

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 2327
OFFERED BY MR BOEHNER OF OHIO**

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Comprehensive Access and Responsibility in Health Care Act of 1999”.

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

Sec. 1. Short title and table of contents.

**TITLE I—AMENDMENTS TO THE EMPLOYEE RETIREMENT
INCOME SECURITY ACT OF 1974**

Subtitle A—Patient Protections

Sec. 101. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.

Sec. 102. Required disclosure to network providers.

Sec. 103. Effective date and related rules.

Subtitle B—Patient Access to Information

Sec. 111. Patient access to information regarding plan coverage, managed care procedures, health care providers, and quality of medical care.-

Sec. 112. Effective date and related rules.

Subtitle C—Group Health Plan Review Standards

Sec. 121. Special rules for group health plans.

Sec. 122. Special rule for access to specialty care.

Sec. 123. Protection for certain information developed to reduce mortality or morbidity or for improving patient care and safety.

Sec. 124. Effective date.

Subtitle E—Health Care Access, Affordability, and Quality Commission

Sec. 131. Establishment of commission.

Sec. 132. Effective date.

TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

Sec. 201. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.

Sec. 202. Requiring health maintenance organizations to offer option of point-of-service coverage.

Sec. 203. Effective date and related rules.

Subtitle B—Patient Access to Information

Sec. 211. Patient access to information regarding plan coverage, managed care procedures, health care providers, and quality of medical care.

Sec. 212. Effective date and related rules.

TITLE III—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

Sec. 301. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.

TITLE IV—HEALTH CARE LAWSUIT REFORM

Subtitle A—General Provisions

Sec. 401. Federal reform of health care liability actions.

Sec. 402. Definitions.

Sec. 403. Effective date.

Subtitle B—Uniform Standards for Health Care Liability Actions

Sec. 411. Statute of limitations.

Sec. 412. Calculation and payment of damages.

Sec. 413. Alternative dispute resolution.

Sec. 414. Reporting on fraud and abuse enforcement activities.

1 **TITLE I—AMENDMENTS TO THE**
2 **EMPLOYEE RETIREMENT IN-**
3 **COME SECURITY ACT OF 1974**
4 **Subtitle A—Patient Protections**

5 **SEC. 101. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
6 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
7 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
8 **ATRIC CARE, AND CONTINUITY OF CARE.**

9 (a) IN GENERAL.—Subpart B of part 7 of subtitle
10 B of title I of the Employee Retirement Income Security
11 Act of 1974 is amended by adding at the end the following
12 new section:

13 **“SEC. 714. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
14 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
15 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
16 **ATRIC CARE, AND CONTINUITY OF CARE.**

17 **“(a) PATIENT ACCESS TO UNRESTRICTED MEDICAL**
18 **ADVICE.—**

19 **“(1) IN GENERAL.—**In the case of any health
20 care professional acting within the lawful scope of
21 practice in the course of carrying out a contractual
22 employment arrangement or other direct contractual
23 arrangement between such professional and a group
24 health plan or a health insurance issuer offering
25 health insurance coverage in connection with a group

1 health plan, the plan or issuer with which such con-
2 tractual employment arrangement or other direct
3 contractual arrangement is maintained by the pro-
4 fessional may not impose on such professional under
5 such arrangement any prohibition or restriction with
6 respect to advice, provided to a participant or bene-
7 ficiary under the plan who is a patient, about the
8 health status of the participant or beneficiary or the
9 medical care or treatment for the condition or dis-
10 ease of the participant or beneficiary, regardless of
11 whether benefits for such care or treatment are pro-
12 vided under the plan or health insurance coverage
13 offered in connection with the plan.

14 “(2) HEALTH CARE PROFESSIONAL DEFINED.—
15 For purposes of this paragraph, the term ‘health
16 care professional’ means a physician (as defined in
17 section 1861(r) of the Social Security Act) or other
18 health care professional if coverage for the profes-
19 sional’s services is provided under the group health
20 plan for the services of the professional. Such term
21 includes a podiatrist, optometrist, chiropractor, psy-
22 chologist, dentist, physician assistant, physical or oc-
23 cupational therapist and therapy assistant, speech-
24 language pathologist, audiologist, registered or li-
25 censed practical nurse (including nurse practitioner,

1 clinical nurse specialist, certified registered nurse
2 anesthetist, and certified nurse-midwife), licensed
3 certified social worker, registered respiratory thera-
4 pist, and certified respiratory therapy technician.

5 “(3) RULE OF CONSTRUCTION.—Nothing in
6 this subsection shall be construed to require the
7 sponsor of a group health plan or a health insurance
8 issuer offering health insurance coverage in connec-
9 tion with the group health plan to engage in any
10 practice that would violate its religious beliefs or
11 moral convictions.

12 “(b) PATIENT ACCESS TO EMERGENCY MEDICAL
13 CARE.—

14 “(1) COVERAGE OF EMERGENCY SERVICES.—

15 “(A) IN GENERAL.—If a group health
16 plan, or health insurance coverage offered by a
17 health insurance issuer, provides any benefits
18 with respect to emergency services (as defined
19 in subparagraph (B)(ii)), or ambulance services,
20 the plan or issuer shall cover emergency serv-
21 ices (including emergency ambulance services as
22 defined in subparagraph (B)(iii)) furnished
23 under the plan or coverage—

24 “(i) without the need for any prior
25 authorization determination;

1 “(ii) whether or not the health care
2 provider furnishing such services is a par-
3 ticipating provider with respect to such
4 services;

5 “(iii) in a manner so that, if such
6 services are provided to a participant or
7 beneficiary by a nonparticipating health
8 care provider, the participant or bene-
9 ficiary is not liable for amounts that ex-
10 ceed the amounts of liability that would be
11 incurred if the services were provided by a
12 participating provider; and

13 “(iv) without regard to any other term
14 or condition of such plan or coverage
15 (other than exclusion or coordination of
16 benefits, or an affiliation or waiting period,
17 permitted under section 701 and other
18 than applicable cost sharing).

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

20 “(i) EMERGENCY MEDICAL CONDI-
21 TION.—The term ‘emergency medical con-
22 dition’ means—

23 “(I) a medical condition mani-
24 festing itself by acute symptoms of
25 sufficient severity (including severe

1 pain) such that a prudent layperson,
2 who possesses an average knowledge
3 of health and medicine, could reason-
4 ably expect the absence of immediate
5 medical attention to result in a condi-
6 tion described in clause (i), (ii), or
7 (iii) of section 1867(e)(1)(A) of the
8 Social Security Act (42 U.S.C.
9 1395dd(e)(1)(A)); and

10 “(II) a medical condition mani-
11 festing itself in a neonate by acute
12 symptoms of sufficient severity (in-
13 cluding severe pain) such that a pru-
14 dent health care professional could
15 reasonably expect the absence of im-
16 mediate medical attention to result in
17 a condition described in clause (i),
18 (ii), or (iii) of section 1867(e)(1)(A)
19 of the Social Security Act.

20 “(ii) EMERGENCY SERVICES.—The
21 term ‘emergency services’ means—

22 “(I) with respect to an emer-
23 gency medical condition described in
24 clause (i)(I), a medical screening ex-
25 amination (as required under section

1 1867 of the Social Security Act, 42
2 U.S.C. 1395dd)) that is within the ca-
3 pability of the emergency department
4 of a hospital, including ancillary serv-
5 ices routinely available to the emer-
6 gency department to evaluate an
7 emergency medical condition (as de-
8 fined in clause (i)) and also, within
9 the capabilities of the staff and facili-
10 ties at the hospital, such further med-
11 ical examination and treatment as are
12 required under section 1867 of such
13 Act to stabilize the patient; or

14 “(II) with respect to an emer-
15 gency medical condition described in
16 clause (i)(II), medical treatment for
17 such condition rendered by a health
18 care provider in a hospital to a
19 neonate, including available hospital
20 ancillary services in response to an ur-
21 gent request of a health care profes-
22 sional and to the extent necessary to
23 stabilize the neonate.

24 “(iii) EMERGENCY AMBULANCE SERV-
25 ICES.—The term ‘emergency ambulance

1 services' means ambulance services (as de-
2 fined for purposes of section 1861(s)(7) of
3 the Social Security Act) furnished to trans-
4 port an individual who has an emergency
5 medical condition (as defined in clause (i))
6 to a hospital for the receipt of emergency
7 services (as defined in clause (ii)) in a case
8 in which appropriate emergency medical
9 screening examinations are covered under
10 the plan or coverage pursuant to para-
11 graph (1)(A) and a prudent layperson,
12 with an average knowledge of health and
13 medicine, could reasonably expect that the
14 absence of such transport would result in
15 placing the health of the individual in seri-
16 ous jeopardy, serious impairment of bodily
17 function, or serious dysfunction of any
18 bodily organ or part.

19 “(iv) STABILIZE.—The term ‘to sta-
20 bilize’ means, with respect to an emergency
21 medical condition, to provide such medical
22 treatment of the condition as may be nec-
23 essary to assure, within reasonable medical
24 probability, that no material deterioration
25 of the condition is likely to result from or

1 occur during the transfer of the individual
2 from a facility.

3 “(v) NONPARTICIPATING.—The term
4 ‘nonparticipating’ means, with respect to a
5 health care provider that provides health
6 care items and services to a participant or
7 beneficiary under group health plan or
8 under group health insurance coverage, a
9 health care provider that is not a partici-
10 pating health care provider with respect to
11 such items and services.

12 “(vi) PARTICIPATING.—The term
13 ‘participating’ means, with respect to a
14 health care provider that provides health
15 care items and services to a participant or
16 beneficiary under group health plan or
17 health insurance coverage offered by a
18 health insurance issuer in connection with
19 such a plan, a health care provider that
20 furnishes such items and services under a
21 contract or other arrangement with the
22 plan or issuer.

23 “(c) PATIENT RIGHT TO OBSTETRIC AND GYNECO-
24 LOGICAL CARE.—

1 “(1) IN GENERAL.—In any case in which a
2 group health plan (or a health insurance issuer of-
3 fering health insurance coverage in connection with
4 the plan)—

5 “(A) provides benefits under the terms of
6 the plan consisting of—

7 “(i) gynecological care (such as pre-
8 ventive women’s health examinations); or

9 “(ii) obstetric care (such as preg-
10 nancy-related services),

11 provided by a participating health care profes-
12 sional who specializes in such care (or provides
13 benefits consisting of payment for such care);
14 and

15 “(B) requires or provides for designation
16 by a participant or beneficiary of a partici-
17 pating primary care provider,

18 if the primary care provider designated by such a
19 participant or beneficiary is not such a health care
20 professional, then the plan (or issuer) shall meet the
21 requirements of paragraph (2).

22 “(2) REQUIREMENTS.—A group health plan (or
23 a health insurance issuer offering health insurance
24 coverage in connection with the plan) meets the re-
25 quirements of this paragraph, in connection with

1 benefits described in paragraph (1) consisting of
2 care described in clause (i) or (ii) of paragraph
3 (1)(A) (or consisting of payment therefor), if the
4 plan (or issuer)—

5 “(A) does not require authorization or a
6 referral by the primary care provider in order
7 to obtain such benefits; and

8 “(B) treats the ordering of other care of
9 the same type, by the participating health care
10 professional providing the care described in
11 clause (i) or (ii) of paragraph (1)(A), as the au-
12 thorization of the primary care provider with
13 respect to such care.

14 “(3) HEALTH CARE PROFESSIONAL DEFINED.—
15 For purposes of this subsection, the term ‘health
16 care professional’ means an individual (including,
17 but not limited to, a nurse midwife or nurse practi-
18 tioner) who is licensed, accredited, or certified under
19 State law to provide obstetric and gynecological
20 health care services and who is operating within the
21 scope of such licensure, accreditation, or certifi-
22 cation.

23 “(4) CONSTRUCTION.—Nothing in paragraph
24 (1) shall be construed as preventing a plan from of-
25 fering (but not requiring a participant or beneficiary

1 to accept) a health care professional trained,
2 credentialed, and operating within the scope of their
3 licensure to perform obstetric and gynecological
4 health care services. Nothing in paragraph (2)(B)
5 shall waive any requirements of coverage relating to
6 medical necessity or appropriateness with respect to
7 coverage of gynecological or obstetric care so or-
8 dered.

9 “(5) TREATMENT OF MULTIPLE COVERAGE OP-
10 TIONS.—In the case of a plan providing benefits
11 under two or more coverage options, the require-
12 ments of this subsection shall apply separately with
13 respect to each coverage option.

14 “(d) PATIENT RIGHT TO PEDIATRIC CARE.—

15 “(1) IN GENERAL.—In any case in which a
16 group health plan (or a health insurance issuer of-
17 fering health insurance coverage in connection with
18 the plan) provides benefits consisting of routine pe-
19 diatric care provided by a participating health care
20 professional who specializes in pediatrics (or con-
21 sisting of payment for such care) and the plan re-
22 quires or provides for designation by a participant or
23 beneficiary of a participating primary care provider,
24 the plan (or issuer) shall provide that such a partici-
25 pating health care professional may be designated, if

1 available, by a parent or guardian of any beneficiary
2 under the plan is who under 18 years of age, as the
3 primary care provider with respect to any such bene-
4 fits.

5 “(2) HEALTH CARE PROFESSIONAL DEFINED.—
6 For purposes of this subsection, the term ‘health
7 care professional’ means an individual (including,
8 but not limited to, a nurse practitioner) who is li-
9 censed, accredited, or certified under State law to
10 provide pediatric health care services and who is op-
11 erating within the scope of such licensure, accredita-
12 tion, or certification.

13 “(3) CONSTRUCTION.—Nothing in paragraph
14 (1) shall be construed as preventing a plan from of-
15 fering (but not requiring a participant or beneficiary
16 to accept) a health care professional trained,
17 credentialed, and operating within the scope of their
18 licensure to perform pediatric health care services.
19 Nothing in paragraph (1) shall waive any require-
20 ments of coverage relating to medical necessity or
21 appropriateness with respect to coverage of pediatric
22 care so ordered.

23 “(4) TREATMENT OF MULTIPLE COVERAGE OP-
24 TIONS.—In the case of a plan providing benefits
25 under two or more coverage options, the require-

1 ments of this subsection shall apply separately with
2 respect to each coverage option.

3 “(e) CONTINUITY OF CARE.—

4 “(1) IN GENERAL.—

5 “(A) TERMINATION OF PROVIDER.—If a
6 contract between a group health plan, or a
7 health insurance issuer offering health insur-
8 ance coverage in connection with a group health
9 plan, and a health care provider is terminated
10 (as defined in subparagraph (D)(ii)), or benefits
11 or coverage provided by a health care provider
12 are terminated because of a change in the
13 terms of provider participation in a group
14 health plan, and an individual who, at the time
15 of such termination, is a participant or bene-
16 ficiary in the plan and is scheduled to undergo
17 surgery (including an organ transplantation), is
18 undergoing treatment for pregnancy, or is de-
19 termined to be terminally ill (as defined in sec-
20 tion 1861(dd)(3)(A) of the Social Security Act)
21 and is undergoing treatment for the terminal
22 illness, the plan or issuer shall—

23 “(i) notify the individual on a timely
24 basis of such termination and of the right
25 to elect continuation of coverage of treat-

1 ment by the provider under this sub-
2 section; and

3 “(ii) subject to paragraph (3), permit
4 the individual to elect to continue to be
5 covered with respect to treatment by the
6 provider for such surgery, pregnancy, or
7 illness during a transitional period (pro-
8 vided under paragraph (2)).

9 “(B) TREATMENT OF TERMINATION OF
10 CONTRACT WITH HEALTH INSURANCE
11 ISSUER.—If a contract for the provision of
12 health insurance coverage between a group
13 health plan and a health insurance issuer is ter-
14 minated and, as a result of such termination,
15 coverage of services of a health care provider is
16 terminated with respect to an individual, the
17 provisions of subparagraph (A) (and the suc-
18 ceeding provisions of this subsection) shall
19 apply under the plan in the same manner as if
20 there had been a contract between the plan and
21 the provider that had been terminated, but only
22 with respect to benefits that are covered under
23 the plan after the contract termination.

24 “(C) TERMINATION DEFINED.—For pur-
25 poses of this subsection, the term ‘terminated’

1 includes, with respect to a contract, the expira-
2 tion or nonrenewal of the contract, but does not
3 include a termination of the contract by the
4 plan or issuer for failure to meet applicable
5 quality standards or for fraud.

