008.

1 **“SEC. 417E-3. CLINICAL TRIALS.**

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

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

7 “(1) an outreach program;

8 “(2) a diversity assurance program;

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

12 “(4) culturally appropriate materials.

13 “(c) OUTREACH PROGRAM.—In carrying out the out-  
14 reach program described in subsection (a), the Director  
15 of the Institute shall regularly provide information to can-  
16 cer care providers, professional and patient organizations,  
17 including community-based organizations, and patients to  
18 increase provider participation and patient enrollment in  
19 clinical trials.

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



1 **“SEC. 417E–4. CANCER CARE RESEARCHERS.**

2       “(a) SUPPLY OF CANCER RESEARCHERS.—In order  
3 to ensure a sufficient number of researchers trained in the  
4 prevention, early detection, diagnosis, cure, and treatment  
5 of cancer in future fiscal years, the Director of the Insti-  
6 tute, in coordination with the Secretary of Veterans Af-  
7 fairs, shall carry out activities to—

8               “(1) increase the number and amount of insti-  
9 tutional training grants to institutions supporting  
10 cancer research; and

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

19       “(b) LOAN REPAYMENT.—

20               “(1) ESTABLISHMENT.—The Director of the  
21 Institute, in consultation with the Director of the  
22 National Institutes of Health, shall establish a can-  
23 cer research loan repayment program.

24               “(2) CONTRACTS.—Under the program estab-  
25 lished under paragraph (1), the Director of the In-  
26 stitute shall enter into contracts with qualified

1 health professionals under which such professionals  
2 will agree to conduct cancer research, in consider-  
3 ation of the Federal Government agreeing to repay,  
4 for each year of such services, not more than  
5 \$35,000 of the principal and interest of the edu-  
6 cational loans of such professionals obtained to sup-  
7 port training for degrees or licenses, as determined  
8 appropriate by the Director of the Institute.

9 “(c) POSTDOCTORAL STIPENDS.—

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

21 “(2) AUTHORIZATION OF APPROPRIATIONS.—

22 There is authorized to be appropriated to carry out  
23 this subsection, \$79,000,000 for fiscal year 2004,  
24 and \$86,000,000 for fiscal year 2005, \$95,000,000

1 for fiscal year 2006, \$105,000,000 for fiscal year  
2 2007, and \$115,000,000 for fiscal year 2008.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
4 is authorized to be appropriated to carry out this section,  
5 \$10,500,000 for fiscal year 2004, and \$10,500,000 for  
6 each of fiscal years 2005 through 2008.

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

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

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

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

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

18 “(3) award grants, scholarships, fellowships,  
19 and loans to eligible individuals to increase the can-  
20 cer care workforce;

21 “(4) make awards to eligible individuals to in-  
22 crease cancer care workforce training for all individ-  
23 uals to become cancer care providers, especially but  
24 not limited to, such individuals who make a commit-  
25 ment to serve in underserved communities or areas

1 with disproportionately high cancer incidence or  
2 mortality and for health professions for which there  
3 are anticipated shortages, including providers, phar-  
4 macists, nurses for all settings, allied health profes-  
5 sionals, physicians, specialists, and public health  
6 professionals; and

7 “(5) be coordinated with existing programs to  
8 prevent duplication.

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

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

24 “(1) care and treatment of cancer patients and  
25 survivors;

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

2 “(3) early detection and diagnosis;

3 “(4) cancer prevention;

4 “(5) genetic testing and counseling;

5 “(6) language and cultural competency in can-  
6 cer care; and

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

8 “(e) **AUTHORIZATION OF APPROPRIATIONS.**—There  
9 is authorized to be appropriated to carry out this section,  
10 \$100,000,000 in fiscal year 2004 and such sums as may  
11 be necessary in each year for fiscal years 2005, 2006,  
12 2007, and 2008.

13 **“SEC. 417E-6. CENTERS FOR DISEASE CONTROL AND PRE-**  
14 **VENTION.**

15 “(a) **PROGRAM.**—The Director of the Centers for  
16 Disease Control and Prevention shall—

17 “(1) expand and update the National Com-  
18 prehensive Cancer Control Program;

19 “(2) assist States, territories, tribal organiza-  
20 tions, and the District of Columbia in developing  
21 and implementing a cancer prevention and control  
22 program so that each entity will have an active plan  
23 in place and so that States, territories, tribal organi-  
24 zations, and the District of Columbia will conduct

1 activities to prevent and control cancer and so that  
2 disparities in specific populations will be addressed;

3 “(3) establish programs that demonstrate how  
4 to prevent and control cancer and improve access to  
5 and the quality of cancer care among racial and eth-  
6 nic minority and medically underserved populations  
7 with disproportionate incidence of or death from  
8 cancer;

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

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

13 “(b) AUTHORIZATION OF APPROPRIATIONS.—There  
14 is authorized to be appropriated to carry out this section,  
15 \$65,000,000 for fiscal year 2004 and such sums as may  
16 be necessary for fiscal years 2005, 2006, 2007, and 2008.

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

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

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

3           “(1) the expansion of current cancer surveil-  
4 lance systems to track the health status of cancer  
5 survivors and determine whether cancer survivors  
6 are at-risk for other chronic and disabling condi-  
7 tions;

8           “(2) assess the unique challenges associated  
9 with cancer survivorship; and

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

16           “(A) develop unique and innovative post-  
17 treatment programs, services, and demonstra-  
18 tions designed to support and advance cancer  
19 survivorship through—

20           “(i) promotion of physical activity and  
21 healthy lifestyles;

22           “(ii) educational outreach programs  
23 for health care providers;

1           “(iii) support for innovative programs  
2           to improve the quality of life among cancer  
3           survivors;

4           “(iv) home and community-based  
5           interventions;

6           “(v) peer support and mentor pro-  
7           grams;

8           “(vi) public awareness and outreach  
9           campaigns; and

10          “(vii) information dissemination to in-  
11          form health care providers and cancer sur-  
12          vivors of their health care options and  
13          available survivorship programs; and

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

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

23          “(d) REPORT TO CONGRESS.—Not later than Octo-  
24          ber 1, 2004, the Secretary shall submit to Congress a re-  
25          port describing the results of the study conducted under



1 subsection (a), and as applicable, the strategies developed  
2 under such subsection.

3 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
4 is authorized to be appropriated to carry out this section,  
5 \$35,000,000 for fiscal year 2004, and such sums as may  
6 be necessary for each of fiscal years 2005 through 2008.

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

8 “(a) ESTABLISHMENT.—There is established within  
9 the Institute an Office on Cancer Survivorship (in this sec-  
10 tion referred to as the ‘Office’), to be headed by an Asso-  
11 ciate Director, to implement and direct the expansion and  
12 coordination of the activities of the Institute with respect  
13 to cancer survivorship research.

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

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

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

1 such sums as may be necessary for each of fiscal years  
2 2004 through 2008.

3 **“SEC. 417E-9. MONITORING AND EVALUATING QUALITY**  
4 **CANCER CARE AND CANCER SURVIVORSHIP.**

5 “(a) IN GENERAL.—The Secretary, acting through  
6 the Director of the Institute and the Director of the Cen-  
7 ters for Disease Control and Prevention, shall make grants  
8 to eligible entities for the purpose of enabling such entities  
9 to monitor and evaluate quality cancer care, develop infor-  
10 mation concerning quality cancer care, and monitor cancer  
11 survivorship.

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

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

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

21 “(c) CONTRACTING AUTHORITY.—In carrying the  
22 purpose described in subsection (a), an eligible entity may  
23 expend a grant under such subsection to enter into con-  
24 tracts with academic institutions, cancer centers, and

1 other entities, when determined appropriate by the Sec-  
2 retary.

3 “(d) APPLICATION.—To be eligible for a grant under  
4 subsection (a), an eligible entity shall submit to the Sec-  
5 retary an application at such time, in such manner, and  
6 containing such agreements, assurances, and information  
7 as the Secretary determines to be necessary to carry out  
8 this section.

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

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

17 **“SEC. 417E-10. MODEL COMMUNITY CANCER AND CHRONIC**  
18 **DISEASE CARE AND PREVENTION; PATIENT**  
19 **NAVIGATORS.**

20 “(a) DEFINITIONS.—In this section:

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

24 “(2) CULTURALLY COMPETENT.—The term  
25 ‘culturally competent’, with respect to providing

1 health-related services, means services that, in ac-  
2 cordance with standards and measures of the Sec-  
3 retary, are designed to effectively and efficiently re-  
4 spond to the cultural and linguistic needs of pa-  
5 tients.

6 “(3) ELIGIBLE ENTITY.—The term ‘eligible en-  
7 tity’ means any public or private entity determined  
8 to be appropriate by the Director of the Institute  
9 that provides services described in subsection  
10 (b)(1)(A) for cancer and chronic diseases, or any of  
11 the following entities that demonstrates the ability to  
12 perform all of the functions outlined in subsections  
13 (b) through (d):

14 “(A) A designated cancer center of the In-  
15 stitute.

16 “(B) An academic institution.

17 “(C) An Indian Health Service Clinic.

18 “(D) A tribal government.

19 “(E) An urban Indian organization.

20 “(F) A tribal organization.

21 “(G) A hospital.

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

1           “(4) HEALTH DISPARITY POPULATION.—The  
2 term ‘health disparity population’ means a popu-  
3 lation where there exists a significant disparity in  
4 the overall rate of disease incidence, morbidity, mor-  
5 tality, or survival rates in the population as com-  
6 pared to the health status of the general population.  
7 Such term includes—

8           “(A) racial and ethnic minority groups (as  
9 defined under section 1707); and

10           “(B) medically underserved groups, such  
11 as rural and low-income individuals and individ-  
12 uals with low levels of literacy.