6 “(2) TRANSITIONAL PERIOD.—

7 “(A) IN GENERAL.—Except as provided in
8 subparagraphs (B) through (D), the transi-
9 tional period under this paragraph shall extend
10 up to 90 days (as determined by the treating
11 health care professional) after the date of the
12 notice described in paragraph (1)(A)(i) of the
13 provider’s termination.

14 “(B) SCHEDULED SURGERY.—If surgery
15 was scheduled for an individual before the date
16 of the announcement of the termination of the
17 provider status under paragraph (1)(A)(i), the
18 transitional period under this paragraph with
19 respect to the surgery shall extend beyond the
20 period under subparagraph (A) and until the
21 date of discharge of the individual after comple-
22 tion of the surgery.

23 “(C) PREGNANCY.—If—

24 “(i) a participant or beneficiary was
25 determined to be pregnant at the time of

1 a provider's termination of participation,
2 and

3 "(ii) the provider was treating the
4 pregnancy before date of the termination,
5 the transitional period under this paragraph
6 with respect to provider's treatment of the
7 pregnancy shall extend through the provision of
8 post-partum care directly related to the deliv-
9 ery.

10 "(D) TERMINAL ILLNESS.—If—

11 "(i) a participant or beneficiary was
12 determined to be terminally ill (as deter-
13 mined under section 1861(dd)(3)(A) of the
14 Social Security Act) at the time of a pro-
15 vider's termination of participation, and

16 "(ii) the provider was treating the ter-
17 minal illness before the date of termi-
18 nation,

19 the transitional period under this paragraph
20 shall extend for the remainder of the individ-
21 ual's life for care directly related to the treat-
22 ment of the terminal illness or its medical
23 manifestations.

24 "(3) PERMISSIBLE TERMS AND CONDITIONS.—

25 A group health plan or health insurance issuer may

1 condition coverage of continued treatment by a pro-
2 vider under paragraph (1)(A)(i) upon the individual
3 notifying the plan of the election of continued cov-
4 erage and upon the provider agreeing to the fol-
5 lowing terms and conditions:

6 “(A) The provider agrees to accept reim-
7 bursement from the plan or issuer and indi-
8 vidual involved (with respect to cost-sharing) at
9 the rates applicable prior to the start of the
10 transitional period as payment in full (or, in the
11 case described in paragraph (1)(B), at the rates
12 applicable under the replacement plan or issuer
13 after the date of the termination of the contract
14 with the health insurance issuer) and not to im-
15 pose cost-sharing with respect to the individual
16 in an amount that would exceed the cost-shar-
17 ing that could have been imposed if the contract
18 referred to in paragraph (1)(A) had not been
19 terminated.

20 “(B) The provider agrees to adhere to the
21 quality assurance standards of the plan or
22 issuer responsible for payment under subpara-
23 graph (A) and to provide to such plan or issuer
24 necessary medical information related to the
25 care provided.

1 “(C) The provider agrees otherwise to ad-
2 here to such plan’s or issuer’s policies and pro-
3 cedures, including procedures regarding refer-
4 rals and obtaining prior authorization and pro-
5 viding services pursuant to a treatment plan (if
6 any) approved by the plan or issuer.

7 “(D) The provider agrees to provide tran-
8 sitional care to all participants and beneficiaries
9 who are eligible for and elect to have coverage
10 of such care from such provider.

11 “(E) If the provider initiates the termi-
12 nation, the provider has notified the plan within
13 30 days prior to the effective date of the termi-
14 nation of—

15 “(i) whether the provider agrees to
16 permissible terms and conditions (as set
17 forth in this paragraph) required by the
18 plan, and

19 “(ii) if the provider agrees to the
20 terms and conditions, the specific plan
21 beneficiaries and participants undergoing a
22 course of treatment from the provider who
23 the provider believes, at the time of the no-
24 tification, would be eligible for transitional
25 care under this subsection.

1 “(4) CONSTRUCTION.—Nothing in this sub-
2 section shall be construed to—

3 “(A) require the coverage of benefits which
4 would not have been covered if the provider in-
5 volved remained a participating provider, or

6 “(B) prohibit a group health plan from
7 conditioning a provider’s participation on the
8 provider’s agreement to provide transitional
9 care to all participants and beneficiaries eligible
10 to obtain coverage of such care furnished by the
11 provider as set forth under this subsection.

12 “(f) COVERAGE FOR INDIVIDUALS PARTICIPATING IN
13 APPROVED CANCER CLINICAL TRIALS.—

14 “(1) COVERAGE.—

15 “(A) IN GENERAL.—If a group health plan
16 (or a health insurance issuer offering health in-
17 surance coverage in connection with the plan)
18 provides coverage to a qualified individual (as
19 defined in paragraph (2)), the plan or issuer—

20 “(i) may not deny the individual par-
21 ticipation in the clinical trial referred to in
22 paragraph (2)(B);

23 “(ii) subject to paragraphs (2), (3),
24 and (4), may not deny (or limit or impose
25 additional conditions on) the coverage of

1 routine patient costs for items and services
2 furnished in connection with participation
3 in the trial; and

4 “(iii) may not discriminate against the
5 individual on the basis of the participation
6 of the participant or beneficiary in such
7 trial.

8 “(B) EXCLUSION OF CERTAIN COSTS.—
9 For purposes of subparagraph (A)(ii), routine
10 patient costs do not include the cost of the tests
11 or measurements conducted primarily for the
12 purpose of the clinical trial involved.

13 “(C) USE OF IN-NETWORK PROVIDERS.—If
14 one or more participating providers is partici-
15 pating in a clinical trial, nothing in subpara-
16 graph (A) shall be construed as preventing a
17 plan from requiring that a qualified individual
18 participate in the trial through such a partici-
19 pating provider if the provider will accept the
20 individual as a participant in the trial.

21 “(2) QUALIFIED INDIVIDUAL DEFINED.—For
22 purposes of paragraph (1), the term ‘qualified indi-
23 vidual’ means an individual who is a participant or
24 beneficiary in a group health plan and who meets
25 the following conditions:

1 “(A)(i) The individual has been diagnosed
2 with cancer.

3 “(ii) The individual is eligible to partici-
4 pate in an approved clinical trial according to
5 the trial protocol with respect to treatment of
6 cancer.

7 “(iii) The individual’s participation in the
8 trial offers meaningful potential for significant
9 clinical benefit for the individual.

10 “(B) Either—

11 “(i) the referring physician is a par-
12 ticipating health care professional and has
13 concluded that the individual’s participa-
14 tion in such trial would be appropriate
15 based upon satisfaction by the individual of
16 the conditions described in subparagraph
17 (A); or

18 “(ii) the individual provides medical
19 and scientific information establishing that
20 the individual’s participation in such trial
21 would be appropriate based upon the satis-
22 faction by the individual of the conditions
23 described in subparagraph (A).

24 “(3) PAYMENT.—

1 “(A) IN GENERAL.—A group health plan
2 (or a health insurance issuer offering health in-
3 surance coverage in connection with the plan)
4 shall provide for payment for routine patient
5 costs described in paragraph (1)(B) but is not
6 required to pay for costs of items and services
7 that are reasonably expected to be paid for by
8 the sponsors of an approved clinical trial.

9 “(B) ROUTINE PATIENT CARE COSTS.—

10 “(i) IN GENERAL.—For purposes of
11 this paragraph, the term ‘routine patient
12 care costs’ shall include the costs associ-
13 ated with the provision of items and serv-
14 ices that—

15 “(I) would otherwise be covered
16 under the group health plan if such
17 items and services were not provided
18 in connection with an approved clin-
19 ical trial program; and

20 “(II) are furnished according to
21 the protocol of an approved clinical
22 trial program.

23 “(ii) EXCLUSION.—For purposes of
24 this paragraph, ‘routine patient care costs’

1 shall not include the costs associated with
2 the provision of—

3 (I) an investigational drug or de-
4 vice, unless the Secretary has author-
5 ized the manufacturer of such drug or
6 device to charge for such drug or de-
7 vice; or

8 (II) any item or service supplied
9 without charge by the sponsor of the
10 approved clinical trial program.

11 “(C) PAYMENT RATE.—For purposes of
12 this subsection—

13 “(i) PARTICIPATING PROVIDERS.—In
14 the case of covered items and services pro-
15 vided by a participating provider, the pay-
16 ment rate shall be at the agreed upon rate.

17 “(ii) NONPARTICIPATING PRO-
18 VIDERS.—In the case of covered items and
19 services provided by a nonparticipating
20 provider, the payment rate shall be at the
21 rate the plan would normally pay for com-
22 parable items or services under clause (i).

23 “(4) APPROVED CLINICAL TRIAL DEFINED.—

24 “(A) IN GENERAL.—For purposes of this
25 subsection, the term ‘approved clinical trial’

1 means a cancer clinical research study or can-
2 cer clinical investigation approved by an Institu-
3 tional Review Board.

4 “(B) CONDITIONS FOR DEPARTMENTS.—
5 The conditions described in this paragraph, for
6 a study or investigation conducted by a Depart-
7 ment, are that the study or investigation has
8 been reviewed and approved through a system
9 of peer review that the Secretary determines—

10 “(i) to be comparable to the system of
11 peer review of studies and investigations
12 used by the National Institutes of Health,
13 and

14 “(ii) assures unbiased review of the
15 highest scientific standards by qualified in-
16 dividuals who have no interest in the out-
17 come of the review.

18 “(5) CONSTRUCTION.—Nothing in this sub-
19 section shall be construed to limit a plan’s coverage
20 with respect to clinical trials.

21 “(6) PLAN SATISFACTION OF CERTAIN RE-
22 QUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

23 “(A) IN GENERAL.—For purposes of this
24 subsection, insofar as a group health plan pro-
25 vides benefits in the form of health insurance

1 coverage through a health insurance issuer, the
2 plan shall be treated as meeting the require-
3 ments of this subsection with respect to such
4 benefits and not be considered as failing to
5 meet such requirements because of a failure of
6 the issuer to meet such requirements so long as
7 the plan sponsor or its representatives did not
8 cause such failure by the issuer.

9 “(B) CONSTRUCTION.—Nothing in this
10 subsection shall be construed to affect or mod-
11 ify the responsibilities of the fiduciaries of a
12 group health plan under part 4.

13 “(7) STUDY AND REPORT.—

14 “(A) STUDY.—The Secretary shall analyze
15 cancer clinical research and its cost implications
16 for managed care, including differentiation in—

17 “(i) the cost of patient care in trials
18 versus standard care;

19 “(ii) the cost effectiveness achieved in
20 different sites of service;

21 “(iii) research outcomes;

22 “(iv) volume of research subjects
23 available in different sites of service;

24 “(v) access to research sites and clin-
25 ical trials by cancer patients;

1 “(vi) patient cost sharing or copay-
2 ment costs realized in different sites of
3 service;

4 “(vii) health outcomes experienced in
5 different sites of service;

6 “(viii) long term health care services
7 and costs experienced in different sites of
8 service;

9 “(ix) morbidity and mortality experi-
10 enced in different sites of service; and

11 “(x) patient satisfaction and pref-
12 erence of sites of service.

13 “(B) REPORT TO CONGRESS.—Not later
14 than January 1, 2005, the Secretary shall sub-
15 mit a report to Congress that contains—

16 “(i) an assessment of any incremental
17 cost to group health plans resulting from
18 the provisions of this section;

19 “(ii) a projection of expenditures to
20 such plans resulting from this section;

21 “(iii) an assessment of any impact on
22 premiums resulting from this section; and

23 “(iv) recommendations regarding ac-
24 tion on other diseases.”.

1 (b) CONFORMING AMENDMENT.—The table of con-
2 tents in section 1 of such Act is amended by adding at
3 the end of the items relating to subpart B of part 7 of
4 subtitle B of title I of such Act the following new item:

“Sec. 714. Patient access to unrestricted medical advice, emergency medical
care, obstetric and gynecological care, pediatric care, and con-
tinuity of care.”.

5 **SEC. 102. REQUIRED DISCLOSURE TO NETWORK PRO-**
6 **VIDERS.**

7 (a) IN GENERAL.—Subpart B of part 7 of subtitle
8 B of title I of the Employee Retirement Income Security
9 Act of 1974 (as amended by section 101) is amended fur-
10 ther by adding at the end the following new section:

11 **“SEC. 715. REQUIRED DISCLOSURE TO NETWORK PRO-**
12 **VIDERS.**

13 “(a) IN GENERAL.—If a group health plan reim-
14 burses, through a contract or other arrangement, a health
15 care provider at a discounted payment rate because the
16 provider participates in a provider network, the plan shall
17 disclose to the provider the following information before
18 the provider furnishes covered items or services under the
19 plan:

20 “(1) The identity of the plan sponsor or other
21 entity that is to utilize the discounted payment rates
22 in reimbursing network providers in that network.

23 “(2) The existence of any substantial benefit
24 differentials established for the purpose of actively

1 encouraging participants or beneficiaries under the
2 plan to utilize the providers in that network.

3 “(3) The methods and materials by which pro-
4 viders in the network are identified to such partici-
5 pants or beneficiaries as part of the network.

6 “(b) PERMITTED MEANS OF DISCLOSURE.—Disclo-
7 sure required under subsection (a) by a plan may be
8 made—

9 “(1) by another entity under a contract or
10 other arrangement between the plan and the entity;
11 and

12 “(2) by making such information available in
13 written format, in an electronic format, on the Inter-
14 net, or on a proprietary computer network which is
15 readily accessible to the network providers.

16 “(c) CONSTRUCTION.—Nothing in this section shall
17 be construed to require, directly or indirectly, disclosure
18 of specific fee arrangements or other reimbursement
19 arrangements—

20 “(1) between (i) group health plans or provider
21 networks and (ii) health care providers, or

22 “(2) among health care providers.

23 “(d) DEFINITIONS.—For purposes of this subsection:

24 “(1) BENEFIT DIFFERENTIAL.—The term ‘ben-
25 efit differential’ means, with respect to a group

1 health plan, differences in the case of any partici-
2 pant or beneficiary, in the financial responsibility for
3 payment of coinsurance, copayments, deductibles,
4 balance billing requirements, or any other charge,
5 based upon whether a health care provider from
6 whom covered items or services are obtained is a
7 network provider.

8 “(2) DISCOUNTED PAYMENT RATE.—The term
9 ‘discounted payment rate’ means, with respect to a
10 provider, a payment rate that is below the charge
11 imposed by the provider.

12 “(3) NETWORK PROVIDER.—The term ‘network
13 provider’ means, with respect to a group health plan,
14 a health care provider that furnishes health care
15 items and services to participants or beneficiaries
16 under the plan pursuant to a contract or other ar-
17 rangement with a provider network in which the pro-
18 vider is participating.

19 “(4) PROVIDER NETWORK.—The term ‘provider
20 network’ means, with respect to a group health plan
21 offering health insurance coverage, an association of
22 network providers through whom the plan provides,
23 through contract or other arrangement, health care
24 items and services to participants and bene-
25 ficiaries.”.

1 (b) CONFORMING AMENDMENT.—The table of con-
2 tents in section 1 of such Act is amended by adding at
3 the end of the items relating to subpart B of part 7 of
4 subtitle B of title I of such Act the following new item:

“Sec. 715. Required disclosure to network providers.”.

5 **SEC. 103. EFFECTIVE DATE AND RELATED RULES.**

6 (a) IN GENERAL.—The amendments made by this
7 subtitle shall apply with respect to plan years beginning
8 on or after January 1 of the second calendar year fol-
9 lowing the date of the enactment of this Act, except that
10 the Secretary of Labor may issue regulations before such
11 date under such amendments. The Secretary shall first
12 issue regulations necessary to carry out the amendments
13 made by this subtitle before the effective date thereof.

14 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
15 enforcement action shall be taken, pursuant to the amend-
16 ments made by this subtitle, against a group health plan
17 or health insurance issuer with respect to a violation of
18 a requirement imposed by such amendments before the
19 date of issuance of regulations issued in connection with
20 such requirement, if the plan or issuer has sought to com-
21 ply in good faith with such requirement.

22 (c) SPECIAL RULE FOR COLLECTIVE BARGAINING
23 AGREEMENTS.—In the case of a group health plan main-
24 tained pursuant to one or more collective bargaining
25 agreements between employee representatives and one or

1 more employers ratified before the date of the enactment
2 of this Act, the amendments made by this subtitle shall
3 not apply with respect to plan years beginning before the
4 later of—

5 (1) the date on which the last of the collective
6 bargaining agreements relating to the plan termi-
7 nates (determined without regard to any extension
8 thereof agreed to after the date of the enactment of
9 this Act); or

10 (2) January 1, 2002.

11 For purposes of this subsection, any plan amendment
12 made pursuant to a collective bargaining agreement relat-
13 ing to the plan which amends the plan solely to conform
14 to any requirement added by this subtitle shall not be
15 treated as a termination of such collective bargaining
16 agreement.

17 **Subtitle B—Patient Access to**
18 **Information**

19 **SEC. 111. PATIENT ACCESS TO INFORMATION REGARDING**
20 **PLAN COVERAGE, MANAGED CARE PROCE-**
21 **DURES, HEALTH CARE PROVIDERS, AND**
22 **QUALITY OF MEDICAL CARE.**

23 (a) IN GENERAL.—Part 1 of subtitle B of title I of
24 the Employee Retirement Income Security Act of 1974 is
25 amended—

1 (1) by redesignating section 111 as section 112;

2 and

3 (2) by inserting after section 110 the following

4 new section:

5 “DISCLOSURE BY GROUP HEALTH PLANS

6 “SEC. 111. (a) DISCLOSURE REQUIREMENT.—The
7 administrator of each group health plan shall take such
8 actions as are necessary to ensure that the summary plan
9 description of the plan required under section 102 (or each
10 summary plan description in any case in which different
11 summary plan descriptions are appropriate under part 1
12 for different options of coverage) contains, among any in-
13 formation otherwise required under this part, the informa-
14 tion required under subsections (b), (c), (d), and
15 (e)(2)(A).

16 “(b) PLAN BENEFITS.—The information required
17 under subsection (a) includes the following:

18 “(1) COVERED ITEMS AND SERVICES.—

19 “(A) CATEGORIZATION OF INCLUDED BEN-
20 EFITS.—A description of covered benefits, cat-
21 egorized by—

22 “(i) types of items and services (in-
23 cluding any special disease management
24 program); and

25 “(ii) types of health care professionals
26 providing such items and services.

1 “(B) EMERGENCY MEDICAL CARE.—A de-
2 scription of the extent to which the plan covers
3 emergency medical care (including the extent to
4 which the plan provides for access to urgent
5 care centers), and any definitions provided
6 under the plan for the relevant plan termi-
7 nology referring to such care.

8 “(C) PREVENTATIVE SERVICES.—A de-
9 scription of the extent to which the plan pro-
10 vides benefits for preventative services.

11 “(D) DRUG FORMULARIES.—A description
12 of the extent to which covered benefits are de-
13 termined by the use or application of a drug
14 formulary and a summary of the process for de-
15 termining what is included in such formulary.

16 “(E) COBRA CONTINUATION COV-
17 ERAGE.—A description of the benefits available
18 under the plan pursuant to part 6.

19 “(2) LIMITATIONS, EXCLUSIONS, AND RESTRIC-
20 TIONS ON COVERED BENEFITS.—

21 “(A) CATEGORIZATION OF EXCLUDED
22 BENEFITS.—A description of benefits specifi-
23 cally excluded from coverage, categorized by
24 types of items and services.

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1 “(B) UTILIZATION REVIEW AND
2 PREAUTHORIZATION REQUIREMENTS.—Whether
3 coverage for medical care is limited or excluded
4 on the basis of utilization review or
5 preauthorization requirements.

6 “(C) LIFETIME, ANNUAL, OR OTHER PE-
7 RIOD LIMITATIONS.—A description of the cir-
8 cumstances under which, and the extent to
9 which, coverage is subject to lifetime, annual, or
10 other period limitations, categorized by types of
11 benefits.

12 “(D) CUSTODIAL CARE.—A description of
13 the circumstances under which, and the extent
14 to which, the coverage of benefits for custodial
15 care is limited or excluded, and a statement of
16 the definition used by the plan for custodial
17 care.

18 “(E) EXPERIMENTAL TREATMENTS.—
19 Whether coverage for any medical care is lim-
20 ited or excluded because it constitutes an inves-
21 tigational item or experimental treatment or
22 technology, and any definitions provided under
23 the plan for the relevant plan terminology refer-
24 ring to such limited or excluded care.

1 “(F) MEDICAL APPROPRIATENESS OR NE-
2 CESSITY.—Whether coverage for medical care
3 may be limited or excluded by reason of a fail-
4 ure to meet the plan’s requirements for medical
5 appropriateness or necessity, and any defini-
6 tions provided under the plan for the relevant
7 plan terminology referring to such limited or
8 excluded care.

9 “(G) SECOND OR SUBSEQUENT OPIN-
10 IONS.—A description of the circumstances
11 under which, and the extent to which, coverage
12 for second or subsequent opinions is limited or
13 excluded.

14 “(H) SPECIALTY CARE.—A description of
15 the circumstances under which, and the extent
16 to which, coverage of benefits for specialty care
17 is conditioned on referral from a primary care
18 provider.

19 “(I) CONTINUITY OF CARE.—A description
20 of the circumstances under which, and the ex-
21 tent to which, coverage of items and services
22 provided by any health care professional is lim-
23 ited or excluded by reason of the departure by
24 the professional from any defined set of pro-
25 viders.

1 “(J) RESTRICTIONS ON COVERAGE OF
2 EMERGENCY SERVICES.—A description of the
3 circumstances under which, and the extent to
4 which, the plan, in covering emergency medical
5 care furnished to a participant or beneficiary of
6 the plan imposes any financial responsibility de-
7 scribed in subsection (c) on participants or
8 beneficiaries or limits or conditions benefits for
9 such care subject to any other term or condition
10 of such plan.

11 “(3) NETWORK CHARACTERISTICS.—If the plan
12 (or health insurance issuer offering health insurance
13 coverage in connection with the plan) utilizes a de-
14 fined set of providers under contract with the plan
15 (or issuer), a detailed list of the names of such pro-
16 viders and their geographic location, set forth sepa-
17 rately with respect to primary care providers and
18 with respect to specialists.

19 “(c) PARTICIPANT’S FINANCIAL RESPONSIBIL-
20 ITIES.—The information required under subsection (a) in-
21 cludes an explanation of—

22 “(1) a participant’s financial responsibility for
23 payment of premiums, coinsurance, copayments,
24 deductibles, and any other charges; and

1 “(2) the circumstances under which, and the
2 extent to which, the participant’s financial responsi-
3 bility described in paragraph (1) may vary, including
4 any distinctions based on whether a health care pro-
5 vider from whom covered benefits are obtained is in-
6 cluded in a defined set of providers.

7 “(d) DISPUTE RESOLUTION PROCEDURES.—The in-
8 formation required under subsection (a) includes a de-
9 scription of the processes adopted by the plan pursuant
10 to section 503, including—

11 “(1) descriptions thereof relating specifically
12 to—

13 “(A) coverage decisions;

14 “(B) internal review of coverage decisions;

15 and

16 “(C) any external review of coverage deci-
17 sions; and

18 “(2) the procedures and time frames applicable
19 to each step of the processes referred to in subpara-
20 graphs (A), (B), and (C) of paragraph (1).

21 “(e) INFORMATION ON PLAN PERFORMANCE.—Any
22 information required under subsection (a) shall include in-
23 formation concerning the number of external reviews
24 under section 503 that have been completed during the
25 prior plan year and the number of such reviews in which

1 a recommendation is made for modification or reversal of
2 an internal review decision under the plan.

3 “(f) INFORMATION INCLUDED WITH ADVERSE COV-
4 ERAGE DECISIONS.—A group health plan shall provide to
5 each participant and beneficiary, together with any notifi-
6 cation of the participant or beneficiary of an adverse cov-
7 erage decision, the following information:

8 “(1) PREAUTHORIZATION AND UTILIZATION RE-
9 VIEW PROCEDURES.—A description of the basis on
10 which any preauthorization requirement or any utili-
11 zation review requirement has resulted in the ad-
12 verse coverage decision.

13 “(2) PROCEDURES FOR DETERMINING EXCLU-
14 SIONS BASED ON MEDICAL NECESSITY OR ON INVES-
15 TIGATIONAL ITEMS OR EXPERIMENTAL TREAT-
16 MENTS.—If the adverse coverage decision is based
17 on a determination relating to medical necessity or
18 to an investigational item or an experimental treat-
19 ment or technology, a description of the procedures
20 and medically-based criteria used in such decision.

21 “(g) INFORMATION AVAILABLE ON REQUEST.—

22 “(1) ACCESS TO PLAN BENEFIT INFORMATION
23 IN ELECTRONIC FORM.—

24 “(A) IN GENERAL.—In addition to the in-
25 formation required to be provided under section

1 104(b)(4), a group health plan may, upon writ-
2 ten request (made not more frequently than an-
3 nually), make available to participants and
4 beneficiaries, in a generally recognized elec-
5 tronic format—

6 “(i) the latest summary plan descrip-
7 tion, including the latest summary of ma-
8 terial modifications, and

9 “(ii) the actual plan provisions setting
10 forth the benefits available under the plan,
11 to the extent such information relates to the
12 coverage options under the plan available to the
13 participant or beneficiary. A reasonable charge
14 may be made to cover the cost of providing
15 such information in such generally recognized
16 electronic format. The Secretary may by regula-
17 tion prescribe a maximum amount which will
18 constitute a reasonable charge under the pre-
19 ceding sentence.

20 “(B) ALTERNATIVE ACCESS.—The require-
21 ments of this paragraph may be met by making
22 such information generally available (rather
23 than upon request) on the Internet or on a pro-
24 prietary computer network in a format which is

1 readily accessible to participants and bene-
2 ficiaries.

3 “(2) ADDITIONAL INFORMATION TO BE PRO-
4 VIDED ON REQUEST.—

5 “(A) INCLUSION IN SUMMARY PLAN DE-
6 SCRIPTON OF SUMMARY OF ADDITIONAL IN-
7 FORMATION.—The information required under
8 subsection (a) includes a summary description
9 of the types of information required by this
10 subsection to be made available to participants
11 and beneficiaries on request.

12 “(B) INFORMATION REQUIRED FROM
13 PLANS AND ISSUERS ON REQUEST.—In addition
14 to information required to be included in sum-
15 mary plan descriptions under this subsection, a
16 group health plan shall provide the following in-
17 formation to a participant or beneficiary on re-
18 quest:

19 “(i) CARE MANAGEMENT INFORMA-
20 TION.—A description of the circumstances
21 under which, and the extent to which, the
22 plan has special disease management pro-
23 grams or programs for persons with dis-
24 abilities, indicating whether these pro-
25 grams are voluntary or mandatory and

1 whether a significant benefit differential
2 results from participation in such pro-
3 grams.

4 “(ii) INCLUSION OF DRUGS AND
5 BIOLOGICALS IN FORMULARIES.—A state-
6 ment of whether a specific drug or biologi-
7 cal is included in a formulary used to de-
8 termine benefits under the plan and a de-
9 scription of the procedures for considering
10 requests for any patient-specific waivers.

11 “(iii) ACCREDITATION STATUS OF
12 HEALTH INSURANCE ISSUERS AND SERV-
13 ICE PROVIDERS.—A description of the ac-
14 creditation and licensing status (if any) of
15 each health insurance issuer offering
16 health insurance coverage in connection
17 with the plan and of any utilization review
18 organization utilized by the issuer or the
19 plan, together with the name and address
20 of the accrediting or licensing authority.

21 “(iv) QUALITY PERFORMANCE MEAS-
22 URES.—The latest information (if any)
23 maintained by the plan relating to quality
24 of performance of the delivery of medical
25 care with respect to coverage options of-

1 ferred under the plan and of health care
2 professionals and facilities providing med-
3 ical care under the plan.

4 “(C) INFORMATION REQUIRED FROM
5 HEALTH CARE PROFESSIONALS.—

6 “(i) QUALIFICATIONS, PRIVILEGES,
7 AND METHOD OF COMPENSATION.—Any
8 health care professional treating a partici-
9 pant or beneficiary under a group health
10 plan shall provide to the participant or
11 beneficiary, on request, a description of his
12 or her professional qualifications (including
13 board certification status, licensing status,
14 and accreditation status, if any), privileges,
15 and experience and a general description
16 by category (including salary, fee-for-serv-
17 ice, capitation, and such other categories
18 as may be specified in regulations of the
19 Secretary) of the applicable method by
20 which such professional is compensated in
21 connection with the provision of such med-
22 ical care.

23 “(ii) COST OF PROCEDURES.—Any
24 health care professional who recommends
25 an elective procedure or treatment while

1 treating a participant or beneficiary under
2 a group health plan that requires a partici-
3 pant or beneficiary to share in the cost of
4 treatment shall inform such participant or
5 beneficiary of each cost associated with the
6 procedure or treatment and an estimate of
7 the magnitude of such costs.

8 “(D) INFORMATION REQUIRED FROM
9 HEALTH CARE FACILITIES ON REQUEST.—Any
10 health care facility from which a participant or
11 beneficiary has sought treatment under a group
12 health plan shall provide to the participant or
13 beneficiary, on request, a description of the fa-
14 cility’s corporate form or other organizational
15 form and all forms of licensing and accredita-
16 tion status (if any) assigned to the facility by
17 standard-setting organizations.

18 “(h) ACCESS TO INFORMATION RELEVANT TO THE
19 COVERAGE OPTIONS UNDER WHICH THE PARTICIPANT OR
20 BENEFICIARY IS ELIGIBLE TO ENROLL.—In addition to
21 information otherwise required to be made available under
22 this section, a group health plan shall, upon written re-
23 quest (made not more frequently than annually), make
24 available to a participant (and an employee who, under
25 the terms of the plan, is eligible for coverage but not en-

1 rolled) in connection with a period of enrollment the sum-
2 mary plan description for any coverage option under the
3 plan under which the participant is eligible to enroll and
4 any information described in clauses (i), (ii), (iii), (vi),
5 (vii), and (viii) of subsection (e)(2)(B).

6 “(i) ADVANCE NOTICE OF CHANGES IN DRUG
7 FORMULARIES.—Not later than 30 days before the effec-
8 tive of date of any exclusion of a specific drug or biological
9 from any drug formulary under the plan that is used in
10 the treatment of a chronic illness or disease, the plan shall
11 take such actions as are necessary to reasonably ensure
12 that plan participants are informed of such exclusion. The
13 requirements of this subsection may be satisfied—

14 “(1) by inclusion of information in publications
15 broadly distributed by plan sponsors, employers, or
16 employee organizations;

17 “(2) by electronic means of communication (in-
18 cluding the Internet or proprietary computer net-
19 works in a format which is readily accessible to par-
20 ticipants);

21 “(3) by timely informing participants who,
22 under an ongoing program maintained under the
23 plan, have submitted their names for such notifica-
24 tion; or

1 “(4) by any other reasonable means of timely
2 informing plan participants.

3 “(j) DEFINITIONS AND RELATED RULES.—

4 “(1) IN GENERAL.—For purposes of this
5 section—

6 “(A) GROUP HEALTH PLAN.—The term
7 ‘group health plan’ has the meaning provided
8 such term under section 733(a)(1).

9 “(B) MEDICAL CARE.—The term ‘medical
10 care’ has the meaning provided such term
11 under section 733(a)(2).

12 “(C) HEALTH INSURANCE COVERAGE.—
13 The term ‘health insurance coverage’ has the
14 meaning provided such term under section
15 733(b)(1).

16 “(D) HEALTH INSURANCE ISSUER.—The
17 term ‘health insurance issuer’ has the meaning
18 provided such term under section 733(b)(2).

19 “(2) APPLICABILITY ONLY IN CONNECTION
20 WITH INCLUDED GROUP HEALTH PLAN BENEFITS.—

21 “(A) IN GENERAL.—The requirements of
22 this section shall apply only in connection with
23 included group health plan benefits.

24 “(B) INCLUDED GROUP HEALTH PLAN
25 BENEFIT.—For purposes of subparagraph (A),

1 the term ‘included group health plan benefit’
2 means a benefit which is not an excepted ben-
3 efit (as defined in section 733(c)).”.

4 **(b) CONFORMING AMENDMENTS.—**

5 (1) Section 102(b) of such Act (29 U.S.C.
6 1022(b)) is amended by inserting before the period
7 at the end the following: “; and, in the case of a
8 group health plan (as defined in section
9 112(j)(1)(A)) providing included group health plan
10 benefits (as defined in section 111(j)(2)(B)), the in-
11 formation required to be included under section
12 111(a)”.