13           “(5) PATIENT NAVIGATOR.—

14           “(A) IN GENERAL.—The term ‘patient  
15 navigator’ means an individual whose functions  
16 include—

17           “(i) assisting and guiding patients  
18 with a symptom, abnormal finding, or di-  
19 agnosis of cancer or other chronic disease  
20 within the health care system to accom-  
21 plish the follow-up and diagnosis of an ab-  
22 normal finding as well as the treatment  
23 and appropriate follow-up care of cancer or  
24 other chronic disease, including providing  
25 information about clinical trials; and

1           “(ii) identifying, anticipating, and  
2           helping patients overcome barriers within  
3           the health care system to ensure prompt  
4           diagnostic and treatment resolution of an  
5           abnormal finding of cancer or other chron-  
6           ic disease.

7           “(B) INCLUSIONS.—The term ‘patient nav-  
8           igator’ includes representatives of the target  
9           health disparity population, such as nurses, so-  
10          cial workers, cancer survivors, and patient ad-  
11          vocates.

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

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

17                         “(A) provide to individuals of health dis-  
18                         parity populations prevention, early detection,  
19                         treatment, and appropriate follow-up care serv-  
20                         ices for cancer and chronic diseases;

21                         “(B) ensure that the health services are  
22                         provided to such individuals in a culturally com-  
23                         petent manner;

24                         “(C) assign patient navigators, in accord-  
25                         ance with applicable criteria of the Secretary,

1 for managing the care of individuals of health  
2 disparity populations to—

3 “(i) accomplish, to the extent possible,  
4 the follow-up and diagnosis of an abnormal  
5 finding and the treatment and appropriate  
6 follow-up care of cancer or other chronic  
7 disease; and

8 “(ii) facilitate access to appropriate  
9 health care services within the health care  
10 system to ensure optimal patient utiliza-  
11 tion of such services, including aid in co-  
12 ordinating and scheduling appointments  
13 and referrals, community outreach, assist-  
14 ance with transportation arrangements,  
15 and assistance with insurance issues and  
16 other barriers to care and providing infor-  
17 mation about clinical trials;

18 “(D) require training for patient naviga-  
19 tors employed through such model programs to  
20 ensure the ability of navigators to perform all  
21 of the duties required in this subsection and in  
22 subsection (c), including training to ensure that  
23 navigators are informed about health insurance  
24 systems and are able to aid patients in resolv-  
25 ing access issues; and

1           “(E) ensure that consumers have direct ac-  
2           cess to patient navigators during regularly  
3           scheduled hours of business operation.

4           “(2) APPLICATION FOR GRANT.—An eligible en-  
5           tity that desires to receive a grant under paragraph  
6           (1) shall submit an application to the Director of the  
7           Institute at such time, in such manner, and con-  
8           taining such agreements, assurances, and informa-  
9           tion as the Director of the Institute determines to be  
10          necessary to carry out this section.

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

23          “(4) DATA COLLECTION AND REPORT.—In  
24          order to allow for effective program evaluation, an  
25          eligible entity that receives a grant under this sub-



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

22 “(5) EVALUATIONS.—

23 “(A) IN GENERAL.—The Director of the  
24 Institute, directly or through grants or con-  
25 tracts, shall provide for evaluations to deter-

1 mine which outreach activities under paragraph  
2 (3) were most effective in informing the public  
3 and the specific community that the program is  
4 serving of the model program services and to  
5 determine the extent to which such programs  
6 were effective in providing culturally competent  
7 services to the health disparity population  
8 served by the programs.

9 “(B) DISSEMINATION OF FINDINGS.—The  
10 Director of the Institute shall, as appropriate,  
11 disseminate to public and private entities the  
12 findings made in evaluations under subpara-  
13 graph (A).

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

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

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

19 and

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

24 “(c) PROGRAM FOR PATIENT NAVIGATORS.—

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

5                   “(A) assigning patient navigators, in ac-  
6                   cordance with applicable criteria of the Sec-  
7                   retary, for managing the care of individuals of  
8                   health disparity populations for the duration of  
9                   receipt of health services from the health cen-  
10                  ters, including aid in coordinating and sched-  
11                  uling appointments and referrals, community  
12                  outreach, assistance with transportation ar-  
13                  rangements, assistance with insurance issues  
14                  and other barriers to care, and providing infor-  
15                  mation about clinical trials;

16                   “(B) ensuring that the services provided by  
17                   the patient navigators to such individuals in-  
18                   clude case management and psychosocial as-  
19                   sessment and care or information and referral  
20                   to such services;

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

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

3                   “(i) coordination of health services,  
4 including psychosocial assessment and  
5 care;

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

8                   “(iii) determining coverage under  
9 health insurance and health plans for all  
10 services;

11                   “(iv) ensuring the initiation, continu-  
12 ation, or sustained access to care pre-  
13 scribed by the patients’ health care pro-  
14 viders; and

15                   “(v) aiding patients with health insur-  
16 ance coverage issues;

17           “(E) requiring training for patient naviga-  
18 tors to ensure the ability of navigators to per-  
19 form all of the duties required in this sub-  
20 section and in subsection (b), including train-  
21 ing, to ensure that navigators are informed  
22 about health insurance systems and are able to  
23 aid patients in resolving access issues; and

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

4           “(2) APPLICATION FOR GRANT.—An eligible en-  
5           tity that desires to receive a grant under paragraph  
6           (1) shall submit an application to the Director of the  
7           Institute at such time, in such manner, and con-  
8           taining such agreements, assurances, and informa-  
9           tion as the Director of the Institute determines to be  
10          necessary to carry out this section.

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

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

1       lish and implement procedures and protocols, con-  
2       sistent with applicable Federal and State laws (in-  
3       cluding sections 160 and 164 of title 45, Code of  
4       Federal Regulations) to ensure the confidentiality of  
5       all information shared by a participant in the pro-  
6       gram, or their personal representative and their  
7       health care providers, group health plans, or health  
8       insurance insurers with the program. The patient  
9       navigator program may, consistent with applicable  
10      Federal and State confidentiality laws, collect, use,  
11      or disclose aggregate information that is not individ-  
12      ually identifiable (as defined in sections 160 and 164  
13      of title 45, Code of Federal Regulations). With this  
14      data, the grantee shall submit an annual report to  
15      the Secretary that summarizes and analyzes the  
16      data and provides information on needs for naviga-  
17      tion services, types of access difficulties resolved,  
18      sources of repeated resolution, and flaws in the sys-  
19      tem of access, including insurance barriers.

20               “(5) EVALUATIONS.—

21                       “(A) IN GENERAL.—The Director of the  
22                       Institute, directly or through grants or con-  
23                       tracts, shall provide for evaluations to deter-  
24                       mine the effects of the services of patient navi-  
25                       gators on the health disparity population for

1           whom the services were provided, taking into  
2           account the matters referred to in paragraph  
3           (1)(C).

4           “(B) DISSEMINATION OF FINDINGS.—The  
5           Director of the Institute shall as appropriate  
6           disseminate to public and private entities the  
7           findings made in evaluations under subpara-  
8           graph (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 330M.

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

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



1 subsections (b) and (c) that may be made to an eligible  
2 entity.

3 “(g) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

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

18 “The Agency for Healthcare Research and Quality  
19 shall regularly convene cancer experts, providers, patients,  
20 representatives of disparity populations, and other rel-  
21 evant experts, including representatives of the Institute,  
22 the Health Resources Administration, and the Centers for  
23 Disease Control and Prevention, to coordinate the develop-  
24 ment and regularly update—

1           “(1) consensus protocols and practice guidelines  
2           for optimal cancer treatments and prevention, in-  
3           cluding palliation, symptom management, and end-  
4           of-life care;

5           “(2) quality of care measures to assist providers  
6           and patients in making and evaluating treatment de-  
7           cisions; and

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

14 **“SEC. 417E-12. RESEARCH AND OTHER ACTIVITIES OF THE**  
15                   **AGENCY FOR HEALTHCARE RESEARCH AND**  
16                   **QUALITY TO IMPROVE THE QUALITY AND**  
17                   **OUTCOMES OF CANCER CARE.**

18          “(a) IN GENERAL.—

19           “(1) RESEARCH.—The Director for Healthcare  
20          Research and Quality shall conduct and support re-  
21          search and other activities to build an evidence base  
22          regarding effective clinical and organizational inter-  
23          vention strategies to improve the quality and out-  
24          comes of cancer care, and access to such care, at all  
25          stages of the health care continuum and to facilitate

1 the prompt use of that information to improve prac-  
2 tice.

3 “(2) FACTORS.—In carrying out paragraph (1),  
4 the Director for Healthcare Research and Quality  
5 shall take into account the breadth of the continuum  
6 of cancer care, from prevention and early detection,  
7 through diagnosis and treatment, to rehabilitation,  
8 long term survivorship and remission, through psy-  
9 chosocial, palliative, and end-of-life care.