13 (2) The table of contents in section 1 of such
14 Act is amended by striking the item relating to sec-
15 tion 111 and inserting the following new items:

“Sec. 111. Disclosure by group health plans.
“Sec. 112. Repeal and effective date.”.

16 **SEC. 112. EFFECTIVE DATE AND RELATED RULES.**

17 (a) **IN GENERAL.—**The amendments made by this
18 subtitle shall apply with respect to plan years beginning
19 on or after January 1 of the second calendar year fol-
20 lowing the date of the enactment of this Act. The Sec-
21 retary of Labor shall first issue all regulations necessary
22 to carry out the amendments made by this subtitle before
23 such date.

1 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
2 enforcement action shall be taken, pursuant to the amend-
3 ments made by this subtitle, against a group health plan
4 or health insurance issuer with respect to a violation of
5 a requirement imposed by such amendments before the
6 date of issuance of final regulations issued in connection
7 with such requirement, if the plan or issuer has sought
8 to comply in good faith with such requirement.

9 **Subtitle C—Group Health Plan**
10 **Review Standards**

11 **SEC. 121. SPECIAL RULES FOR GROUP HEALTH PLANS.**

12 (a) IN GENERAL.—Section 503 of the Employee Re-
13 tirement Income Security Act of 1974 (29 U.S.C. 1133)
14 is amended—

15 (1) by inserting “(a) IN GENERAL.—” after
16 “SEC. 503.”;

17 (2) by inserting (after and below paragraph
18 (2)) the following new flush-left sentence:

19 “This subsection does not apply in the case of included
20 group health plan benefits (as defined in subsection
21 (b)(10)(S)).”; and

22 (3) by adding at the end the following new sub-
23 section:

24 “(b) SPECIAL RULES FOR GROUP HEALTH PLANS.—

1 “(1) COVERAGE DETERMINATIONS.—Every
2 group health plan shall, in the case of included
3 group health plan benefits—

4 “(A) provide adequate notice in writing in
5 accordance with this subsection to any partici-
6 pant or beneficiary of any adverse coverage de-
7 cision with respect to such benefits of such par-
8 ticipant or beneficiary under the plan, setting
9 forth the specific reasons for such coverage de-
10 cision and any rights of review provided under
11 the plan, written in a manner calculated to be
12 understood by the average participant;

13 “(B) provide such notice in writing also to
14 any treating medical care provider of such par-
15 ticipant or beneficiary, if such provider has
16 claimed reimbursement for any item or service
17 involved in such coverage decision, or if a claim
18 submitted by the provider initiated the pro-
19 ceedings leading to such decision;

20 “(C) afford a reasonable opportunity to
21 any participant or beneficiary who is in receipt
22 of the notice of such adverse coverage decision,
23 and who files a written request for review of the
24 initial coverage decision within 90 days after re-
25 ceipt of the notice of the initial decision, for a

1 full and fair review of the decision by an appro-
2 priate named fiduciary who did not make the
3 initial decision; and

4 “(D) meet the additional requirements of
5 this subsection, which shall apply solely with re-
6 spect to such benefits.

7 “(2) TIME LIMITS FOR MAKING INITIAL COV-
8 ERAGE DECISIONS FOR BENEFITS AND COMPLETING
9 INTERNAL APPEALS.—

10 “(A) TIME LIMITS FOR DECIDING RE-
11 QUESTS FOR BENEFIT PAYMENTS, REQUESTS
12 FOR ADVANCE DETERMINATION OF COVERAGE,
13 AND REQUESTS FOR REQUIRED DETERMINA-
14 TION OF MEDICAL NECESSITY.—Except as pro-
15 vided in subparagraph (B)—

16 “(i) INITIAL DECISIONS.—If a request
17 for benefit payments, a request for advance
18 determination of coverage, or a request for
19 required determination of medical necessity
20 is submitted to a group health plan in such
21 reasonable form as may be required under
22 the plan, the plan shall issue in writing an
23 initial coverage decision on the request be-
24 fore the end of the initial decision period
25 under paragraph (10)(I) following the fil-

1 ing completion date. Failure to issue a cov-
2 erage decision on such a request before the
3 end of the period required under this
4 clause shall be treated as an adverse cov-
5 erage decision for purposes of internal re-
6 view under clause (ii).

7 “(ii) INTERNAL REVIEWS OF INITIAL
8 DENIALS.—Upon the written request of a
9 participant or beneficiary for review of an
10 initial adverse coverage decision under
11 clause (i), a review by an appropriate
12 named fiduciary (subject to paragraph (3))
13 of the initial coverage decision shall be
14 completed, including issuance by the plan
15 of a written decision affirming, reversing,
16 or modifying the initial coverage decision,
17 setting forth the grounds for such decision,
18 before the end of the internal review period
19 following the review filing date. Such deci-
20 sion shall be treated as the final decision
21 of the plan, subject to any applicable re-
22 consideration under paragraph (4). Failure
23 to issue before the end of such period such
24 a written decision requested under this

1 clause shall be treated as a final decision
2 affirming the initial coverage decision.

3 “(B) TIME LIMITS FOR MAKING COVERAGE
4 DECISIONS RELATING TO ACCELERATED NEED
5 MEDICAL CARE AND FOR COMPLETING INTER-
6 NAL APPEALS.—

7 “(i) INITIAL DECISIONS.—A group
8 health plan shall issue in writing an initial
9 coverage decision on any request for expedited
10 advance determination of coverage or
11 for expedited required determination of
12 medical necessity submitted, in such reasonable
13 form as may be required under the
14 plan before the end of the accelerated need
15 decision period under paragraph (10)(K),
16 in cases involving accelerated need medical
17 care, following the filing completion date.
18 Failure to approve or deny such a request
19 before the end of the applicable decision
20 period shall be treated as a denial of the
21 request for purposes of internal review
22 under clause (ii).

23 “(ii) INTERNAL REVIEWS OF INITIAL
24 DENIALS.—Upon the written request of a
25 participant or beneficiary for review of an

1 initial adverse coverage decision under
2 clause (i), a review by an appropriate
3 named fiduciary (subject to paragraph (3))
4 of the initial coverage decision shall be
5 completed, including issuance by the plan
6 of a written decision affirming, reversing,
7 or modifying the initial converge decision,
8 setting forth the grounds for the decision
9 before the end of the accelerated need deci-
10 sion period under paragraph (10)(K) fol-
11 lowing the review filing date. Such decision
12 shall be treated as the final decision of the
13 plan, subject to any applicable reconsider-
14 ation under paragraph (4). Failure to issue
15 before the end of the applicable decision
16 period such a written decision requested
17 under this clause shall be treated as a final
18 decision affirming the initial coverage deci-
19 sion.

20 “(3) PHYSICIANS MUST REVIEW INITIAL COV-
21 ERAGE DECISIONS INVOLVING MEDICAL APPRO-
22 PRIATENESS OR NECESSITY OR INVESTIGATIONAL
23 ITEMS OR EXPERIMENTAL TREATMENT.—If an ini-
24 tial coverage decision under paragraph (2)(A)(i) or
25 (2)(B)(i) is based on a determination that provision

1 of a particular item or service is excluded from cov-
2 erage under the terms of the plan because the provi-
3 sion of such item or service does not meet the re-
4 quirements for medical appropriateness or necessity
5 or would constitute provision of investigational items
6 or experimental treatment or technology, the review
7 under paragraph (2)(A)(ii) or (2)(B)(ii), to the ex-
8 tent that it relates to medical appropriateness or ne-
9 cessity or to investigational items or experimental
10 treatment or technology, shall be conducted by a
11 physician who is selected by the plan and who did
12 not make the initial denial.

13 “(4) ELECTIVE EXTERNAL REVIEW BY INDE-
14 PENDENT MEDICAL EXPERT AND RECONSIDERATION
15 OF INITIAL REVIEW DECISION.—

16 “(A) IN GENERAL.—In any case in which
17 a participant or beneficiary, who has received
18 an adverse coverage decision which is not re-
19 versed upon review conducted pursuant to para-
20 graph (1)(C) (including review under paragraph
21 (2)(A)(ii) or (2)(B)(ii)) and who has not com-
22 menced review of the coverage decision under
23 section 502, makes a request in writing, within
24 30 days after the date of such review decision,
25 for reconsideration of such review decision, the

1 requirements of subparagraphs (B), (C), (D)
2 and (E) shall apply in the case of such adverse
3 coverage decision, if the requirements of clause
4 (i) or (ii) are met, subject to clause (iii).

5 “(i) MEDICAL APPROPRIATENESS OR
6 INVESTIGATIONAL ITEM OR EXPERI-
7 MENTAL TREATMENT OR TECHNOLOGY.—
8 The requirements of this clause are met if
9 such coverage decision is based on a deter-
10 mination that provision of a particular
11 item or service that would otherwise be
12 covered is excluded from coverage because
13 the provision of such item or service—

14 “(I) is not medically appropriate
15 or necessary; or

16 “(II) would constitute provision
17 of an investigational item or experi-
18 mental treatment or technology.

19 “(ii) EXCLUSION OF ITEM OR SERVICE
20 REQUIRING EVALUATION OF MEDICAL
21 FACTS OR EVIDENCE.—The requirements
22 of this clause are met if—

23 “(I) such coverage decision is
24 based on a determination that a par-
25 ticular item or service is not covered

1 under the terms of the plan because
2 provision of such item or service is
3 specifically or categorically excluded
4 from coverage under the terms of the
5 plan, and

6 “(II) an independent contract ex-
7 pert finds under subparagraph (C), in
8 advance of any review of the decision
9 under subparagraph (D), that such
10 determination primarily requires the
11 evaluation of medical facts or medical
12 evidence by a health professional.

13 “(iii) MATTERS SPECIFICALLY NOT
14 SUBJECT TO REVIEW.—The requirements
15 of subparagraphs (B), (C), (D), and (E)
16 shall not apply in the case of any adverse
17 coverage decision if such decision is based
18 on—

19 “(I) a determination of eligibility
20 for benefits,

21 “(II) the application of explicit
22 plan limits on the number, cost, or
23 duration of any benefit, or

24 “(III) a limitation on the amount
25 of any benefit payment or a require-

1 ment to make copayments under the
2 terms of the plan.

3 Review under this paragraph shall not be avail-
4 able for any coverage decision that has pre-
5 viously undergone review under this paragraph.

6 “(B) LIMITS ON ALLOWABLE ADVANCE
7 PAYMENTS.—The review under this paragraph
8 in connection with an adverse coverage decision
9 shall be available subject to any requirement of
10 the plan (unless waived by the plan for financial
11 or other reasons) for payment in advance to the
12 plan by the participant or beneficiary seeking
13 review of an amount not to exceed the greater
14 of—

15 “(i) the lesser of \$100 or 10 percent
16 of the cost of the medical care involved in
17 the decision, or

18 “(ii) \$25,
19 with such dollar amount subject to compounded
20 annual adjustments in the same manner and to
21 the same extent as apply under section 215(i)
22 of the Social Security Act, except that, for any
23 calendar year, such amount as so adjusted shall
24 be deemed, solely for such calendar year, to be
25 equal to such amount rounded to the nearest

1 §10. No such payment may be required in the
2 case of any participant or beneficiary whose en-
3 rollment under the plan is paid for, in whole or
4 in part, under a State plan under title XIX or
5 XXI of the Social Security Act. Any such ad-
6 vance payment shall be subject to reimburse-
7 ment if the recommendation of the independent
8 medical expert (or panel of such experts) under
9 subparagraph (D)(ii)(IV) is to reverse or mod-
10 ify the coverage decision.

11 “(C) REQUEST TO INDEPENDENT CON-
12 TRACT EXPERT FOR DETERMINATION OF
13 WHETHER COVERAGE DECISION REQUIRED
14 EVALUATION OF MEDICAL FACTS OR EVI-
15 DENCE.—

16 “(i) IN GENERAL.—In the case of a
17 request for review made by a participant or
18 beneficiary as described in subparagraph
19 (A), if the requirements of subparagraph
20 (A)(ii) are met (and review is not other-
21 wise precluded under subparagraph
22 (A)(iii)), the terms of the plan shall pro-
23 vide for a procedure for initial review by
24 an independent contract expert selected in
25 accordance with subparagraph (H) under

1 which the expert will determine whether
2 the coverage decision requires the evalua-
3 tion of medical facts or evidence by a
4 health professional. If the expert deter-
5 mines that the coverage decision requires
6 such evaluation, reconsideration of such
7 adverse decision shall proceed under this
8 paragraph. If the expert determines that
9 the coverage decision does not require such
10 evaluation, the adverse decision shall re-
11 main the final decision of the plan.

12 “(ii) INDEPENDENT CONTRACT EX-
13 PERTS.—For purposes of this subpara-
14 graph, the term ‘independent contract ex-
15 pert’ means a professional—

16 “(I) who has appropriate creden-
17 tials and has attained recognized ex-
18 pertise in the applicable area of con-
19 tract interpretation;

20 “(II) who was not involved in the
21 initial decision or any earlier review
22 thereof; and

23 “(III) who is selected in accord-
24 ance with subparagraph (H)(i) and

1 meets the requirements of subpara-
2 graph (H)(iii).

3 “(D) RECONSIDERATION OF INITIAL RE-
4 VIEW DECISION.—

5 “(i) IN GENERAL.—In the case of a
6 request for review made by a participant or
7 beneficiary as described in subparagraph
8 (A), if the requirements of subparagraph
9 (A)(i) are met or reconsideration proceeds
10 under this paragraph pursuant to subpara-
11 graph (C), the terms of the plan shall pro-
12 vide for a procedure for such reconsider-
13 ation in accordance with clause (ii).

14 “(ii) PROCEDURE FOR RECONSIDER-
15 ATION.—The procedure required under
16 clause (i) shall include the following—

17 “(I) An independent medical ex-
18 pert (or a panel of such experts, as
19 determined necessary) will be selected
20 in accordance with subparagraph (H)
21 to reconsider any coverage decision
22 described in subparagraph (A) to de-
23 termine whether such decision was in
24 accordance with the terms of the plan
25 and this title.

1 “(II) The record for review (in-
2 cluding a specification of the terms of
3 the plan and other criteria serving as
4 the basis for the initial review deci-
5 sion) will be presented to such expert
6 (or panel) and maintained in a man-
7 ner which will ensure confidentiality
8 of such record.

9 “(III) Such expert (or panel) will
10 reconsider the initial review decision
11 to determine whether such decision
12 was in accordance with the terms of
13 the plan and this title. The expert (or
14 panel) in its reconsideration will take
15 into account the medical condition of
16 the patient, the recommendation of
17 the treating physician, the initial cov-
18 erage decision (including the reasons
19 for such decision) and the decision
20 upon review conducted pursuant to
21 paragraph (1)(C) (including review
22 under paragraph (2)(A)(ii) or
23 (2)(B)(ii)) , any guidelines adopted by
24 the plan through a process involving
25 medical practitioners and peer-re-

1 viewed medical literature identified as
2 such under criteria established by the
3 Food and Drug Administration, and
4 any other valid, relevant, scientific or
5 clinical evidence the expert (or panel)
6 determines appropriate for its review.
7 The expert (or panel) may consult the
8 participant or beneficiary, the treating
9 physician, the medical director of the
10 plan, or any other party who, in the
11 opinion of the expert (or panel), may
12 have relevant information for consid-
13 eration.

14 “(E) ISSUANCE OF BINDING FINAL
15 DECISION.—Upon completion of the proce-
16 dure for review under subparagraph (D),
17 the independent medical expert (or panel
18 of such experts) shall issue a written deci-
19 sion affirming, modifying, or reversing the
20 initial review decision, setting forth the
21 grounds for the decision. Such decision
22 shall be the final decision of the plan and
23 shall be binding on the plan. Such decision
24 shall set forth specifically the determina-
25 tion of the expert (or panel) of the appro-

1 priate period for timely compliance by the
2 plan with the decision. Such decision shall
3 be issued concurrently to the participant or
4 beneficiary, to the treating physician, and
5 to the plan, shall constitute conclusive,
6 written authorization for the provision of
7 benefits under the plan in accordance with
8 the decision, and shall be treated as terms
9 of the plan for purposes of any action by
10 the participant or beneficiary under section
11 502.

12 “(F) TIME LIMITS FOR RECONSIDER-
13 ATION.—Any review under this paragraph (in-
14 cluding any review under subparagraph (C))
15 shall be completed before the end of the recon-
16 sideration period (as defined in paragraph
17 (10)(L)) following the review filing date in con-
18 nection with such review. Failure to issue a
19 written decision before the end of the reconsid-
20 eration period in any reconsideration requested
21 under this paragraph shall be treated as a final
22 decision affirming the initial review decision of
23 the plan.

24 “(G) INDEPENDENT MEDICAL EXPERTS.—

1 “(i) IN GENERAL.—For purposes of
2 this paragraph, the term ‘independent
3 medical expert’ means, in connection with
4 any coverage decision by a group health
5 plan, a professional—

6 “(I) who is a physician or, if ap-
7 propriate, another medical profes-
8 sional,

9 “(II) who has appropriate cre-
10 dentials and has attained recognized
11 expertise in the applicable medical
12 field,

13 “(III) who was not involved in
14 the initial decision or any earlier re-
15 view thereof,

16 “(IV) who has no history of dis-
17 ciplinary action or sanctions (includ-
18 ing, but not limited to, loss of staff
19 privileges or participation restriction)
20 taken or pending by any hospital,
21 health carrier, government, or regu-
22 latory body, and

23 “(V) who is selected in accord-
24 ance with subparagraph (H)(i) and

1 meets the requirements of subpara-
2 graph (H)(iii).

3 “(H) SELECTION OF EXPERTS.—

4 “(i) IN GENERAL.—An independent
5 contract expert or independent medical ex-
6 pert (or each member of any panel of inde-
7 pendent medical experts selected under
8 subparagraph (D)(ii)) is selected in accord-
9 ance with this clause if—

10 “(I) the expert is selected by an
11 intermediary which itself meets the re-
12 quirements of clauses (ii) and (iii), by
13 means of a method which ensures that
14 the identity of the expert is not dis-
15 closed to the plan, any health insur-
16 ance issuer offering health insurance
17 coverage to the aggrieved participant
18 or beneficiary in connection with the
19 plan, and the aggrieved participant or
20 beneficiary under the plan, and the
21 identities of the plan, the issuer, and
22 the aggrieved participant or bene-
23 ficiary are not disclosed to the expert;

24 “(II) the expert is selected by an
25 appropriately credentialed panel of

1 physicians meeting the requirements
2 of clauses (ii) and (iii) established by
3 a fully accredited teaching hospital
4 meeting such requirements;

5 “(III) the expert is selected by an
6 organization described in section
7 1152(1)(A) of the Social Security Act
8 which meets the requirements of
9 clauses (ii) and (iii);

10 “(IV) the expert is selected by an
11 external review organization which
12 meets the requirements of clauses (ii)
13 and (iii) and is accredited by a private
14 standard-setting organization meeting
15 such requirements;

16 “(V) the expert is selected by a
17 State agency which is established for
18 the purpose of conducting independent
19 external reviews and which meets the
20 requirements of clauses (ii) and (iii);
21 or

22 “(VI) the expert is selected, by
23 an intermediary or otherwise, in a
24 manner that is, under regulations
25 issued pursuant to negotiated rule-

1 making, sufficient to ensure the ex-
2 pert's independence, and the method
3 of selection is devised to reasonably
4 ensure that the expert selected meets
5 the requirements of clauses (ii) and
6 (iii).

7 “(ii) STANDARDS OF PERFORMANCE
8 FOR INTERMEDIARIES.—The Secretary
9 shall prescribe by regulation standards (in
10 addition to the requirements of clause (iii))
11 which entities making selections under sub-
12 clause (I), (II), (III), (IV), (V), or (VI) of
13 clause (ii) must meet in order to be eligible
14 for making such selections. Such standards
15 shall include (but are not limited to)—

16 “(I) assurance that the entity
17 will carry out specified duties in the
18 course of exercising the entity's re-
19 sponsibilities under clause (i)(I),

20 “(II) assurance that applicable
21 deadlines will be met in the exercise of
22 such responsibilities, and

23 “(III) assurance that the entity
24 meets appropriate indicators of sol-
25 vency and fiscal integrity.

1 Each such entity shall provide to the Sec-
2 retary, in such manner and at such times
3 as the Secretary may prescribe, informa-
4 tion relating the volume of claims with re-
5 spect to which the entity has served under
6 this subparagraph, the types of such
7 claims, and such other information regard-
8 ing such claims as the Secretary may de-
9 termine appropriate.

10 “(iii) INDEPENDENCE REQUIRE-
11 MENTS.—An independent contract expert
12 or independent medical expert or another
13 entity described in clause (i) meets the
14 independence requirements of this clause
15 if—

16 “(I) the expert or entity is not
17 affiliated with any related party;

18 “(II) any compensation received
19 by such expert or entity in connection
20 with the external review is reasonable
21 and not contingent on any decision
22 rendered by the expert or entity;

23 “(III) under the terms of the
24 plan and any health insurance cov-
25 erage offered in connection with the

1 plan, the plan and the issuer (if any)
2 have no recourse against the expert or
3 entity in connection with the external
4 review; and

5 “(IV) the expert or entity does
6 not otherwise have a conflict of inter-
7 est with a related party as determined
8 under any regulations which the Sec-
9 retary may prescribe.

10 “(iv) RELATED PARTY.—For purposes
11 of clause (i)(I), the term ‘related party’
12 means—

13 “(I) the plan or any health insur-
14 ance issuer offering health insurance
15 coverage in connection with the plan
16 (or any officer, director, or manage-
17 ment employee of such plan or issuer);

18 “(II) the physician or other med-
19 ical care provider that provided the
20 medical care involved in the coverage
21 decision;

22 “(III) the institution at which
23 the medical care involved in the cov-
24 erage decision is provided;

1 “(IV) the manufacturer of any
2 drug or other item that was included
3 in the medical care involved in the
4 coverage decision; or

5 “(V) any other party determined
6 under any regulations which the Sec-
7 retary may prescribe to have a sub-
8 stantial interest in the coverage deci-
9 sion.

10 “(v) AFFILIATED.—For purposes of
11 clause (ii)(I), the term ‘affiliated’ means,
12 in connection with any entity, having a fa-
13 miliar, financial, or professional relation-
14 ship with, or interest in, such entity.

15 “(I) MISBEHAVIOR BY EXPERTS.—Any ac-
16 tion by the expert or experts in applying for
17 their selection under this paragraph or in the
18 course of carrying out their duties under this
19 paragraph which constitutes—

20 “(i) fraud or intentional misrepresen-
21 tation by such expert or experts, or

22 “(ii) demonstrates failure to adhere to
23 the standards for selection set forth in sub-
24 paragraph (H)(iii),

1 shall be treated as a failure to meet the require-
2 ments of this paragraph and therefore as a
3 cause of action which may be brought by a fidu-
4 ciary under section 502(a)(3).

5 “(J) BENEFIT EXCLUSIONS MAIN-
6 TAINED.—Nothing in this paragraph shall be
7 construed as providing for or requiring the cov-
8 erage of items or services for which benefits are
9 specifically excluded under the group health
10 plan or any health insurance coverage offered in
11 connection with the plan.

12 “(5) PERMITTED ALTERNATIVES TO REQUIRED
13 FORMS OF REVIEW.—

14 “(A) IN GENERAL.—In accordance with
15 such regulations (if any) as may be prescribed
16 by the Secretary for purposes of this paragraph,
17 in the case of any initial coverage decision or
18 any decision upon review thereof under para-
19 graph (2)(A)(ii) or (2)(B)(ii), a group health
20 plan may provide an alternative dispute resolu-
21 tion procedure meeting the requirements of sub-
22 paragraph (B) for use in lieu of the procedures
23 set forth under the preceding provisions of this
24 subsection relating review of such decision.
25 Such procedure may be provided in one form

1 for all participants and beneficiaries or in a dif-
2 ferent form for each group of similarly situated
3 participants and beneficiaries. Upon voluntary
4 election of such procedure by the plan and by
5 the aggrieved participant or beneficiary in con-
6 nection with the decision, the plan may provide
7 under such procedure (in a manner consistent
8 with such regulations as the Secretary may pre-
9 scribe to ensure equitable procedures) for waiv-
10 er of the review of the decision under paragraph
11 (3) or waiver of further review of the decision
12 under paragraph (4) or section 502 or for elec-
13 tion by such parties of an alternative means of
14 external review (other than review under para-
15 graph (4)).

16 “(B) REQUIREMENTS.—An alternative dis-
17 pute resolution procedure meets the require-
18 ments of this subparagraph, in connection with
19 any decision, if—

20 “(i) such procedure is utilized solely—

21 “(I) in accordance with the appli-
22 cable terms of a bona fide collective
23 bargaining agreement pursuant to
24 which the plan (or the applicable por-

1 tion thereof governed by the agree-
2 ment) is established or maintained, or

3 “(II) upon election by both the
4 aggrieved participant or beneficiary
5 and the plan,

6 “(ii) the procedure incorporates any
7 otherwise applicable requirement for review
8 by a physician under paragraph (3), unless
9 waived by the participant or beneficiary (in
10 a manner consistent with such regulations
11 as the Secretary may prescribe to ensure
12 equitable procedures); and

13 “(iii) the means of resolution of dis-
14 pute allow for adequate presentation by
15 each party of scientific and medical evi-
16 dence supporting the position of such
17 party.

18 “(6) REVIEW REQUIREMENTS.—In any review
19 of a decision issued under this subsection—

20 “(A) the record shall be maintained for
21 purposes of any further review in accordance
22 with standards which shall be prescribed in reg-
23 ulations of the Secretary designed to facilitate
24 such further review, and

1 “(B) any decision upon review which modi-
2 fies or reverses a decision below shall specifi-
3 cally set forth a determination that the record
4 upon review is sufficient to rebut a presumption
5 in favor of the decision below.

6 “(7) COMPLIANCE WITH FIDUCIARY STAND-
7 ARDS.—The issuance of a decision under a plan
8 upon review in good faith compliance with the re-
9 quirements of this subsection shall not be treated as
10 a violation of part 4 of subtitle B of title I of the
11 Employee Retirement Income Security Act of 1974.

12 “(8) LIMITATION ON APPLICABILITY OF SPE-
13 CIAL RULES.—The provisions of this subsection shall
14 not apply with respect to employee benefit plans that
15 are not group health plans or with respect to bene-
16 fits that are not included group health plan benefits
17 (as defined in paragraph (10)(S)).

18 “(9) GROUP HEALTH PLAN DEFINED.—For
19 purposes of this section—

20 “(A) IN GENERAL.—The term ‘group
21 health plan’ shall have the meaning provided in
22 section 733(a).

23 “(B) TREATMENT OF PARTNERSHIPS.—
24 The provisions of paragraphs (1), (2), and (3)
25 of section 732(d) shall apply.

1 “(10) OTHER DEFINITIONS.—For purposes of
2 this subsection—

3 “(A) REQUEST FOR BENEFIT PAY-
4 MENTS.—The term ‘request for benefit pay-
5 ments’ means a request, for payment of benefits
6 by a group health plan for medical care, which
7 is made by, or (if expressly authorized) on be-
8 half of, a participant or beneficiary after such
9 medical care has been provided.

10 “(B) REQUIRED DETERMINATION OF MED-
11 ICAL NECESSITY.—The term ‘required deter-
12 mination of medical necessity’ means a deter-
13 mination required under a group health plan
14 solely that proposed medical care meets, under
15 the facts and circumstances at the time of the
16 determination, the requirements for medical ap-
17 propriateness or necessity (which may be sub-
18 ject to exceptions under the plan for fraud or
19 misrepresentation), irrespective of whether the
20 proposed medical care otherwise meets other
21 terms and conditions of coverage, but only if
22 such determination does not constitute an ad-
23 vance determination of coverage (as defined in
24 subparagraph (C)).

1 “(C) ADVANCE DETERMINATION OF COV-
2 ERAGE.—The term ‘advance determination of
3 coverage’ means a determination under a group
4 health plan that proposed medical care meets,
5 under the facts and circumstances at the time
6 of the determination, the plan’s terms and con-
7 ditions of coverage (which may be subject to ex-
8 ceptions under the plan for fraud or misrepre-
9 sentation).

10 “(D) REQUEST FOR ADVANCE DETERMINA-
11 TION OF COVERAGE.—The term ‘request for ad-
12 vance determination of coverage’ means a re-
13 quest for an advance determination of coverage
14 of medical care which is made by, or (if ex-
15 pressly authorized) on behalf of, a participant
16 or beneficiary before such medical care is pro-
17 vided.

18 “(E) REQUEST FOR EXPEDITED ADVANCE
19 DETERMINATION OF COVERAGE.—The term ‘re-
20 quest for expedited advance determination of
21 coverage’ means a request for advance deter-
22 mination of coverage, in any case in which the
23 proposed medical care constitutes accelerated
24 need medical care.

1 “(F) REQUEST FOR REQUIRED DETER-
2 MINATION OF MEDICAL NECESSITY.—The term
3 ‘request for required determination of medical
4 necessity’ means a request for a required deter-
5 mination of medical necessity for medical care
6 which is made by or on behalf of a participant
7 or beneficiary before the medical care is pro-
8 vided.

9 “(G) REQUEST FOR EXPEDITED REQUIRED
10 DETERMINATION OF MEDICAL NECESSITY.—
11 The term ‘request for expedited required deter-
12 mination of medical necessity’ means a request
13 for required determination of medical necessity
14 in any case in which the proposed medical care
15 constitutes accelerated need medical care.

16 “(H) ACCELERATED NEED MEDICAL
17 CARE.—The term ‘accelerated need medical
18 care’ means medical care in any case in which
19 an appropriate physician has certified in writing
20 (or as otherwise provided in regulations of the
21 Secretary) that the participant or beneficiary is
22 stabilized and—

23 “(i) that failure to immediately pro-
24 vide the care to the participant or bene-

1 ficiary could reasonably be expected to re-
2 sult in—

3 “(I) placing the health of such
4 participant or beneficiary (or, with re-
5 spect to such a participant or bene-
6 ficiary who is a pregnant woman, the
7 health of the woman or her unborn
8 child) in serious jeopardy;

9 “(II) serious impairment to bod-
10 ily functions; or

11 “(III) serious dysfunction of any
12 bodily organ or part; or

13 “(ii) that immediate provision of the
14 care is necessary because the participant
15 or beneficiary has made or is at serious
16 risk of making an attempt to harm himself
17 or herself or another individual.

18 “(I) INITIAL DECISION PERIOD.—The term
19 ‘initial decision period’ means a period of 30
20 days, or such period as may be prescribed in
21 regulations of the Secretary.

22 “(J) INTERNAL REVIEW PERIOD.—The
23 term ‘internal review period’ means a period of
24 30 days, or such period as may be prescribed
25 in regulations of the Secretary.

1 “(K) ACCELERATED NEED DECISION PE-
2 RIOD.—The term ‘accelerated need decision pe-
3 riod’ means a period of 3 days, or such period
4 as may be prescribed in regulations of the Sec-
5 retary.

6 “(L) RECONSIDERATION PERIOD.—The
7 term ‘reconsideration period’ means a period of
8 25 days, or such period as may be prescribed
9 in regulations of the Secretary, except that, in
10 the case of a decision involving accelerated need
11 medical care, such term means the accelerated
12 need decision period.

13 “(M) FILING COMPLETION DATE.—The
14 term ‘filing completion date’ means, in connec-
15 tion with a group health plan, the date as of
16 which the plan is in receipt of all information
17 reasonably required (in writing or in such other
18 reasonable form as may be specified by the
19 plan) to make an initial coverage decision.

20 “(N) REVIEW FILING DATE.—The term
21 ‘review filing date’ means, in connection with a
22 group health plan, the date as of which the ap-
23 propriate named fiduciary (or the independent
24 medical expert or panel of such experts in the
25 case of a review under paragraph (4)) is in re-

1 ceipt of all information reasonably required (in
2 writing or in such other reasonable form as may
3 be specified by the plan) to make a decision to
4 affirm, modify, or reverse a coverage decision.

5 “(O) MEDICAL CARE.—The term ‘medical
6 care’ has the meaning provided such term by
7 section 733(a)(2).

8 “(P) HEALTH INSURANCE COVERAGE.—
9 The term ‘health insurance coverage’ has the
10 meaning provided such term by section
11 733(b)(1).