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

12 “(1) conduct and support research to develop  
13 new scientific knowledge regarding the effectiveness  
14 and cost-effectiveness of interventions that improve  
15 the quality and outcomes of cancer care, and access  
16 to such care;

17 “(2) regularly assess and synthesize existing  
18 scientific evidence on the effectiveness of such inter-  
19 ventions;

20 “(3) ensure the targeted dissemination of the  
21 most current scientific evidence in appropriate for-  
22 mats for use by professional societies and organiza-  
23 tions representing clinicians and other caregivers, or-  
24 ganizations through which health care and support

1 services are delivered, and organizations rep-  
2 resenting cancer patients and their families;

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

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

12 “(6) collect information, as appropriate, and  
13 conduct and support research on trends in medical  
14 care practice patterns and the relationship of such  
15 trends to the quality and outcomes of cancer care;  
16 and

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

20 “(c) COORDINATION OF FEDERAL QUALITY IM-  
21 PROVEMENT ACTIVITIES AND REPORTING OF DATA.—In  
22 carrying out subsection (b)—

23 “(1) the Director for Healthcare Research and  
24 Quality, working through the Quality Interagency  
25 Coordination (QUIC) Task Force, and in collabora-

1       tion with the Director of the Institute, shall facili-  
2       tate coordination of Federal research and implemen-  
3       tation initiatives to improve the quality and out-  
4       comes of cancer care;

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

9               “(3) the Director for Healthcare Research and  
10      Quality and the Director of the Institute shall work  
11      cooperatively to develop data in order to set bench-  
12      marks for, and subsequently measure changes in the  
13      quality of cancer care for inclusion, as soon as prac-  
14      ticable, in the annual report required by section  
15      913(b)(2); and

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

20              “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
21      is authorized to be appropriated to carry out this section  
22      such sums as may be necessary for each of fiscal years  
23      2004 through 2008.

1 **“SEC. 417E-13. INSTITUTE OF MEDICINE STUDY ON CAN-**  
2 **CER.**

3 “(a) INSTITUTE OF MEDICINE STUDY.—The Sec-  
4 retary shall request the Institute of Medicine of the Na-  
5 tional Academies of Sciences to initiate a study by Janu-  
6 ary 1, 2004, of the feasibility and costs of providing medi-  
7 care coverage under title XVIII of the Social Security Act  
8 to individuals who are diagnosed with cancer and cancer  
9 survivors through 5 years of remission of cancer at any  
10 age and who have no other means of purchasing health  
11 care or health insurance, as determined under criteria es-  
12 tablished by the Secretary.

13 “(b) CONTENT.—

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

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

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

19 “(B) estimate the cost to the medicare pro-  
20 gram and to current and future beneficiaries;  
21 and

22 “(C) identify advantages associated with  
23 medicare coverage in terms of access to cancer  
24 care, improved quality of care and patient out-  
25 comes and assess the feasibility of providing  
26 medicare coverage to uninsured cancer patients

1 through 5 years of remission and make a rec-  
2 ommendation to Congress about whether medi-  
3 care should be expanded to this population  
4 group.

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

6 “(A) identify changes in medicare benefits  
7 to facilitate the provision of care consistent with  
8 quality cancer care standards, including pre-  
9 scription drug benefits and benefits to improve  
10 home care, symptom management, psychosocial  
11 services, and palliative and hospice care;

12 “(B) estimate the cost to the medicare pro-  
13 gram and to beneficiaries; and

14 “(C) assess the medical advantages and  
15 disadvantages associated with expanding bene-  
16 fits.

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

20 “(c) AUTHORIZATION OF APPROPRIATIONS.—There  
21 are authorized to be appropriated to carry out this section  
22 \$1,000,000 in fiscal year 2004 and \$1,200,000 in fiscal  
23 year 2005.”.

1 **SEC. 104. NATIONAL INSTITUTE FOR ENVIRONMENTAL**  
2 **HEALTH SCIENCES.**

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

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

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

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

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

20 (2) in paragraph (1)(B), by striking “cancer  
21 patients” and all that follows and inserting the fol-  
22 lowing: “cancer patients, families of cancer patients,  
23 and cancer survivors, and”; and

24 (3) in paragraph (3), by inserting “and con-  
25 cerning cancer survivorship programs,” after “con-  
26 trol of cancer”.



1 **SEC. 106. BREAST, CERVICAL, AND COLORECTAL CANCER**  
2 **SCREENING.**

3 (a) BREAST AND CERVICAL CANCER.—Section  
4 1510(a) of the Public Health Service Act (42 U.S.C.  
5 300n–5(a)) is amended by striking “\$50,000,000” and all  
6 that follows through the period, and inserting  
7 “\$250,000,000 for fiscal year 2004, and such sums as  
8 may be necessary for fiscal years 2005 through 2008.”.

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

12 **“SEC. 1511. COLORECTAL CANCER SCREENING DEM-**  
13 **ONSTRATION PROJECT.**

14 “(a) IN GENERAL.—The Secretary, acting through  
15 the Director of the Centers for Disease Control and Pre-  
16 vention, shall award competitive grants to public and non-  
17 profit private entities to enable such entities to establish  
18 demonstration programs pursuant to the general authority  
19 of title III to carry out colorectal screening activities in-  
20 cluding—

21 “(1) screening asymptomatic individuals for  
22 colorectal cancer as a preventive health measure ac-  
23 cording to scientific evidence-based screening guide-  
24 lines;

25 “(2) providing appropriate referrals for medical  
26 treatment of individuals screened pursuant to this

1 section and to ensure, to the extent practicable, the  
2 provision of appropriate follow-up services and sup-  
3 port services such as case management;

4 “(3) activities to improve the education, train-  
5 ing, and skills of health professionals (including al-  
6 lied health professionals) in the detection and con-  
7 trol of colorectal cancer;

8 “(4) activities to evaluate the programs under  
9 this section through appropriate surveillance or pro-  
10 gram monitoring activities;

11 “(5) the development and dissemination of find-  
12 ings derived through such evaluations through public  
13 and professional education; and

14 “(6) activities to promote the benefits of  
15 colorectal cancer screening.

16 “(b) PAYMENTS FOR SCREENINGS.—The amount  
17 paid by a grantee under this section to an entity on behalf  
18 of an individual for the furnishing of services to such indi-  
19 vidual shall not exceed the amount that would be paid  
20 under part B of title XVIII of the Social Security Act for  
21 such services if such payment were made under such part  
22 for such services.

23 “(c) REQUIREMENTS.—

24 “(1) PRIORITY.—To be eligible for a grant  
25 under subsection (a), an entity shall agree to give

1 priority with respect to activities and services under  
2 the grant to a low-income—

3 “(A) individual who is at least 50 years of  
4 age; or

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

8 “(2) RELATIONSHIP TO ITEMS AND SERVICES  
9 UNDER OTHER PROGRAMS.—To be eligible for a  
10 grant under subsection (a), an entity shall agree  
11 that grant funds will not be expended to make pay-  
12 ments for any item or service to the extent that pay-  
13 ment has been made, or can reasonably be expected  
14 to be made, with respect to such item or service—

15 “(A) under any State compensation pro-  
16 gram, under an insurance policy, or under any  
17 Federal or State health benefits program; or

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

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

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

4           “(A) establish such fiscal control and fund  
5 accounting procedures as may be necessary to  
6 ensure proper disbursement of, and accounting for,  
7 amounts received under this section; and

8           “(B) provide agreed upon annual reports  
9 to the Secretary or the Comptroller of the  
10 United States for the purposes of auditing the  
11 expenditures by the entity.

12           “(5) REPORTS.—To be eligible for a grant  
13 under subsection (a), an entity shall agree to submit  
14 to the Secretary such reports as the Secretary deter-  
15 mines appropriate.

16           “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
17 is authorized to be appropriated to carry out this section,  
18 \$50,000,000 for fiscal year 2004, and such sums as may  
19 be necessary for each of fiscal years 2005 through 2008.”.

20 **SEC. 107. IHS GRANTS FOR MODEL COMMUNITY CANCER**  
21 **AND CHRONIC DISEASE CARE AND PREVEN-**  
22 **TION; IHS GRANTS FOR PATIENT NAVIGA-**  
23 **TORS.**

24           (a) DEFINITIONS.—In this section:

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

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

8           (b) MODEL COMMUNITY CANCER AND CHRONIC DIS-  
9           EASE CARE AND PREVENTION.—

10           (1) IN GENERAL.—The Director of the Indian  
11           Health Service may make grants, for the develop-  
12           ment and operation of model programs that perform  
13           the same functions outlined in section 417E–  
14           10(b)(1) of the Public Health Service Act, to Indian  
15           Health Service Centers, tribal governments, urban  
16           Indian organizations, tribal organizations, and quali-  
17           fied nonprofit entities demonstrating the ability to  
18           perform all of the functions in this subsection and  
19           subsections (c) and (d) that partner with providers  
20           or centers providing health care services to Native  
21           American populations to provide navigation services.

22           (2) APPLICATION FOR GRANT.—An entity that  
23           desires to receive a grant under paragraph (1) shall  
24           submit an application to the Secretary at such time,  
25           in such manner, and containing such agreements,

1       assurances, and information as the Secretary deter-  
2       mines to be necessary to carry out this section.

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

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

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

14 (5) EVALUATIONS.—

15 (A) IN GENERAL.—The Secretary, acting  
16 through the Director of the Indian Health Serv-  
17 ice, shall, directly or through grants or con-  
18 tracts, provide for evaluations to determine  
19 which outreach activities under paragraph (3)  
20 were most effective in informing the public and  
21 the specific community that the program is  
22 serving of the model program services and to  
23 determine the extent to which such programs  
24 were effective in providing culturally competent

1 services to the health disparity population  
2 served by the programs.