12 “(Q) HEALTH INSURANCE ISSUER.—The
13 term ‘health insurance issuer’ has the meaning
14 provided such term by section 733(b)(2).

15 “(R) WRITTEN OR IN WRITING.—

16 “(i) IN GENERAL.—A request or deci-
17 sion shall be deemed to be ‘written’ or ‘in
18 writing’ if such request or decision is pre-
19 sented in a generally recognized printable
20 or electronic format. The Secretary may by
21 regulation provide for presentation of in-
22 formation otherwise required to be in writ-
23 ten form in such other forms as may be
24 appropriate under the circumstances.

1 “(ii) MEDICAL APPROPRIATENESS OR
2 INVESTIGATIONAL ITEMS OR EXPERI-
3 MENTAL TREATMENT DETERMINATIONS.—

4 For purposes of this subparagraph, in the
5 case of a request for advance determina-
6 tion of coverage, a request for expedited
7 advance determination of coverage, a re-
8 quest for required determination of medical
9 necessity, or a request for expedited re-
10 quired determination of medical necessity,
11 if the decision on such request is conveyed
12 to the provider of medical care or to the
13 participant or beneficiary by means of tele-
14 phonic or other electronic communications,
15 such decision shall be treated as a written
16 decision.

17 “(S) INCLUDED GROUP HEALTH PLAN
18 BENEFIT.—The term ‘included group health
19 plan benefit’ means a benefit under a group
20 health plan which is not an excepted benefit (as
21 defined in section 733(c)).”.

22 (b) CIVIL PENALTIES.—

23 (1) IN GENERAL.—Section 502(c) of such Act
24 (29 U.S.C. 1132(c)) is amended by redesignating
25 paragraphs (6) and (7) as paragraphs (7) and (8),

1 respectively, and by inserting after paragraph (5)
2 the following new paragraph:

3 “(6)(A)(i) In the case of any failure to timely provide
4 an included group health plan benefit (as defined in sec-
5 tion 503(b)(10)(S)) to a participant or beneficiary, which
6 occurs after the issuance of, and in violation of, a final
7 decision rendered upon completion of external review
8 (under section 503(b)(4)) of an adverse coverage decision
9 by the plan relating to such benefit, any person acting in
10 the capacity of a fiduciary of the plan so as to cause such
11 failure may, in the court’s discretion, be liable to the ag-
12 grieved participant or beneficiary for a civil penalty.

13 “(ii) Except as provided in clause (iii), such civil pen-
14 alty shall be in an amount of up to \$1,000 a day from
15 the date that occurs on or after the date of the issuance
16 of the decision under section 503(b)(4) and upon which
17 the plan otherwise could have been reasonably expected
18 to commence compliance with the decision until the date
19 the failure to provide the benefit is corrected.

20 “(iii) In any case in which it is proven by clear and
21 convincing evidence that the person referred to in clause
22 (i) acted willfully and in bad faith, the daily penalty under
23 clause (ii) shall be increased to an amount of up to \$5,000
24 a day.

1 “(iv) In any case in which it is further proven by clear
2 and convincing evidence that—

3 “(I) the plan is not in full compliance with the
4 decision of the independent medical expert (or panel
5 of such experts) under section 503(b)(4)(E)) within
6 the appropriate period specified in such decision,
7 and

8 “(II) the failure to be in full compliance was
9 caused by the plan or by a health insurance issuer
10 offering health insurance coverage in connection
11 with the plan,

12 the plan shall pay the cost of all medical care which was
13 not provided by reason of such failure to fully comply and
14 which is otherwise obtained by the participant or bene-
15 ficiary from any provider.

16 “(B) For purposes of subparagraph (A), the plan,
17 and any health insurance issuer offering health insurance
18 coverage in connection with the plan, shall be deemed to
19 be in compliance with any decision of an independent med-
20 ical expert (or panel of such experts) under section
21 503(b)(4) with respect to any participant or beneficiary
22 upon transmission to such entity (or panel) and to such
23 participant or beneficiary by the plan or issuer of timely
24 notice of an authorization of coverage by the plan or issuer
25 which is consistent with such decision.

1 “(C) In any action commenced under subsection (a)
2 by a participant or beneficiary with respect to an included
3 group health plan benefit in which the plaintiff alleges that
4 a person, in the capacity of a fiduciary and in violation
5 of the terms of the plan or this title, has taken an action
6 resulting in an adverse coverage decision in violation of
7 the terms of the plan, or has failed to take an action for
8 which such person is responsible under the plan and which
9 is necessary under the plan for a favorable coverage deci-
10 sion, upon finding in favor of the plaintiff, if such action
11 was commenced after a final decision of the plan upon
12 review which included a review under section 503(b)(4)
13 or such action was commenced under subsection (b)(4) of
14 this section, the court shall cause to be served on the de-
15 fendant an order requiring the defendant—

16 “(i) to cease and desist from the alleged action
17 or failure to act; and

18 “(ii) to pay to the plaintiff a reasonable attor-
19 ney’s fee and other reasonable costs relating to the
20 prosecution of the action on the charges on which
21 the plaintiff prevails.

22 The remedies provided under this subparagraph shall be
23 in addition to remedies otherwise provided under this sec-
24 tion.

1 “(D)(i) The Secretary may assess a civil penalty
2 against a person acting in the capacity of a fiduciary of
3 one or more group health plans (as defined in section
4 503(b)(9)) for—

5 “(I) any pattern or practice of repeated adverse
6 coverage decisions in connection with included group
7 health plan benefits in violation of the terms of the
8 plan or plans or this title; or

9 “(II) any pattern or practice of repeated viola-
10 tions of the requirements of section 503 in connec-
11 tion with such benefits.

12 Such penalty shall be payable only upon proof by clear
13 and convincing evidence of such pattern or practice.

14 “(ii) Such penalty shall be in an amount not to exceed
15 the lesser of—

16 “(I) 5 percent of the aggregate value of benefits
17 shown by the Secretary to have not been provided,
18 or unlawfully delayed in violation of section 503,
19 under such pattern or practice; or

20 “(II) \$100,000.

21 “(iii) Any person acting in the capacity of a fiduciary
22 of a group health plan or plans who has engaged in any
23 such pattern or practice in connection with included group
24 health plan benefits, upon the petition of the Secretary,
25 may be removed by the court from that position, and from

1 any other involvement, with respect to such plan or plans,
2 and may be precluded from returning to any such position
3 or involvement for a period determined by the court.

4 “(E) For purposes of this paragraph, the term ‘in-
5 cluded group health plan benefit’ has the meaning pro-
6 vided in section 503(b)(10)(S).

7 “(F) The preceding provisions of this paragraph shall
8 not apply with respect to employee benefit plans that are
9 not group health plans or with respect to benefits that are
10 not included group health plan benefits (as defined in
11 paragraph (10)(S)).”.

12 (2) CONFORMING AMENDMENT.—Section
13 502(a)(6) of such Act (29 U.S.C. 1132(a)(6)) is
14 amended by striking “, or (6)” and inserting “, (6),
15 or (7)”.

16 (c) EXPEDITED COURT REVIEW.—Section 502 of
17 such Act (29 U.S.C. 1132) is amended—

18 (1) in subsection (a)(8), by striking “or” at the
19 end;

20 (2) in subsection (a)(9), by striking the period
21 and inserting “; or”;

22 (3) by adding at the end of subsection (a) the
23 following new paragraph:

24 “(10) by a participant or beneficiary for appropriate
25 relief under subsection (b)(4).”.

1 (4) by adding at the end of subsection (b) the
2 following new paragraph:

3 “(4) In the case of a group health plan, if exhaustion
4 of administrative remedies in accordance with paragraph
5 (2)(A)(ii) or (2)(B)(ii) of section 503(b) otherwise nec-
6 essary for an action for relief under paragraph (1)(B) or
7 (3) of subsection (a) has not been obtained and it is dem-
8 onstrated to the court by means of certification by an ap-
9 propriate physician that such exhaustion is not reasonably
10 attainable under the facts and circumstances without
11 undue risk of irreparable harm to the health of the partici-
12 pant or beneficiary, a civil action may be brought by the
13 participant or beneficiary to obtain appropriate equitable
14 relief. Any determinations made under paragraph
15 (2)(A)(ii) or (2)(B)(ii) of section 503(b) made while an
16 action under this paragraph is pending shall be given due
17 consideration by the court in any such action. This para-
18 graph shall not apply with respect to benefits that are not
19 included group health plan benefits (as defined in section
20 503(b)(10)(S)).”.

21 (d) ATTORNEY’S FEES.—Section 502(g) of such Act
22 (29 U.S.C. 1132(g)) is amended—

23 (1) in paragraph (1), by striking “paragraph
24 (2)” and inserting “paragraph (2) or (3)”; and

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

3 “(3) In any action under this title by a participant
4 or beneficiary in connection with an included group health
5 plan benefit (as defined in section 503(b)(10)(S)) in which
6 judgment in favor of the participant or beneficiary is
7 awarded, the court shall allow a reasonable attorney’s fee
8 and costs of action to the participant or beneficiary.”.

9 (e) STANDARD OF REVIEW UNAFFECTED.—The
10 standard of review under section 502 of the Employee Re-
11 tirement Income Security Act of 1974 (as amended by this
12 section) shall continue on and after the date of the enact-
13 ment of this Act to be the standard of review which was
14 applicable under such section as of immediately before
15 such date.

16 (f) CONCURRENT JURISDICTION.—Section 502(e)(1)
17 of such Act (29 U.S.C. 1132(e)(1)) is amended—

18 (1) in the first sentence, by striking “under
19 subsection (a)(1)(B) of this section” and inserting
20 “under subsection (a)(1)(A) for relief under sub-
21 section (c)(6), under subsection (a)(1)(B), and
22 under subsection (b)(4)”; and

23 (2) in the last sentence, by striking “of actions
24 under paragraphs (1)(B) and (7) of subsection (a)
25 of this section” and inserting “of actions under

1 paragraph (1)(A) of subsection (a) for relief under
2 subsection (c)(6) and of actions under paragraphs
3 (1)(B) and (7) of subsection (a) and paragraph (4)
4 of subsection (b)’’.

5 **SEC. 122. SPECIAL RULE FOR ACCESS TO SPECIALTY CARE.**

6 Section 503(b) of such Act (as added by the pre-
7 ceding provisions of this subtitle) is amended by adding
8 at the end the following new paragraph:

9 “(11) SPECIAL RULE FOR ACCESS TO SPE-
10 CIALTY CARE.—

11 “(A) IN GENERAL.—In the case of a re-
12 quest for advance determination of coverage
13 consisting of a request by a physician for a de-
14 termination of coverage of the services of a spe-
15 cialist with respect to any condition, if coverage
16 of the services of such specialist for such condi-
17 tion is otherwise provided under the plan, the
18 initial coverage decision referred to in subpara-
19 graph (A)(i) or (B)(i) of paragraph (2) shall be
20 issued within the accelerated need decision pe-
21 riod.

22 “(B) SPECIALIST.—For purposes of this
23 paragraph, the term ‘specialist’ means, with re-
24 spect to a condition, a physician who has a high
25 level of expertise through appropriate training

1 and experience (including, in the case of a pa-
2 tient who is a child, appropriate pediatric exper-
3 tise) to treat the condition.”.

4 **SEC. 123. PROTECTION FOR CERTAIN INFORMATION DE-**
5 **VELOPED TO REDUCE MORTALITY OR MOR-**
6 **BIDITY OR FOR IMPROVING PATIENT CARE**
7 **AND SAFETY.**

8 (a) PROTECTION OF CERTAIN INFORMATION.—Not-
9 withstanding any other provision of Federal or State law,
10 health care response information shall be exempt from any
11 disclosure requirement (regardless of whether the require-
12 ment relates to subpoenas, discovery, introduction of evi-
13 dence, testimony, or any other form of disclosure), in con-
14 nection with a civil or administrative proceeding under
15 Federal or State law, to the same extent as information
16 developed by a health care provider with respect to any
17 of the following:

- 18 (1) Peer review.
- 19 (2) Utilization review.
- 20 (3) Quality management or improvement.
- 21 (4) Quality control.
- 22 (5) Risk management.
- 23 (6) Internal review for purposes of reducing
24 mortality, morbidity, or for improving patient care
25 or safety.

1 (b) NO WAIVER OF PROTECTION THROUGH INTER-
2 ACTION WITH ACCREDITING BODY.—Notwithstanding any
3 other provision of Federal or State law, the protection of
4 health care response information from disclosure provided
5 under subsection (a) shall not be deemed to be modified
6 or in any way waived by—

7 (1) the development of such information in con-
8 nection with a request or requirement of an accred-
9 iting body; or

10 (2) the transfer of such information to an ac-
11 crediting body.

12 (c) DEFINITIONS.—For purposes of this section:

13 (1) The term “accrediting body” means a na-
14 tional, not-for-profit organization that—

15 (A) accredits health care providers; and

16 (B) is recognized as an accrediting body by
17 statute or by a Federal or State agency that
18 regulates health care providers.

19 (2) The term “health care provider” has the
20 meaning given such term in section 1188 of the So-
21 cial Security Act (as added by section 5001 of this
22 Act).

23 (3) The term “health care response informa-
24 tion” means information (including any data, report,
25 record, memorandum, analysis, statement, or other

1 communication) developed by, or on behalf of, a
2 health care provider in response to a serious, ad-
3 verse, patient-related event—

4 (A) during the course of analyzing or
5 studying the event and its causes; and

6 (B) for purposes of—

7 (i) reducing mortality or morbidity; or

8 (ii) improving patient care or safety
9 (including the provider's notification to an
10 accrediting body and the provider's plans
11 of action in response to such event).

12 (5) The term "State" includes the District of
13 Columbia, Puerto Rico, the Virgin Islands, Guam,
14 American Samoa, and the Northern Mariana Is-
15 lands.

16 **SEC. 124. EFFECTIVE DATE.**

17 (a) **IN GENERAL.**—The amendments made by sec-
18 tions 801 and 802 shall apply with respect to grievances
19 arising in plan years beginning on or after January 1 of
20 the second calendar year following 12 months after the
21 date the Secretary of Labor issues all regulations nec-
22 essary to carry out amendments made by this title. The
23 amendments made by section 803 shall take effect on such
24 January 1.

1 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
2 enforcement action shall be taken, pursuant to the amend-
3 ments made by this title, against a group health plan or
4 health insurance issuer with respect to a violation of a re-
5 quirement imposed by such amendments before the date
6 of issuance of final regulations issued in connection with
7 such requirement, if the plan or issuer has sought to com-
8 ply in good faith with such requirement.

9 (c) COLLECTIVE BARGAINING AGREEMENTS.—Any
10 plan amendment made pursuant to a collective bargaining
11 agreement relating to the plan which amends the plan
12 solely to conform to any requirement added by this title
13 shall not be treated as a termination of such collective bar-
14 gaining agreement.

15 **Subtitle D—Health Care Access, Af-**
16 **fordability, and Quality Com-**
17 **mission**

18 **SEC. 131. ESTABLISHMENT OF COMMISSION.**

19 Part 5 of the Employee Retirement Income Security
20 Act of 1974 is amended by adding at the end the following
21 new section:

22 “SEC. 518. HEALTH POLICY COMMISSION.

23 “(a) ESTABLISHMENT.—There is hereby established
24 a commission to be known as the Health Care Access, Af-
25 fordability, and Quality Commission (hereinafter in this
26 Act referred to as the “Commission”).

1 “(b) DUTIES OF COMMISSION.—The duties of the
2 Commission shall be as follows:

3 “(1) STUDIES OF CRITICAL AREAS.—Based on
4 information gathered by appropriate Federal agen-
5 cies, advisory groups, and other appropriate sources
6 for health care information, studies, and data, the
7 Commission shall study and report on in each of the
8 following areas:

9 “(A) Independent expert external review
10 programs.

11 “(B) Consumer friendly information pro-
12 grams.

13 “(C) The extent to which the following af-
14 fect patient quality and satisfaction:

15 “(i) health plan enrollees’ attitudes
16 based on surveys;

17 “(ii) outcomes measurements; and

18 “(iii) accreditation by private organi-
19 zations.

20 “(D) Available systems to ensure the time-
21 ly processing of claims.

22 “(2) ESTABLISHMENT OF FORM FOR REMIT-
23 TANCE OF CLAIMS TO PROVIDERS.—Not later than
24 2 years after the date of the first meeting of the
25 Commission, the Commission shall develop and

1 transmit to the Secretary a proposed form for use
2 by health insurance issuers (as defined in section
3 733(b)(2)) for the remittance of claims to health
4 care providers. Effective for plan years beginning
5 after 5 years after the date of the Comprehensive
6 Access and Responsibility in Health Care Act of
7 1999, a health insurance issuer offering health in-
8 surance coverage in connection with a group health
9 plan shall use such form for the remittance of all
10 claims to providers.

11 “(3) EVALUATION OF HEALTH BENEFITS MAN-
12 DATES.—At the request of the chairmen or ranking
13 minority members of the appropriate committees of
14 Congress, the Commission shall evaluate, taking into
15 consideration the overall cost effect, availability of
16 treatment, and the effect on the health of the gen-
17 eral population, existing and proposed benefit re-
18 quirements for group health plans.

19 “(4) COMMENTS ON CERTAIN SECRETARIAL RE-
20 PORTS.—If the Secretary submits to Congress (or a
21 committee of Congress) a report that is required by
22 law and that relates to policies under this section,
23 the Secretary shall transmit a copy of the report to
24 the Commission. The Commission shall review the
25 report and, not later than 6 months after the date

1 of submittal of the Secretary's report to Congress,
2 shall submit to the appropriate committees of Con-
3 gress written comments on such report. Such com-
4 ments may include such recommendations as the
5 Commission deems appropriate.

6 “(5) AGENDA AND ADDITIONAL REVIEW.—The
7 Commission shall consult periodically with the chair-
8 men and ranking minority members of the appro-
9 priate committees of Congress regarding the Com-
10 mission's agenda and progress toward achieving the
11 agenda. The Commission may conduct additional re-
12 views, and submit additional reports to the appro-
13 priate committees of Congress, from time to time on
14 such topics as may be requested by such chairmen
15 and members and as the Commission deems appro-
16 priate.

17 “(6) AVAILABILITY OF REPORTS.—The Com-
18 mission shall transmit to the Secretary a copy of
19 each report submitted under this subsection and
20 shall make such reports available to the public.

21 “(c) MEMBERSHIP.—

22 “(1) NUMBER AND APPOINTMENT.—The Com-
23 mission shall be composed of 11 members appointed
24 by the Comptroller General.

25 “(2) QUALIFICATIONS.—

1 “(A) IN GENERAL.—The membership of
2 the Commission shall include—

3 “(i) physicians and other health pro-
4 fessionals;

5 “(ii) representatives of employers, in-
6 cluding multiemployer plans;

7 “(ii) representatives of insured em-
8 ployees;

9 “(iv) third-party payers; and

10 “(v) health services and health eco-
11 nomics researchers with expertise in out-
12 comes and effectiveness research and tech-
13 nology assessment.

14 “(B) ETHICAL DISCLOSURE.—The Comp-
15 troller General shall establish a system for pub-
16 lic disclosure by members of the Commission of
17 financial and other potential conflicts of interest
18 relating to such members.

19 “(3) TERMS.—

20 “(A) IN GENERAL.—Each member shall be
21 appointed for a term of 3 years, except that the
22 Comptroller shall designate staggered terms for
23 the members first appointed.

24 “(B) VACANCIES.—Any member appointed
25 to fill a vacancy occurring before the expiration

1 of the term for which the member's predecessor
2 was appointed shall be appointed only for the
3 remainder of that term. A member may serve
4 after the expiration of that member's term until
5 a successor has taken office. A vacancy in the
6 Commission shall be filled in the manner in
7 which the original appointment was made.

8 “(4) BASIC PAY.—

9 “(A) RATES OF PAY.—Except as provided
10 in subparagraph (B), members shall each be
11 paid at a rate equal to the rate of basic pay
12 payable for level IV of the Executive Schedule
13 for each day (including travel time) during
14 which they are engaged in the actual perform-
15 ance of duties vested in the Commission.

16 “(B) PROHIBITION OF COMPENSATION OF
17 FEDERAL EMPLOYEES.—Members of the Com-
18 mission who are full-time officers or employees
19 of the United States (or Members of Congress)
20 may not receive additional pay, allowances, or
21 benefits by reason of their service on the Com-
22 mission.

23 “(5) TRAVEL EXPENSES.—Each member shall
24 receive travel expenses, including per diem in lieu of

1 subsistence, in accordance with sections 5702 and
2 5703 of title 5, United States Code.

3 “(6) CHAIRPERSON.—The Chairperson of the
4 Commission shall be designated by the Comptroller
5 at the time of the appointment. The term of office
6 of the Chairperson shall be 3 years.

7 “(7) MEETINGS.—The Commission shall meet 4
8 times each year.

9 “(d) DIRECTOR AND STAFF OF COMMISSION.—

10 “(1) DIRECTOR.—The Commission shall have a
11 Director who shall be appointed by the Chairperson.
12 The Director shall be paid at a rate not to exceed
13 the maximum rate of basic pay payable for GS-13
14 of the General Schedule.

15 “(2) STAFF.—The Director may appoint 2 ad-
16 ditional staff members.

17 “(3) APPLICABILITY OF CERTAIN CIVIL SERV-
18 ICE LAWS.—The Director and staff of the Commis-
19 sion shall be appointed subject to the provisions of
20 title 5, United States Code, governing appointments
21 in the competitive service, and shall be paid in ac-
22 cordance with the provisions of chapter 51 and sub-
23 chapter III of chapter 53 of that title relating to
24 classification and General Schedule pay rates.

25 “(e) POWERS OF COMMISSION.—

1 “(1) HEARINGS AND SESSIONS.—The Commis-
2 sion may, for the purpose of carrying out this Act,
3 hold hearings, sit and act at times and places, take
4 testimony, and receive evidence as the Commission
5 considers appropriate. The Commission may admin-
6 ister oaths or affirmations to witnesses appearing
7 before it.

8 “(2) POWERS OF MEMBERS AND AGENTS.—Any
9 member or agent of the Commission may, if author-
10 ized by the Commission, take any action which the
11 Commission is authorized to take by this section.

12 “(3) OBTAINING OFFICIAL DATA.—The Com-
13 mission may secure directly from any department or
14 agency of the United States information necessary
15 to enable it to carry out this Act. Upon request of
16 the Chairperson of the Commission, the head of that
17 department or agency shall furnish that information
18 to the Commission.

19 “(4) MAILS.—The Commission may use the
20 United States mails in the same manner and under
21 the same conditions as other departments and agen-
22 cies of the United States.

23 “(5) ADMINISTRATIVE SUPPORT SERVICES.—
24 Upon the request of the Commission, the Adminis-
25 trator of General Services shall provide to the Com-

1 mission, on a reimbursable basis, the administrative
2 support services necessary for the Commission to
3 carry out its responsibilities under this Act.

4 “(6) CONTRACT AUTHORITY.—The Commission
5 may contract with and compensate government and
6 private agencies or persons for services, without re-
7 gard to section 3709 of the Revised Statutes (41
8 U.S.C. 5).

9 “(f) REPORTS.—Beginning December 31, 2000, and
10 each year thereafter, the Commission shall submit to the
11 Congress an annual report detailing the following informa-
12 tion:

13 “(1) Access to care, affordability to employers
14 and employees, and quality of care under employer-
15 sponsored health plans and recommendations for im-
16 proving such access, affordability, and quality.

17 “(2) Any issues the Commission deems appro-
18 priate or any issues (such as the appropriateness
19 and availability of particular medical treatment) that
20 the chairmen or ranking members of the appropriate
21 committees of Congress requested the Commission
22 to evaluate.

23 “(g) DEFINITION OF APPROPRIATE COMMITTEES OF
24 CONGRESS.—For purposes of this section the term ‘appro-
25 priate committees of Congress’ means any committee in

1 the Senate or House of Representatives having jurisdiction
2 over the Employee Retirement Income Security Act of
3 1974.

4 “(h) TERMINATION.—Section 14(a)(2)(B) of the
5 Federal Advisory Committee Act (5 U.S.C. App.; relating
6 to the termination of advisory committees) shall not apply
7 to the Commission.

8 “(i) AUTHORIZATION OF APPROPRIATIONS.—There is
9 authorized to be appropriated for fiscal years 2000
10 through 2004 such sums as may be necessary to carry
11 out this section.”.

12 **SEC. 132. EFFECTIVE DATE.**

13 This subtitle shall be effective 6 months after the
14 date of the enactment of this Act.

1 **TITLE II—AMENDMENTS TO THE**
2 **PUBLIC HEALTH SERVICE ACT**
3 **Subtitle A—Patient Protections**
4 **and Point of Service Coverage**
5 **Requirements**

6 **SEC. 201. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
7 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
8 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
9 **ATRIC CARE, AND CONTINUITY OF CARE.**

10 (a) IN GENERAL.—Subpart 2 of part A of title
11 XXVII of the Public Health Service Act is amended by
12 adding at the end the following new section:

13 **“SEC. 2707. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
14 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
15 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
16 **ATRIC CARE, AND CONTINUITY OF CARE.**

17 **“(a) PATIENT ACCESS TO UNRESTRICTED MEDICAL**
18 **ADVICE.—**

19 **“(1) IN GENERAL.—**In the case of any health
20 care professional acting within the lawful scope of
21 practice in the course of carrying out a contractual
22 employment arrangement or other direct contractual
23 arrangement between such professional and a group
24 health plan or a health insurance issuer offering
25 health insurance coverage in connection with a group

1 health plan, the plan or issuer with which such con-
2 tractual employment arrangement or other direct
3 contractual arrangement is maintained by the pro-
4 fessional may not impose on such professional under
5 such arrangement any prohibition or restriction with
6 respect to advice, provided to a participant or bene-
7 ficiary under the plan who is a patient, about the
8 health status of the participant or beneficiary or the
9 medical care or treatment for the condition or dis-
10 ease of the participant or beneficiary, regardless of
11 whether benefits for such care or treatment are pro-
12 vided under the plan or health insurance coverage
13 offered in connection with the plan.

14 “(2) HEALTH CARE PROFESSIONAL DEFINED.—
15 For purposes of this paragraph, the term ‘health
16 care professional’ means a physician (as defined in
17 section 1861(r) of the Social Security Act) or other
18 health care professional if coverage for the profes-
19 sional’s services is provided under the group health
20 plan for the services of the professional. Such term
21 includes a podiatrist, optometrist, chiropractor, psy-
22 chologist, dentist, physician assistant, physical or oc-
23 cupational therapist and therapy assistant, speech-
24 language pathologist, audiologist, registered or li-
25 censed practical nurse (including nurse practitioner,

1 clinical nurse specialist, certified registered nurse
2 anesthetist, and certified nurse-midwife), licensed
3 certified social worker, registered respiratory thera-
4 pist, and certified respiratory therapy technician.

5 “(3) RULE OF CONSTRUCTION.—Nothing in
6 this subsection shall be construed to require the
7 sponsor of a group health plan or a health insurance
8 issuer offering health insurance coverage in connec-
9 tion with the group health plan to engage in any
10 practice that would violate its religious beliefs or
11 moral convictions.

12 “(b) PATIENT ACCESS TO EMERGENCY MEDICAL
13 CARE.—

14 “(1) COVERAGE OF EMERGENCY SERVICES.—

15 “(A) IN GENERAL.—If a group health
16 plan, or health insurance coverage offered by a
17 health insurance issuer, provides any benefits
18 with respect to emergency services (as defined
19 in subparagraph (B)(ii)), or ambulance services,
20 the plan or issuer shall cover emergency serv-
21 ices (including emergency ambulance services as
22 defined in subparagraph (B)(iii)) furnished
23 under the plan or coverage—

24 “(i) without the need for any prior
25 authorization determination;

1 “(ii) whether or not the health care
2 provider furnishing such services is a par-
3 ticipating provider with respect to such
4 services;

5 “(iii) in a manner so that, if such
6 services are provided to a participant, ben-
7 efiary, or enrollee by a nonparticipating
8 health care provider, the participant, bene-
9 ficiary, or enrollee is not liable for amounts
10 that exceed the amounts of liability that
11 would be incurred if the services were pro-
12 vided by a participating provider; and

13 “(iv) without regard to any other term
14 or condition of such plan or coverage
15 (other than exclusion or coordination of
16 benefits, or an affiliation or waiting period,
17 permitted under section 2701 and other
18 than applicable cost sharing).

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

20 “(i) EMERGENCY MEDICAL CONDI-
21 TION.—The term ‘emergency medical con-
22 dition’ means—

23 “(I) a medical condition mani-
24 festing itself by acute symptoms of
25 sufficient severity (including severe

1 pain) such that a prudent layperson,
2 who possesses an average knowledge
3 of health and medicine, could reason-
4 ably expect the absence of immediate
5 medical attention to result in a condi-
6 tion described in clause (i), (ii), or
7 (iii) of section 1867(e)(1)(A) of the
8 Social Security Act (42 U.S.C.
9 1395dd(e)(1)(A)); and

10 “(II) a medical condition mani-
11 festing itself in a neonate by acute
12 symptoms of sufficient severity (in-
13 cluding severe pain) such that a pru-
14 dent health care professional could
15 reasonably expect the absence of im-
16 mediate medical attention to result in
17 a condition described in clause (i),
18 (ii), or (iii) of section 1867(e)(1)(A)
19 of the Social Security Act.

20 “(ii) EMERGENCY SERVICES.—The
21 term ‘emergency services’ means—

22 “(I) with respect to an emer-
23 gency medical condition described in
24 clause (i)(I), a medical screening ex-
25 amination (as required under section

1 1867 of the Social Security Act, 42
2 U.S.C. 1395dd) that is within the ca-
3 pability of the emergency department
4 of a hospital, including ancillary serv-
5 ices routinely available to the emer-
6 gency department to evaluate an
7 emergency medical condition (as de-
8 fined in clause (i)) and also, within
9 the capabilities of the staff and facili-
10 ties at the hospital, such further med-
11 ical examination and treatment as are
12 required under section 1867 of such
13 Act to stabilize the patient; or

14 “(II) with respect to an emer-
15 gency medical condition described in
16 clause (i)(II), medical treatment for
17 such condition rendered by a health
18 care provider in a hospital to a
19 neonate, including available hospital
20 ancillary services in response to an ur-
21 gent request of a health care profes-
22 sional and to the extent necessary to
23 stabilize the neonate.

24 “(iii) EMERGENCY AMBULANCE SERV-
25 ICES.—The term ‘emergency ambulance

1 services' means ambulance services (as de-
2 fined for purposes of section 1861(s)(7) of
3 the Social Security Act) furnished to trans-
4 port an individual who has an emergency
5 medical condition (as defined in clause (i))
6 to a hospital for the receipt of emergency
7 services (as defined in clause (ii)) in a case
8 in which appropriate emergency medical
9 screening examinations are covered under
10 the plan or coverage pursuant to para-
11 graph (1)(A) and a prudent layperson,
12 with an average knowledge of health and
13 medicine, could reasonably expect that the
14 absence of such transport would result in
15 placing the health of the individual in seri-
16 ous jeopardy, serious impairment of bodily
17 function, or serious dysfunction of any
18 bodily organ or part.

19 “(iv) STABILIZE.—The term ‘to sta-
20 bilize’ means, with respect to an emergency
21 medical condition, to provide such medical
22 treatment of the condition as may be nec-
23 essary to assure, within reasonable medical
24 probability, that no material deterioration
25 of the condition is likely to result from or

1 occur during the transfer of the individual
2 from a facility.

3 “(v) NONPARTICIPATING.—The term
4 ‘nonparticipating’ means, with respect to a
5 health care provider that provides health
6 care items and services to a participant or
7 beneficiary under group health plan or
8 under group health insurance coverage, a
9 health care provider that is not a partici-
10 pating health care provider with respect to
11 such items and services.

12 “(vi) PARTICIPATING.—The term
13 ‘participating’ means, with respect to a
14 health care provider that provides health
15 care items and services to a participant or
16 beneficiary under group health plan or
17 health insurance coverage offered by a
18 health insurance issuer in connection with
19 such a plan, a health care provider that
20 furnishes such items and services under a
21 contract or other arrangement with the
22 plan or issuer.