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

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

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

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

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

17 (c) PROGRAM FOR PATIENT NAVIGATORS.—

18 (1) IN GENERAL.—The Secretary, acting  
19 through the Director of the Indian Health Service,  
20 may make grants to Indian Health Service Centers,  
21 tribal governments, urban Indian organizations, trib-  
22 al organizations, and qualified nonprofit entities  
23 demonstrating the ability to perform all of the func-  
24 tions in this subsection and subsections (b) and (d)  
25 that partner with providers or centers providing



1 health care services to Native American populations  
2 to provide navigation services, for the development  
3 and operation of model programs to pay the costs  
4 of such entities in carrying out the same activities  
5 outlined in section 417E–10(c)(1) of the Public  
6 Health Service Act.

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

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

22 (4) DATA COLLECTION AND REPORT.—In order  
23 to allow for effective patient navigator program eval-  
24 uation, an entity that receives a grant under this  
25 subsection shall collect specific patient data record-

1 ing navigation services provided to each patient  
2 served by the program and shall establish and imple-  
3 ment procedures and protocols, consistent with ap-  
4 plicable Federal and State laws (including sections  
5 160 and 164 of title 45, Code of Federal Regula-  
6 tions) to ensure the confidentiality of all information  
7 shared by a participant in the program, or their per-  
8 sonal representative and their health care providers,  
9 group health plans, or health insurance insurers  
10 with the program. The patient navigator program  
11 may, consistent with applicable Federal and State  
12 confidentiality laws, collect, use, or disclose aggre-  
13 gate information that is not individually identifiable  
14 (as defined in sections 160 and 164 of title 45, Code  
15 of Federal Regulations). With this data, the grantee  
16 shall submit an annual report to the Secretary that  
17 summarizes and analyzes the data and provides in-  
18 formation on needs for navigation services, types of  
19 access difficulties resolved, sources of repeated reso-  
20 lution, and flaws in the system of access, including  
21 insurance barriers.

22 (5) EVALUATIONS.—

23 (A) IN GENERAL.—The Secretary, acting  
24 through the Director of the Indian Health Serv-  
25 ice, shall, directly or through grants or con-

1 tracts, provide for evaluations to determine the  
2 effects of the services of patient navigators on  
3 the individuals of health disparity populations  
4 for whom the services were provided, taking  
5 into account the matters referred to in section  
6 417E-10(c)(1)(C) of the Public Health Service  
7 Act.

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

12 (6) COORDINATION WITH OTHER PROGRAMS.—  
13 The Secretary shall coordinate the program under  
14 this subsection with the programs under subsection  
15 (b) and section 417E–10 of the Public Health Serv-  
16 ice Act.

17 (d) REQUIREMENTS REGARDING FEES.—

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

22 (A) a schedule of fees or payments for the  
23 provision of such program’s health care services  
24 related to the prevention and treatment of dis-  
25 ease that is consistent with locally prevailing

1 rates or charges and is designed to cover such  
2 program's reasonable costs of operation; and

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

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

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

19 (f) DURATION OF GRANT.—The period during which  
20 payments are made to an entity from a grant under sub-  
21 section (b)(1) or (c)(1) may not exceed 5 years. The provi-  
22 sion of such payments are subject to annual approval by  
23 the Secretary and subject to the availability of appropria-  
24 tions for the fiscal year involved. Nothing in this sub-  
25 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 POLICY.—  
8 Amounts appropriated under subparagraph (A)  
9 or (B) shall be administered through the Office  
10 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).

16 **TITLE II—EXPANDING ACCESS**  
17 **TO CANCER DRUGS AND**  
18 **TREATMENT**

19 **SEC. 201. ACCELERATION OF THE DRUG TREATMENT AP-**  
20 **PROVAL PROCESS OF THE FOOD AND DRUG**  
21 **ADMINISTRATION.**

22 Not later than July 1, 2004, the Commissioner of  
23 Food and Drugs shall prepare and submit to Congress a  
24 strategic plan that outlines the steps that the Commis-

1 sioner is taking to accelerate the process for reviewing and  
2 approving new cancer drugs and treatments.

3 **SEC. 202. FDA AMENDMENT.**

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

8 **TITLE III—CANCER-RELATED**  
9 **HEALTH INSURANCE COVERAGE**  
10 **Subtitle A—Clinical Trials**  
11 **Coverage**

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

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

17 **“SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING**  
18 **IN CLINICAL TRIALS.**

19 “(a) COVERAGE.—

20 “(1) IN GENERAL.—If a group health plan, or  
21 health insurance issuer that is providing health in-  
22 surance coverage, provides coverage to a qualified in-  
23 dividual (as defined in subsection (b)), the plan or  
24 issuer—

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

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

9           “(C) may not discriminate against the in-  
10          dividual on the basis of the enrollee’s partici-  
11          pation in such trial.

12          “(2) EXCLUSION OF CERTAIN COSTS.—For pur-  
13          poses of paragraph (1)(B), routine patient costs do  
14          not include the cost of the tests or measurements  
15          conducted primarily for the purpose of the clinical  
16          trial involved.

17          “(3) USE OF IN-NETWORK PROVIDERS.—If 1 or  
18          more participating providers is participating in a  
19          clinical trial, nothing in paragraph (1) shall be con-  
20          strued as preventing a plan or issuer from requiring  
21          that, if a qualified individual is enrolling in the same  
22          clinical trial, the qualified individual participate in  
23          the trial through such a participating provider if the  
24          provider will accept the individual as a participant in  
25          that same trial. If the qualified individual is to enroll



1 in a trial and no acceptable in-network provider is  
2 participating in the trial or if a participating pro-  
3 vider cannot accept new enrollees, then the qualified  
4 individual may enroll in the trial through an out-of-  
5 network provider.

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

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

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

25 “(c) PAYMENT.—

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

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

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

13                   “(B) a nonparticipating provider, the pay-  
14 ment rate shall be at the rate the plan or issuer  
15 would normally pay for comparable services  
16 under subparagraph (A).

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

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

22                           “(A) the National Institutes of Health;

23                           “(B) a cooperative group or center of the  
24 National Institutes of Health, including a quali-  
25 fied nongovernmental research entity to which

1 the National Cancer Institute has awarded a  
2 center support grant;

3 “(C) the Department of Veterans Affairs,  
4 if the conditions described in subsection (e) are  
5 met; or

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

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

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

14 “(A) is registered with the Department of  
15 Health and Human Services; and

16 “(B) is associated with an institution that  
17 has a Federal assurance approved by the De-  
18 partment of Health and Human Services speci-  
19 fying compliance with section 46 of title 45,  
20 Code of Federal Regulations.

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

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

4           “(2) assures unbiased review of the highest eth-  
5 ical standards by an institutional review board or  
6 other body that meets the standards outlined in sec-  
7 tion 46 of title 45, and sections 50 and 56 of title  
8 21, Code of Federal Regulations.

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

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

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

16           “The provisions of section 2707 shall apply to health  
17 insurance coverage offered by a health insurance issuer  
18 in the individual market in the same manner as such pro-  
19 visions apply to health insurance coverage offered by a  
20 health insurance issuer in connection with a group health  
21 plan.”.

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

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

8 **“SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**  
9 **CLINICAL TRIALS.**

10 “(a) COVERAGE.—

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

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

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

24 “(C) may not discriminate against the in-  
25 dividual on the basis of the enrollee’s participa-  
26 tion in such trial.

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

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

20          “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-  
21          poses of subsection (a), the term ‘qualified individual’  
22          means an individual who has cancer and is a participant  
23          or beneficiary in a group health plan, or who is an enrollee  
24          under health insurance coverage, and who meets the fol-  
25          lowing conditions:

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

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

14          “(c) PAYMENT.—

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

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

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

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

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

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

12           “(A) the National Institutes of Health;

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

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

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

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



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

5                   “(A) is registered with the Department of  
6 Health and Human Services; and

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

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

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

20                   “(2) assures unbiased review of the highest eth-  
21 ical standards by an institutional review board or  
22 other body that meets the standards outlined in sec-  
23 tion 46 of title 45, and sections 50 and 56 of title  
24 21, Code of Federal Regulations.

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

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

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

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

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

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

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

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

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

24               (5) programs offered by the Department of De-  
25 fense;

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

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

5           **Subtitle B—Cancer Screening and**  
6           **Other Coverage**

7           **SEC. 311. CANCER SCREENING COVERAGE.**

8           (a) GROUP HEALTH PLANS.—

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

11           (A) IN GENERAL.—Subpart 2 of part A of  
12           title XXVII of the Public Health Service Act  
13           (42 U.S.C. 300gg–4 et seq.), as amended by  
14           section 301(a), is further amended by adding at  
15           the end the following:

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

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

24           “(1) MAMMOGRAMS.—In the case of a female  
25           participant or beneficiary who is 40 years of age or

1 older, or is under 40 years of age but is at high risk  
2 (as defined in subsection (e)) of developing breast  
3 cancer, an annual mammography (as defined in sec-  
4 tion 1861(jj) of the Social Security Act) conducted  
5 by a facility that has a certificate (or provisional cer-  
6 tificate) issued under section 354.

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

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

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

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

21 “(A) an annual diagnostic laboratory test  
22 (popularly known as a ‘pap smear’) consisting  
23 of a routine exfoliative cytology test (Papani-  
24 colaou test) provided to a woman for the pur-  
25 pose of early detection of cervical or vaginal

1 cancer and including an interpretation by a  
2 qualified health professional of the results of  
3 the test; and

4 “(B) an annual pelvic examination.

5 “(4) COLORECTAL CANCER SCREENING PROCE-  
6 DURES.—

7 “(A) IN GENERAL.—In the case of a par-  
8 ticipant or beneficiary who is 50 years of age or  
9 older, or who is under 50 years of age and is  
10 an individual at high risk for colorectal cancer,  
11 the group health plan or health insurance issuer  
12 shall cover methods of colorectal cancer screen-  
13 ing that—

14 “(i) are deemed appropriate by a phy-  
15 sician (as defined in section 1861(r) of the  
16 Social Security Act (42 U.S.C. 1395x(r)))  
17 treating the participant or beneficiary, in  
18 consultation with the participant or bene-  
19 ficiary;

20 “(ii) are—

21 “(I) described in section  
22 1861(pp)(1) of the Social Security Act  
23 (42 U.S.C. 1395x(pp)(1)) or section  
24 410.37 of title 42, Code of Federal  
25 Regulations; or

1           “(II) specified by the Secretary  
2           based upon the recommendations of  
3           appropriate organizations with special  
4           expertise in the field of colorectal can-  
5           cer; and

6           “(iii) are performed at a frequency  
7           not greater than that—

8           “(I) described for such method in  
9           section 1834(d) of the Social Security  
10          Act (42 U.S.C. 1395m(d)) or section  
11          410.37 of title 42, Code of Federal  
12          Regulations; or

13          “(II) specified by the Secretary  
14          for such method if the Secretary  
15          finds, based upon new scientific  
16          knowledge and consistent with the  
17          recommendations of appropriate orga-  
18          nizations with special expertise in the  
19          field of colorectal cancer, that a dif-  
20          ferent frequency would not adversely  
21          affect the effectiveness of such screen-  
22          ing.

23          “(B) DEFINITION OF HIGH RISK.—In this  
24          paragraph, the term ‘individual at high risk for  
25          colorectal cancer’ has the meaning given the

1 term in section 1861(pp)(2) of the Social Secu-  
2 rity Act (42 U.S.C. 1395x(pp)(2)).

3 “(5) PROSTATE CANCER SCREENING.—In the  
4 case of a male participant or beneficiary who is 50  
5 years of age or older, or who is younger than 50  
6 years of age and is at high risk for prostate cancer  
7 (including African American men or a male who has  
8 a history of prostate cancer in a first degree family  
9 member), the procedures described in section  
10 1861(oo)(2) of Social Security Act (42 U.S.C.  
11 1395x(oo)(2)) shall be furnished to the individual  
12 for the early detection of prostate cancer. The group  
13 health plan or health insurance issuer shall provide  
14 coverage for the method and frequency of prostate  
15 cancer screening determined to be appropriate by a  
16 health care provider treating such participant or  
17 beneficiary, in consultation with the participant or  
18 beneficiary.

19 “(6) TOBACCO THERAPY AND COUNSELING.—

20 “(A) IN GENERAL.—Therapy and coun-  
21 seling for cessation of tobacco use for individ-  
22 uals who use tobacco products or who are being  
23 treated for tobacco use that is furnished—

24 “(i) by or under the supervision of a  
25 physician; or

1           “(ii) by any other health care profes-  
2           sional—

3                   “(I) who is legally authorized to  
4                   furnish such services under State law  
5                   (or the State regulatory mechanism  
6                   provided by State law) of the State in  
7                   which the services are furnished; and

8                   “(II) who, for medicare bene-  
9                   ficiaries, is authorized to receive pay-  
10                  ment for other services under this title  
11                  or is designated by the Secretary for  
12                  this purpose.

13                  “(B) LIMITATION.—Subject to subpara-  
14                  graph (C), such therapy and counseling are lim-  
15                  ited to—

16                   “(i) therapy and counseling services  
17                   recommended in ‘Treating Tobacco Use  
18                   and Dependence: A Clinical Practice  
19                   Guideline’, published by the Public Health  
20                   Service in June 2000, or any subsequent  
21                   modification of such Guideline; and

22                   “(ii) such other therapy and coun-  
23                   seling services that the Secretary recog-  
24                   nizes to be effective.



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

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

11          “(8) GENETIC TESTS AND GENETIC SERV-  
12          ICES.—

13                 “(A) IN GENERAL.—Genetic tests and ge-  
14                 netic services provided by a licensed health care  
15                 professional to obtain predictive genetic infor-  
16                 mation about an individual at risk of cancer for  
17                 purposes of a health assessment, cancer man-  
18                 agement, cancer prevention, other diagnostic or  
19                 therapeutic purposes, or genetic education and  
20                 counseling.

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

22                         “(i) FAMILY MEMBER.—The term  
23                         ‘family member’ means with respect to an  
24                         individual—

25                                 “(I) the spouse of the individual;

1                   “(II) a dependent child of the in-  
2                   dividual, including a child who is born  
3                   to or placed for adoption with the in-  
4                   dividual; and

5                   “(III) all other individuals re-  
6                   lated by blood to the individual or the  
7                   spouse or child described in subclause  
8                   (I) or (II).

9                   “(ii) GENETIC INFORMATION.—The  
10                  term ‘genetic information’ means informa-  
11                  tion about genes, gene products, or inher-  
12                  ited characteristics that may derive from  
13                  an individual or a family member of such  
14                  individual (including information about a  
15                  request for or the receipt of genetic serv-  
16                  ices by such individual or family member  
17                  of such individual).

18                  “(iii) GENETIC SERVICES.—The term  
19                  ‘genetic services’ means health services, in-  
20                  cluding genetic tests, provided to obtain,  
21                  assess, or interpret genetic information for  
22                  diagnostic and therapeutic purposes, and  
23                  for genetic education and counseling.

24                  “(iv) GENETIC TEST.—The term ‘ge-  
25                  netic test’ means the analysis of human

1 DNA, RNA, chromosomes, proteins, and  
2 certain metabolites in order to detect  
3 genotypes, mutations, or chromosomal  
4 changes.

5 “(v) PREDICTIVE GENETIC INFORMA-  
6 TION.—

7 “(I) IN GENERAL.—The term  
8 ‘predictive genetic information’  
9 means—

10 “(aa) information about an  
11 individual’s genetic tests;

12 “(bb) information about ge-  
13 netic tests of family members of  
14 the individual; or

15 “(cc) information about the  
16 occurrence of a disease or dis-  
17 order in family members.

18 “(II) LIMITATIONS.—The term  
19 ‘predictive genetic information’ shall  
20 not include—

21 “(aa) information about the  
22 sex or age of the individual;

23 “(bb) information about  
24 chemical, blood, or urine analyses

1 of the individual, unless these  
2 analyses are genetic tests; or

3 “(cc) information about  
4 physical exams of the individual,  
5 and other information relevant to  
6 determining the current health  
7 status of the individual.

8 “(9) OTHER TESTS AND PROCEDURES.—Such  
9 other tests or procedures for the detection of cancer,  
10 and modifications to the tests and procedures, with  
11 such frequency, as the Secretary determines to be  
12 appropriate, in consultation with appropriate organi-  
13 zations and agencies, for the diagnosis or detection  
14 of cancer.

15 “(b) PROHIBITIONS.—A group health plan, and a  
16 health insurance issuer offering group health insurance  
17 coverage in connection with a group health plan, shall  
18 not—

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

23 “(2) provide monetary payments or rebates to  
24 individuals to encourage such individuals to accept

1 less than the minimum protections available under  
2 this section;

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

7 “(4) provide incentives (monetary or otherwise)  
8 to a provider to induce such provider to provide care  
9 to an individual participant or beneficiary in a man-  
10 ner inconsistent with this section.

11 “(c) RULES OF CONSTRUCTION.—

12 “(1) Nothing in this section shall be construed  
13 to require an individual who is a participant or bene-  
14 ficiary to undergo a procedure, examination, or test  
15 described in subsection (a).

16 “(2) Nothing in this section shall be construed  
17 as preventing a group health plan or issuer from im-  
18 posing deductibles, coinsurance, or other cost-shar-  
19 ing in relation to benefits described in subsection (a)  
20 consistent with such subsection, except that such co-  
21 insurance or other cost-sharing shall not discrimi-  
22 nate on any basis related to the coverage required  
23 under this section.

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

4           “(d) NOTICE.—A group health plan under this part  
5           shall comply with the notice requirement under section  
6           714(d) of the Employee Retirement Income Security Act  
7           of 1974 with respect to the requirements of this section  
8           as if such section applied to such plan.

9           “(e) RISK DEFINED.—For purposes of this section,  
10          an individual is considered to be at ‘risk’ of developing  
11          a particular type of cancer if, under guidelines developed  
12          or recognized by the Secretary based upon scientific evi-  
13          dence, the individual—

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

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

17                 “(3) has the presence of an appropriate recog-  
18                 nized gene marker that is identified as putting the  
19                 individual at a higher risk of developing that type of  
20                 cancer; or

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

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

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

5 “(a) DISCLOSURE REQUIREMENT.—A group health  
6 plan, and health insurance issuer offering group health in-  
7 surance coverage shall—

8 “(1) provide to participants and beneficiaries at  
9 the time of initial coverage under the plan (or the  
10 effective date of this section, in the case of individ-  
11 uals who are participants or beneficiaries as of such  
12 date), and at least annually thereafter, the informa-  
13 tion described in subsection (b) in printed form;

14 “(2) provide to participants and beneficiaries,  
15 within a reasonable period (as specified by the ap-  
16 propriate Secretary) before or after the date of sig-  
17 nificant changes in the information described in sub-  
18 section (b), information in printed form regarding  
19 such significant changes; and

20 “(3) upon request, make available to partici-  
21 pants and beneficiaries, the applicable authority, and  
22 prospective participants and beneficiaries, the infor-  
23 mation described in subsection (b) in printed form.

24 “(b) INFORMATION PROVIDED.—The information de-  
25 scribed in subsection (a) that shall be disclosed includes

1 the following, as such relates to cancer screening required  
2 under section 2708(a):

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

5 “(A) covered benefits, including benefit  
6 limits and coverage exclusions;

7 “(B) cost-sharing, such as deductibles, co-  
8 insurance, and copayment amounts, including  
9 any liability for balance billing, any maximum  
10 limitations on out of pocket expenses, and the  
11 maximum out of pocket costs for services that  
12 are provided by nonparticipating providers or  
13 that are furnished without meeting the applica-  
14 ble utilization review requirements;

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

17 “(D) the extent to which a participant,  
18 beneficiary, or enrollee may select from among  
19 participating providers and the types of pro-  
20 viders participating in the plan or issuer net-  
21 work.

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

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



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

3           “(C) Any point-of-service option (including  
4           any supplemental premium or cost-sharing for  
5           such option).

6           “(D) The procedures for participants,  
7           beneficiaries, and enrollees to select, access, and  
8           change participating primary and specialty pro-  
9           viders.

10          “(E) The rights and procedures for obtain-  
11          ing referrals (including standing referrals) to  
12          participating and nonparticipating providers.

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

17          “(G) How the plan or issuer addresses the  
18          needs of participants, beneficiaries, and enroll-  
19          ees and others who do not speak English or  
20          who have other special communications needs in  
21          accessing providers under the plan or coverage,  
22          including the provision of information under  
23          this subsection.”.

24                 (B) TECHNICAL AMENDMENT.—Section  
25                 2723(c) of the Public Health Service Act (42

1 U.S.C. 300gg-23(c)) is amended by striking  
2 “section 2704” and inserting “sections 2704  
3 and 2708”.

4 (2) ERISA AMENDMENTS.—

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

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

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

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

1 tificate) issued under section 354 of the Public  
2 Health Service Act.

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

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

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

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

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

25 “(B) an annual pelvic examination.

1           “(4) COLORECTAL CANCER SCREENING PROCE-  
2           DURES.—

3           “(A) IN GENERAL.—In the case of a par-  
4           ticipant or beneficiary who is 50 years of age or  
5           older, or who is under 50 years of age and is  
6           an individual at high risk for colorectal cancer,  
7           the group health plan or health insurance issuer  
8           shall cover methods of colorectal cancer screen-  
9           ing that—

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

16           “(ii) are—

17           “(I) described in section  
18           1861(pp)(1) of the Social Security Act  
19           (42 U.S.C. 1395x(pp)(1)) or section  
20           410.37 of title 42, Code of Federal  
21           Regulations; or

22           “(II) specified by the Secretary  
23           based upon the recommendations of  
24           appropriate organizations with special

1 expertise in the field of colorectal can-  
2 cer; and

3 “(iii) are performed at a frequency  
4 not greater than that—

5 “(I) described for such method in  
6 section 1834(d) of the Social Security  
7 Act (42 U.S.C. 1395m(d)) or section  
8 410.37 of title 42, Code of Federal  
9 Regulations; or

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

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

1           “(5) PROSTATE CANCER SCREENING.—In the  
2 case of a male participant or beneficiary who is 50  
3 years of age or older, or who is younger than 50  
4 years of age and is at high risk for prostate cancer  
5 (including African American men or a male who has  
6 a history of prostate cancer in a first degree family  
7 member), the procedures described in section  
8 1861(oo)(2) of the Social Security Act (42 U.S.C.  
9 1395x(oo)(2)) shall be furnished to the individual  
10 for the early detection of prostate cancer. The group  
11 health plan or health insurance issuer shall provide  
12 coverage for the method and frequency of prostate  
13 cancer screening determined to be appropriate by a  
14 health care provider treating such participant or  
15 beneficiary, in consultation with the participant or  
16 beneficiary.

17           “(6) TOBACCO THERAPY AND COUNSELING.—

18           “(A) IN GENERAL.—Therapy and coun-  
19 seling for cessation of tobacco use for individ-  
20 uals who use tobacco products or who are being  
21 treated for tobacco use that is furnished—

22                   “(i) by or under the supervision of a  
23 physician; or

24                   “(ii) by any other health care profes-  
25 sional who—

1                   “(I) is legally authorized to fur-  
2                   nish such services under State law (or  
3                   the State regulatory mechanism pro-  
4                   vided by State law) of the State in  
5                   which the services are furnished; and

6                   “(II) for medicare beneficiaries,  
7                   is authorized to receive payment for  
8                   other services under this title or is  
9                   designated by the Secretary for this  
10                  purpose.

11                 “(B) LIMITATION.—Subject to subpara-  
12                 graph (C), such therapy and counseling are lim-  
13                 ited to—

14                   “(i) therapy and counseling services  
15                   recommended in ‘Treating Tobacco Use  
16                   and Dependence: A Clinical Practice  
17                   Guideline’, published by the Public Health  
18                   Service in June 2000, or any subsequent  
19                   modification of such Guideline; and

20                   “(ii) such other therapy and coun-  
21                   seling services that the Secretary recog-  
22                   nizes to be effective.

23                 “(C) EXCLUSION.—Such therapy and  
24                 counseling shall not include coverage for drugs

1           or biologicals that are not otherwise covered  
2           under the plan or coverage.

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

9           “(8) GENETIC TESTS AND GENETIC SERV-  
10          ICES.—

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

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

20           “(i) FAMILY MEMBER.—The term  
21          ‘family member’ means with respect to an  
22          individual—

23                   “(I) the spouse of the individual;

24                   “(II) a dependent child of the in-  
25          dividual, including a child who is born



1 to or placed for adoption with the in-  
2 dividual; and

3 “(III) all other individuals re-  
4 lated by blood to the individual or the  
5 spouse or child described in subclause  
6 (I) or (II).

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

16 “(iii) GENETIC SERVICES.—The term  
17 ‘genetic services’ means health services, in-  
18 cluding genetic tests, provided to obtain,  
19 assess, or interpret genetic information for  
20 diagnostic and therapeutic purposes, and  
21 for genetic education and counseling.

22 “(iv) GENETIC TEST.—The term ‘ge-  
23 netic test’ means the analysis of human  
24 DNA, RNA, chromosomes, proteins, and  
25 certain metabolites in order to detect

1 genotypes, mutations, or chromosomal  
2 changes.

3 “(v) PREDICTIVE GENETIC INFORMA-  
4 TION.—

5 “(I) IN GENERAL.—The term  
6 ‘predictive genetic information’  
7 means—

8 “(aa) information about an  
9 individual’s genetic tests;

10 “(bb) information about ge-  
11 netic tests of family members of  
12 the individual; or

13 “(cc) information about the  
14 occurrence of a disease or dis-  
15 order in family members.

16 “(II) LIMITATIONS.—The term  
17 ‘predictive genetic information’ shall  
18 not include—

19 “(aa) information about the  
20 sex or age of the individual;

21 “(bb) information about  
22 chemical, blood, or urine analyses  
23 of the individual, unless these  
24 analyses are genetic tests; or

1                   “(cc) information about  
2                   physical exams of the individual,  
3                   and other information relevant to  
4                   determining the current health  
5                   status of the individual.

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

13                  “(b) PROHIBITIONS.—A group health plan, and a  
14                  health insurance issuer offering group health insurance  
15                  coverage in connection with a group health plan, may  
16                  not—

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

21                         “(2) provide monetary payments or rebates to  
22                         individuals to encourage such individuals to accept  
23                         less than the minimum protections available under  
24                         this section;

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

5           “(4) provide incentives (monetary or otherwise)  
6 to a provider to induce such provider to provide care  
7 to an individual participant or beneficiary in a man-  
8 ner inconsistent with this section.

9           “(c) RULES OF CONSTRUCTION.—

10           “(1) Nothing in this section shall be construed  
11 to require an individual who is a participant or bene-  
12 ficiary to undergo a procedure, examination, or test  
13 described in subsection (a).

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

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

1       “(d) NOTICE UNDER GROUP HEALTH PLAN.—The  
2 imposition of the requirement of this section shall be treat-  
3 ed as a material modification in the terms of the plan de-  
4 scribed in section 102(a), for purposes of assuring notice  
5 of such requirements under the plan; except that the sum-  
6 mary description required to be provided under the last  
7 sentence of section 104(b)(1) with respect to such modi-  
8 fication shall be provided by not later than 60 days after  
9 the first day of the first plan year in which such require-  
10 ment apply.

11       “(e) RISK DEFINED.—For purposes of this section,  
12 an individual is considered to be at ‘risk’ of developing  
13 a particular type of cancer if, under guidelines developed  
14 or recognized by the Secretary based upon scientific evi-  
15 dence, the individual—

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

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

19               “(3) has the presence of an appropriate recog-  
20 nized gene marker that is identified as putting the  
21 individual at a higher risk of developing that type of  
22 cancer; or

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

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

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

5 “(a) DISCLOSURE REQUIREMENT.—A group health  
6 plan, and health insurance issuer offering group health in-  
7 surance coverage shall—

8 “(1) provide to participants and beneficiaries at  
9 the time of initial coverage under the plan (or the  
10 effective date of this section, in the case of individ-  
11 uals who are participants or beneficiaries as of such  
12 date), and at least annually thereafter, the informa-  
13 tion described in subsection (b) in printed form;

14 “(2) provide to participants and beneficiaries,  
15 within a reasonable period (as specified by the ap-  
16 propriate Secretary) before or after the date of sig-  
17 nificant changes in the information described in sub-  
18 section (b), information in printed form regarding  
19 such significant changes; and

20 “(3) upon request, make available to partici-  
21 pants and beneficiaries, the applicable authority, and  
22 prospective participants and beneficiaries, the infor-  
23 mation described in subsection (b) in printed form.

24 “(b) INFORMATION PROVIDED.—The information de-  
25 scribed in subsection (a) that shall be disclosed includes

1 the following, as such relates to cancer screening required  
2 under section 715(a):

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

5 “(A) covered benefits, including benefit  
6 limits and coverage exclusions;

7 “(B) cost-sharing, such as deductibles, co-  
8 insurance, and copayment amounts, including  
9 any liability for balance billing, any maximum  
10 limitations on out of pocket expenses, and the  
11 maximum out of pocket costs for services that  
12 are provided by nonparticipating providers or  
13 that are furnished without meeting the applica-  
14 ble utilization review requirements;

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

17 “(D) the extent to which a participant,  
18 beneficiary, or enrollee may select from among  
19 participating providers and the types of pro-  
20 viders participating in the plan or issuer net-  
21 work.

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

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

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

3           “(C) Any point-of-service option (including  
4           any supplemental premium or cost-sharing for  
5           such option).

6           “(D) The procedures for participants,  
7           beneficiaries, and enrollees to select, access, and  
8           change participating primary and specialty pro-  
9           viders.

10          “(E) The rights and procedures for obtain-  
11          ing referrals (including standing referrals) to  
12          participating and nonparticipating providers.

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

17          “(G) How the plan or issuer addresses the  
18          needs of participants, beneficiaries, and enroll-  
19          ees and others who do not speak English or  
20          who have other special communications needs in  
21          accessing providers under the plan or coverage,  
22          including the provision of information under  
23          this subsection.”.

24                   (B) TECHNICAL AMENDMENTS.—



1 (i) Section 731(c) of the Employee  
2 Retirement Income Security Act of 1974  
3 (29 U.S.C. 1191(c)) is amended by strik-  
4 ing “section 711” and inserting “sections  
5 711 and 715”.

6 (ii) Section 732(a) of the Employee  
7 Retirement Income Security Act of 1974  
8 (29 U.S.C. 1191a(a)) is amended by strik-  
9 ing “section 711” and inserting “sections  
10 711 and 715”.

11 (iii) The table of contents in section 1  
12 of the Employee Retirement Income Secu-  
13 rity Act of 1974, as amended by section  
14 302, is further amended by inserting after  
15 the item relating to section 714 the fol-  
16 lowing new items:

“Sec. 715. Coverage of cancer screening.

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

17 (b) INDIVIDUAL HEALTH INSURANCE.—

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

1 **“SEC. 2754. STANDARD RELATING PATIENT FREEDOM OF**  
2 **CHOICE.**

3 “(a) IN GENERAL.—The provisions of section 2708  
4 (other than subsection (d)) shall apply to health insurance  
5 coverage offered by a health insurance issuer in the indi-  
6 vidual market with respect to an enrollee under such cov-  
7 erage in the same manner as they apply to health insur-  
8 ance coverage offered by a health insurance issuer in con-  
9 nection with a group health plan in the small or large  
10 group market to a participant or beneficiary in such plan.

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

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

18 “The provisions of section 2709 shall apply health in-  
19 surance coverage offered by a health insurance issuer in  
20 the individual market with respect to an enrollee under  
21 such coverage in the same manner as they apply to health  
22 insurance coverage offered by a health insurance issuer  
23 in connection with a group health plan in the small or  
24 large group market to a participant or beneficiary in such  
25 plan.”.

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

5           (c) EFFECTIVE DATES.—

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

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

15          (3) COLLECTIVE BARGAINING AGREEMENT.—In  
16          the case of a group health plan maintained pursuant  
17          to 1 or more collective bargaining agreements be-  
18          tween employee representatives and 1 or more em-  
19          ployers ratified before the date of enactment of this  
20          Act, the amendments made to subsection (a) shall  
21          not apply to plan years beginning before the later  
22          of—

23                 (A) the date on which the last collective  
24                 bargaining agreements relating to the plan ter-  
25                 minates (determined without regard to any ex-

1           tension thereof agreed to after the date of en-  
2           actment of this Act), or

3                   (B) January 1, 2004.

4           For purposes of subparagraph (A), any plan amend-  
5           ment made pursuant to a collective bargaining  
6           agreement relating to the plan which amends the  
7           plan solely to conform to any requirement added by  
8           subsection (a) shall not be treated as a termination  
9           of such collective bargaining agreement.

10          (d) COORDINATED REGULATIONS.—Section 104(1)  
11 of the Health Insurance Portability and Accountability  
12 Act of 1996 (Public Law 104–191) is amended by striking  
13 “this subtitle (and the amendments made by this subtitle  
14 and section 401)” and inserting “the provisions of part  
15 7 of subtitle B of title I of the Employee Retirement In-  
16 come Security Act of 1974, the provisions of parts A and  
17 C of title XXVII of the Public Health Service Act, and  
18 chapter 100 of the Internal Revenue Code of 1986”.

19          (e) MODIFICATION OF COVERAGE.—

20               (1) IN GENERAL.—The Secretary of Health and  
21           Human Services may modify the coverage require-  
22           ments for the amendments under this subtitle to  
23           allow such requirements to incorporate and reflect  
24           new scientific and technological advances regarding  
25           cancer screening, practice pattern changes in such

1 screening, or other updated medical practices re-  
2 garding such screening, such as the use of new tests  
3 or other emerging technologies. Such modifications  
4 shall not in any way diminish the coverage require-  
5 ments listed under this subtitle. Such modifications  
6 may be made on the Secretary's own initiative or  
7 upon petition to the Secretary by an individual or  
8 organization.

9 (2) CONSULTATION.—In modifying coverage re-  
10 quirements under paragraph (1), the Secretary of  
11 Health and Human Services shall consult with ap-  
12 propriate organizations, experts, and agencies.

13 (3) PETITIONS.—The Secretary of Health and  
14 Human Services may issue requirements for the pe-  
15 titioning process under paragraph (1), including re-  
16 quirements that the petition be in writing and in-  
17 clude scientific or medical bases for the modification  
18 sought. Upon receipt of such a petition, the Sec-  
19 retary shall respond to the petitioner and decide  
20 whether to propose a regulation proposing a change  
21 within 90 days of such receipt. If a regulation is re-  
22 quired, the Secretary shall propose such regulation  
23 within 6 months of such determination. The Sec-  
24 retary shall provide the petitioner the reasons for  
25 the decision of the Secretary. The Secretary may

1 make changes requested by a petitioner in whole or  
2 in part.

3 **Subtitle C—Physicians and Quality**  
4 **of Care**

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

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

12 **“SEC. 2710. MANAGING PHYSICIANS AND QUALITY OF CARE**  
13 **FOR CANCER PATIENTS.**

14 “(a) MANAGING PHYSICIAN.—A group health plan,  
15 or health insurance issuer that is providing health insur-  
16 ance coverage, shall ensure that with respect to items or  
17 services provided under the plan or coverage relating to  
18 the treatment of cancer, a lead managing physician be des-  
19 ignated at the time of diagnosis by the provider and paid  
20 a bonus by the plan, in consultation with the participant  
21 or beneficiary, and other providers involved to provide for  
22 the overall coordination and management of the cancer  
23 care of the participant or beneficiary among all providers  
24 who provide items or services to the participant or bene-  
25 ficiary and paid for overall coordination of services.

1       “(b) QUALITY OF CARE.—A group health plan, or  
2 health insurance issuer that is providing health insurance  
3 coverage, shall require that all participating health care  
4 professionals who provide primary care cancer services fol-  
5 low the most current quality-of-care cancer care guide-  
6 lines, as developed by medical professionals with expertise  
7 in the field of medicine for which the guidelines are de-  
8 signed and widely recognized as medically necessary and  
9 appropriate.

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

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

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

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

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

5           “(d) RULES OF CONSTRUCTION.—Nothing in this  
6           section shall be construed as preventing a group health  
7           plan or issuer from imposing deductibles, coinsurance, or  
8           other cost-sharing in relation to benefits described in sub-  
9           sections (a) or (b) consistent with such subsections, except  
10          that such coinsurance or other cost-sharing shall not dis-  
11          criminate on any basis related to the coverage required  
12          under this section.

13          “(e) NOTICE.—A group health plan under this part  
14          shall comply with the notice requirement under section  
15          714(d) of the Employee Retirement Income Security Act  
16          of 1974 with respect to the requirements of this section  
17          as if such section applied to such plan.”.

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

21          **“SEC. 2756. MANAGING PHYSICIANS AND QUALITY OF CARE**  
22   **FOR CANCER PATIENTS.**

23          “The provisions of section 2710 shall apply to health  
24          insurance coverage offered by a health insurance issuer  
25          in the individual market in the same manner as such pro-



1 visions apply to health insurance coverage offered by a  
2 health insurance issuer in connection with a group health  
3 plan.”.

4 **SEC. 322. MANAGING PHYSICIANS AND QUALITY OF CARE**  
5 **FOR CANCER PATIENTS UNDER THE EM-**  
6 **PLOYEE RETIREMENT INCOME SECURITY**  
7 **ACT OF 1974.**

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

13 **“SEC. 717. MANAGING PHYSICIANS AND QUALITY OF CARE**  
14 **FOR CANCER PATIENTS.**

15 “(a) MANAGING PHYSICIAN.—A group health plan,  
16 or health insurance issuer that is providing health insur-  
17 ance coverage, shall ensure that with respect to items or  
18 services provided under the plan or coverage relating to  
19 the treatment of cancer, a lead managing physician be des-  
20 ignated at the time of diagnosis by the participant or bene-  
21 ficiary involved to provide for the overall coordination and  
22 management of the cancer care of the participant or bene-  
23 ficiary among all providers who provide items or services  
24 to the participant or beneficiary and paid for overall co-  
25 ordination of services.

1       “(b) QUALITY OF CARE.—A group health plan, or  
2 health insurance issuer that is providing health insurance  
3 coverage, shall require that all participating health care  
4 professionals who provide primary care cancer services fol-  
5 low the most current quality-of-care cancer care guide-  
6 lines, as developed by medical professionals with expertise  
7 in the field of medicine for which the guidelines are de-  
8 signed and widely recognized as medically necessary and  
9 appropriate.

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

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

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

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

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

5           “(d) RULES OF CONSTRUCTION.—Nothing in this  
6 section shall be construed as preventing a group health  
7 plan or issuer from imposing deductibles, coinsurance, or  
8 other cost-sharing in relation to benefits described in sub-  
9 sections (a) or (b) consistent with such subsections, except  
10 that such coinsurance or other cost-sharing shall not dis-  
11 criminate on any basis related to the coverage required  
12 under this section.

13           “(e) NOTICE.—A group health plan under this part  
14 shall comply with the notice requirement under section  
15 714(d) of the Employee Retirement Income Security Act  
16 of 1974 with respect to the requirements of this section  
17 as if such section applied to such plan.”.

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

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

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

3 (a) APPLICATION OF CANCER COVERAGE REQUIRE-  
4 MENTS.—Part B of title XVIII of the Social Security Act  
5 (42 U.S.C. 1395j et seq.) is amended by adding at the  
6 end the following:

7 “APPLICATION OF CANCER COVERAGE REQUIREMENTS  
8 “SEC. 1849. The provisions of sections 2707, 2708,  
9 and 2710 of the Public Health Service Act shall apply to  
10 an individual who has been diagnosed with cancer and who  
11 is covered under the insurance program established under  
12 this part.”.

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

15 (1) by inserting “(1)” after “(m)”; and  
16 (2) by adding at the end the following new  
17 paragraph:

18 “(2) In the case of physicians’ services furnished to  
19 an individual who has been diagnosed with cancer, who  
20 is covered under the insurance program established under  
21 this part who receives care for such cancer from a team  
22 of physicians, and who incurs expenses for physicians’  
23 services that are related to that diagnosis, there shall be  
24 paid to the physician designated by such team of physi-  
25 cians at the time of diagnosis of the individual as the phy-  
26 sician responsible for the overall coordination and manage-

1 ment of the medical and other health services provided to  
2 that individual during the period in which that individual  
3 is undergoing treatment for such cancer (or to an em-  
4 ployer or facility in the cases described in subparagraph  
5 (A) of section 1842(b)(6)) (on a monthly or quarterly  
6 basis) from the Federal Supplementary Medical Insurance  
7 Trust Fund a separate and additional payment amount  
8 for the services under this part in addition to any amount  
9 otherwise paid under this part.”.

10 **SEC. 324. MANAGING PHYSICIANS AND QUALITY OF CARE**  
11 **FOR CANCER PATIENTS UNDER MEDICAID**  
12 **AND SCHIP.**

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

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

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

19 (3) by inserting after paragraph (65) the fol-  
20 lowing:

21 “(66) provide—

22 “(A) that the provisions of sections 2707,  
23 2708, and 2710 of the Public Health Service  
24 Act shall apply to individuals eligible for med-

1           ical assistance under the State plan who have  
2           been diagnosed with cancer; and

3                   “(B) that, in the case of an individual who  
4           has been diagnosed with cancer, who is eligible  
5           for medical assistance under this title, and who  
6           receives care for such cancer from a team of  
7           physicians, and who incurs expenses for physi-  
8           cians’ services that are related to that diag-  
9           nosis, that there shall be paid to the physician  
10          designated by such team of physicians at the  
11          time of diagnosis of the individual as the physi-  
12          cian responsible for the overall coordination and  
13          management of the medical and other health  
14          services provided to that individual during the  
15          period in which that individual is undergoing  
16          treatment for such cancer, a separate and addi-  
17          tional payment amount for the services provided  
18          in addition to any amount otherwise paid under  
19          the State plan.”.

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

23                   “(3) APPLICATION OF CANCER COVERAGE PRO-  
24          VISIONS.—

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

5           “(B) ADDITIONAL PAYMENT.—The State  
6           child health plan shall provide in the case of an  
7           individual who has been diagnosed with cancer,  
8           who is eligible for child health assistance under  
9           this title, and who receives care for such cancer  
10          from a team of physicians, and who incurs ex-  
11          penses for physicians’ services that are related  
12          to that diagnosis, that there shall be paid to the  
13          physician designated by such team of physicians  
14          at the time of diagnosis of the individual as the  
15          physician responsible for the overall coordina-  
16          tion and management of the medical and other  
17          health services provided to that individual dur-  
18          ing the period in which that individual is under-  
19          going treatment for such cancer, a separate and  
20          additional payment amount for the services pro-  
21          vided in addition to any amount otherwise paid  
22          under the State child health plan.”.

## 1       **Subtitle D—General Provisions**

### 2       **SEC. 331. COVERAGE UNDER OTHER PUBLIC HEALTH IN-** 3                                   **SURANCE.**

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

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

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

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

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

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

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

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

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

24                  (1) the coverage described in section 2708 of  
25 the Public Health Service Act (as added by section



1 311) for individuals participating in cancer screening  
2 activities; and

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

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

10 **“§ 8915. Standards relating to coverage of cancer-re-**  
11 **lated activities**

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

15 “(b) Nothing in this section or section 2707, 2708,  
16 2709, or 2710 of the Public Health Service Act shall be  
17 construed as authorizing a health insurance issuer or enti-  
18 ty to impose cost-sharing with respect to the coverage or  
19 benefits required to be provided under such sections that  
20 is inconsistent with the cost-sharing that is otherwise per-  
21 mitted under this chapter.”.

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

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

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

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

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

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

22 “(1) IN GENERAL.—The Secretary, acting  
23 through the Administrator of the Health Resources  
24 and Services Administration, may make grants to  
25 public and nonprofit private health centers (includ-

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

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

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

1 the services of the model program under the grant.  
2 Such activities shall include facilitating access to ap-  
3 propriate health care services and patient navigators  
4 within the health care system to ensure optimal pa-  
5 tient utilization of such services.

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

1 provides information on needs for navigation serv-  
2 ices, types of access difficulties resolved, sources of  
3 repeated resolution, and flaws in the system of ac-  
4 cess, including insurance barriers.

5 “(5) EVALUATIONS.—

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

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

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

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

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

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

7           “(c) PROGRAM FOR PATIENT NAVIGATORS.—

8           “(1) IN GENERAL.—The Secretary, acting  
9 through the Administrator of the Health Resources  
10 and Services Administration, may make grants to  
11 public and nonprofit private health centers (includ-  
12 ing health centers under section 330, Indian Health  
13 Service Centers, tribal governments, urban Indian  
14 organizations, tribal organizations, clinics serving  
15 Asian Americans and Pacific Islanders and Alaskan  
16 Natives, rural health clinics, and qualified nonprofit  
17 entities that partner with 1 or more centers pro-  
18 viding health care to provide navigation services,  
19 that demonstrate the ability to perform all of the  
20 functions outlined in this subsection and subsections  
21 (b) and (d)) for the development and operation of  
22 programs to pay the costs of such health centers in  
23 carrying out the same activities outlined in section  
24 417E–10(c)(1).

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

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

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

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

16 “(5) EVALUATIONS.—

17 “(A) IN GENERAL.—The Secretary, acting  
18 through the Administrator of the Health Re-  
19 sources and Services Administration, shall, di-  
20 rectly or through grants or contracts, provide  
21 for evaluations to determine the effects of the  
22 services of patient navigators on the individuals  
23 of health disparity populations for whom the  
24 services were provided, taking into account the



1 matters referred to in section 417E–  
2 10(c)(1)(C).

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

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

11 “(d) REQUIREMENTS REGARDING FEES.—

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

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

23 “(B) a corresponding schedule of discounts  
24 to be applied to the payment of such fees or

1           payments, which discounts are adjusted on the  
2           basis of the ability of the patient to pay.

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

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

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

25          “(g) AUTHORIZATION OF APPROPRIATIONS.—

1 “(1) IN GENERAL.—

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

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

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

16 “(2) PROGRAMS IN RURAL AREAS.—

17 “(A) MODEL PROGRAMS.—For the purpose  
18 of carrying out subsection (b) in making grants  
19 under such subsection for model 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 “(B) PATIENT NAVIGATORS.—For the pur-  
24 pose of carrying out subsection (c) in making  
25 grants under such subsection for programs in

1 rural areas, there are authorized to be appro-  
2 priated such sums as may be necessary for each  
3 of the fiscal years 2004 through 2008.

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

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

○