23 “(c) PATIENT RIGHT TO OBSTETRIC AND GYNECO-
24 LOGICAL CARE.—

1 “(1) IN GENERAL.—In any case in which a
2 group health plan (or a health insurance issuer of-
3 fering health insurance coverage in connection with
4 the plan)—

5 “(A) provides benefits under the terms of
6 the plan consisting of—

7 “(i) gynecological care (such as pre-
8 ventive women’s health examinations); or

9 “(ii) obstetric care (such as preg-
10 nancy-related services),

11 provided by a participating health care profes-
12 sional who specializes in such care (or provides
13 benefits consisting of payment for such care);
14 and

15 “(B) requires or provides for designation
16 by a participant or beneficiary of a partici-
17 pating primary care provider,

18 if the primary care provider designated by such a
19 participant or beneficiary is not such a health care
20 professional, then the plan (or issuer) shall meet the
21 requirements of paragraph (2).

22 “(1) REQUIREMENTS.—A group health plan (or
23 a health insurance issuer offering health insurance
24 coverage in connection with the plan) meets the re-
25 quirements of this paragraph, in connection with

1 benefits described in paragraph (1) consisting of
2 care described in clause (i) or (ii) of paragraph
3 (1)(A) (or consisting of payment therefor), if the
4 plan (or issuer)—

5 “(A) does not require authorization or a
6 referral by the primary care provider in order
7 to obtain such benefits; and

8 “(B) treats the ordering of other care of
9 the same type, by the participating health care
10 professional providing the care described in
11 clause (i) or (ii) of paragraph (1)(A), as the au-
12 thorization of the primary care provider with
13 respect to such care.

14 “(3) HEALTH CARE PROFESSIONAL DEFINED.—
15 For purposes of this subsection, the term ‘health
16 care professional’ means an individual (including,
17 but not limited to, a nurse midwife or nurse practi-
18 tioner) who is licensed, accredited, or certified under
19 State law to provide obstetric and gynecological
20 health care services and who is operating within the
21 scope of such licensure, accreditation, or certifi-
22 cation.

23 “(4) CONSTRUCTION.—Nothing in paragraph
24 (1) shall be construed as preventing a plan from of-
25 fering (but not requiring a participant or beneficiary

1 to accept) a health care professional trained,
2 credentialed, and operating within the scope of their
3 licensure to perform obstetric and gynecological
4 health care services. Nothing in paragraph (2)(B)
5 shall waive any requirements of coverage relating to
6 medical necessity or appropriateness with respect to
7 coverage of gynecological or obstetric care so or-
8 dered.

9 “(5) TREATMENT OF MULTIPLE COVERAGE OP-
10 TIONS.—In the case of a plan providing benefits
11 under two or more coverage options, the require-
12 ments of this subsection shall apply separately with
13 respect to each coverage option.

14 “(d) PATIENT RIGHT TO PEDIATRIC CARE.—

15 “(1) IN GENERAL.—In any case in which a
16 group health plan (or a health insurance issuer of-
17 fering health insurance coverage in connection with
18 the plan) provides benefits consisting of routine pe-
19 diatric care provided by a participating health care
20 professional who specializes in pediatrics (or con-
21 sisting of payment for such care) and the plan re-
22 quires or provides for designation by a participant or
23 beneficiary of a participating primary care provider,
24 the plan (or issuer) shall provide that such a partici-
25 pating health care professional may be designated, if

1 available, by a parent or guardian of any beneficiary
2 under the plan is who under 18 years of age, as the
3 primary care provider with respect to any such bene-
4 fits.

5 “(2) HEALTH CARE PROFESSIONAL DEFINED.—
6 For purposes of this subsection, the term ‘health
7 care professional’ means an individual (including,
8 but not limited to, a nurse practitioner) who is li-
9 censed, accredited, or certified under State law to
10 provide pediatric health care services and who is op-
11 erating within the scope of such licensure, accredita-
12 tion, or certification.

13 “(3) CONSTRUCTION.—Nothing in paragraph
14 (1) shall be construed as preventing a plan from of-
15 fering (but not requiring a participant or beneficiary
16 to accept) a health care professional trained,
17 credentialed, and operating within the scope of their
18 licensure to perform pediatric health care services.
19 Nothing in paragraph (1) shall waive any require-
20 ments of coverage relating to medical necessity or
21 appropriateness with respect to coverage of pediatric
22 care so ordered.

23 “(4) TREATMENT OF MULTIPLE COVERAGE OP-
24 TIONS.—In the case of a plan providing benefits
25 under two or more coverage options, the require-

1 ments of this subsection shall apply separately with
2 respect to each coverage option.

3 “(e) CONTINUITY OF CARE.—

4 “(1) IN GENERAL.—

5 “(A) TERMINATION OF PROVIDER.—If a
6 contract between a group health plan, or a
7 health insurance issuer offering health insur-
8 ance coverage in connection with a group health
9 plan, and a health care provider is terminated
10 (as defined in subparagraph (D)(ii)), or benefits
11 or coverage provided by a health care provider
12 are terminated because of a change in the
13 terms of provider participation in a group
14 health plan, and an individual who, at the time
15 of such termination, is a participant or bene-
16 ficiary in the plan and is scheduled to undergo
17 surgery (including an organ transplantation), is
18 undergoing treatment for pregnancy, or is de-
19 termined to be terminally ill (as defined in sec-
20 tion 1861(dd)(3)(A) of the Social Security Act)
21 and is undergoing treatment for the terminal
22 illness, the plan or issuer shall—

23 “(i) notify the individual on a timely
24 basis of such termination and of the right
25 to elect continuation of coverage of treat-

1 ment by the provider under this sub-
2 section; and

3 “(ii) subject to paragraph (3), permit
4 the individual to elect to continue to be
5 covered with respect to treatment by the
6 provider for such surgery, pregnancy, or
7 illness during a transitional period (pro-
8 vided under paragraph (2)).

9 “(B) TREATMENT OF TERMINATION OF
10 CONTRACT WITH HEALTH INSURANCE
11 ISSUER.—If a contract for the provision of
12 health insurance coverage between a group
13 health plan and a health insurance issuer is ter-
14 minated and, as a result of such termination,
15 coverage of services of a health care provider is
16 terminated with respect to an individual, the
17 provisions of subparagraph (A) (and the suc-
18 ceeding provisions of this subsection) shall
19 apply under the plan in the same manner as if
20 there had been a contract between the plan and
21 the provider that had been terminated, but only
22 with respect to benefits that are covered under
23 the plan after the contract termination.

24 “(C) TERMINATION DEFINED.—For pur-
25 poses of this subsection, the term ‘terminated’

1 includes, with respect to a contract, the expira-
2 tion or nonrenewal of the contract, but does not
3 include a termination of the contract by the
4 plan or issuer for failure to meet applicable
5 quality standards or for fraud.

6 “(2) TRANSITIONAL PERIOD.—

7 “(A) IN GENERAL.—Except as provided in
8 subparagraphs (B) through (D), the transi-
9 tional period under this paragraph shall extend
10 up to 90 days (as determined by the treating
11 health care professional) after the date of the
12 notice described in paragraph (1)(A)(i) of the
13 provider’s termination.

14 “(B) SCHEDULED SURGERY.—If surgery
15 was scheduled for an individual before the date
16 of the announcement of the termination of the
17 provider status under paragraph (1)(A)(i), the
18 transitional period under this paragraph with
19 respect to the surgery shall extend beyond the
20 period under subparagraph (A) and until the
21 date of discharge of the individual after comple-
22 tion of the surgery.

23 “(C) PREGNANCY.—If—

24 “(i) a participant or beneficiary was
25 determined to be pregnant at the time of

1 a provider's termination of participation,
2 and

3 "(ii) the provider was treating the
4 pregnancy before date of the termination,
5 the transitional period under this paragraph
6 with respect to provider's treatment of the
7 pregnancy shall extend through the provision of
8 post-partum care directly related to the deliv-
9 ery.

10 "(D) TERMINAL ILLNESS.—If—

11 "(i) a participant or beneficiary was
12 determined to be terminally ill (as deter-
13 mined under section 1861(dd)(3)(A) of the
14 Social Security Act) at the time of a pro-
15 vider's termination of participation, and

16 "(ii) the provider was treating the ter-
17 minal illness before the date of termi-
18 nation,

19 the transitional period under this paragraph
20 shall extend for the remainder of the individ-
21 ual's life for care directly related to the treat-
22 ment of the terminal illness or its medical
23 manifestations.

24 "(3) PERMISSIBLE TERMS AND CONDITIONS.—

25 A group health plan or health insurance issuer may

1 condition coverage of continued treatment by a pro-
2 vider under paragraph (1)(A)(i) upon the individual
3 notifying the plan of the election of continued cov-
4 erage and upon the provider agreeing to the fol-
5 lowing terms and conditions:

6 “(A) The provider agrees to accept reim-
7 bursement from the plan or issuer and indi-
8 vidual involved (with respect to cost-sharing) at
9 the rates applicable prior to the start of the
10 transitional period as payment in full (or, in the
11 case described in paragraph (1)(B), at the rates
12 applicable under the replacement plan or issuer
13 after the date of the termination of the contract
14 with the health insurance issuer) and not to im-
15 pose cost-sharing with respect to the individual
16 in an amount that would exceed the cost-shar-
17 ing that could have been imposed if the contract
18 referred to in paragraph (1)(A) had not been
19 terminated.

20 “(B) The provider agrees to adhere to the
21 quality assurance standards of the plan or
22 issuer responsible for payment under subpara-
23 graph (A) and to provide to such plan or issuer
24 necessary medical information related to the
25 care provided.

1 “(C) The provider agrees otherwise to ad-
2 here to such plan’s or issuer’s policies and pro-
3 cedures, including procedures regarding refer-
4 rals and obtaining prior authorization and pro-
5 viding services pursuant to a treatment plan (if
6 any) approved by the plan or issuer.

7 “(D) The provider agrees to provide tran-
8 sitional care to all participants and beneficiaries
9 who are eligible for and elect to have coverage
10 of such care from such provider.

11 “(E) If the provider initiates the termi-
12 nation, the provider has notified the plan within
13 30 days prior to the effective date of the termi-
14 nation of—

15 “(i) whether the provider agrees to
16 permissible terms and conditions (as set
17 forth in this paragraph) required by the
18 plan, and

19 “(ii) if the provider agrees to the
20 terms and conditions, the specific plan
21 beneficiaries and participants undergoing a
22 course of treatment from the provider who
23 the provider believes, at the time of the no-
24 tification, would be eligible for transitional
25 care under this subsection.

1 “(4) CONSTRUCTION.—Nothing in this sub-
2 section shall be construed to—

3 “(A) require the coverage of benefits which
4 would not have been covered if the provider in-
5 volved remained a participating provider, or

6 “(B) prohibit a group health plan from
7 conditioning a provider’s participation on the
8 provider’s agreement to provide transitional
9 care to all participants and beneficiaries eligible
10 to obtain coverage of such care furnished by the
11 provider as set forth under this subsection.

12 “(f) COVERAGE FOR INDIVIDUALS PARTICIPATING IN
13 APPROVED CANCER CLINICAL TRIALS.—

14 “(1) COVERAGE.—

15 “(A) IN GENERAL.—If a group health plan
16 (or a health insurance issuer offering health in-
17 surance coverage) provides coverage to a quali-
18 fied individual (as defined in paragraph (2)),
19 the plan or issuer—

20 “(i) may not deny the individual par-
21 ticipation in the clinical trial referred to in
22 paragraph (2)(B);

23 “(ii) subject to paragraphs (2), (3),
24 and (4), may not deny (or limit or impose
25 additional conditions on) the coverage of

1 routine patient costs for items and services
2 furnished in connection with participation
3 in the trial; and

4 “(iii) may not discriminate against the
5 individual on the basis of the participation
6 of the participant or beneficiary in such
7 trial.

8 “(B) EXCLUSION OF CERTAIN COSTS.—
9 For purposes of subparagraph (A)(ii), routine
10 patient costs do not include the cost of the tests
11 or measurements conducted primarily for the
12 purpose of the clinical trial involved.

13 “(C) USE OF IN-NETWORK PROVIDERS.—If
14 one or more participating providers is partici-
15 pating in a clinical trial, nothing in subpara-
16 graph (A) shall be construed as preventing a
17 plan from requiring that a qualified individual
18 participate in the trial through such a partici-
19 pating provider if the provider will accept the
20 individual as a participant in the trial.

21 “(2) QUALIFIED INDIVIDUAL DEFINED.—For
22 purposes of paragraph (1), the term ‘qualified indi-
23 vidual’ means an individual who is a participant or
24 beneficiary in a group health plan and who meets
25 the following conditions:

1 “(A)(i) The individual has been diagnosed
2 with cancer.

3 “(ii) The individual is eligible to partici-
4 pate in an approved clinical trial according to
5 the trial protocol with respect to treatment of
6 cancer.

7 “(iii) The individual’s participation in the
8 trial offers meaningful potential for significant
9 clinical benefit for the individual.

10 “(B) Either—

11 “(i) the referring physician is a par-
12 ticipating health care professional and has
13 concluded that the individual’s participa-
14 tion in such trial would be appropriate
15 based upon satisfaction by the individual of
16 the conditions described in subparagraph
17 (A); or

18 “(ii) the individual provides medical
19 and scientific information establishing that
20 the individual’s participation in such trial
21 would be appropriate based upon the satis-
22 faction by the individual of the conditions
23 described in subparagraph (A).

24 “(3) PAYMENT.—

1 “(A) IN GENERAL.—A group health plan
2 (or a health insurance issuer offering health in-
3 surance coverage) shall provide for payment for
4 routine patient costs described in paragraph
5 (1)(B) but is not required to pay for costs of
6 items and services that are reasonably expected
7 to be paid for by the sponsors of an approved
8 clinical trial.

9 “(B) ROUTINE PATIENT CARE COSTS.—

10 “(i) IN GENERAL.—For purposes of
11 this paragraph, the term ‘routine patient
12 care costs’ shall include the costs associ-
13 ated with the provision of items and serv-
14 ices that—

15 “(I) would otherwise be covered
16 under the group health plan if such
17 items and services were not provided
18 in connection with an approved clin-
19 ical trial program; and

20 “(II) are furnished according to
21 the protocol of an approved clinical
22 trial program.

23 “(ii) EXCLUSION.—For purposes of
24 this paragraph, ‘routine patient care costs’

1 shall not include the costs associated with
2 the provision of—

3 “(I) an investigational drug or
4 device, unless the Secretary has au-
5 thORIZED the manufacturer of such
6 drug or device to charge for such drug
7 or device; or

8 “(II) any item or service supplied
9 without charge by the sponsor of the
10 approved clinical trial program.

11 “(C) PAYMENT RATE.—For purposes of
12 this subsection—

13 “(i) PARTICIPATING PROVIDERS.—In
14 the case of covered items and services pro-
15 vided by a participating provider, the pay-
16 ment rate shall be at the agreed upon rate.

17 “(ii) NONPARTICIPATING PRO-
18 VIDERS.—In the case of covered items and
19 services provided by a nonparticipating
20 provider, the payment rate shall be at the
21 rate the plan would normally pay for com-
22 parable items or services under clause (i).

23 “(4) APPROVED CLINICAL TRIAL DEFINED.—

24 “(A) IN GENERAL.—For purposes of this
25 subsection, the term ‘approved clinical trial’

1 means a cancer clinical research study or can-
2 cer clinical investigation approved by an Institu-
3 tional Review Board.

4 “(B) CONDITIONS FOR DEPARTMENTS.—
5 The conditions described in this paragraph, for
6 a study or investigation conducted by a Depart-
7 ment, are that the study or investigation has
8 been reviewed and approved through a system
9 of peer review that the Secretary determines—

10 “(i) to be comparable to the system of
11 peer review of studies and investigations
12 used by the National Institutes of Health,
13 and

14 “(ii) assures unbiased review of the
15 highest scientific standards by qualified in-
16 dividuals who have no interest in the out-
17 come of the review.

18 “(5) CONSTRUCTION.—Nothing in this sub-
19 section shall be construed to limit a plan’s coverage
20 with respect to clinical trials.

21 “(6) PLAN SATISFACTION OF CERTAIN RE-
22 QUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

23 “(A) IN GENERAL.—For purposes of this
24 subsection, insofar as a group health plan pro-
25 vides benefits in the form of health insurance

1 coverage through a health insurance issuer, the
2 plan shall be treated as meeting the require-
3 ments of this subsection with respect to such
4 benefits and not be considered as failing to
5 meet such requirements because of a failure of
6 the issuer to meet such requirements so long as
7 the plan sponsor or its representatives did not
8 cause such failure by the issuer.

9 “(B) CONSTRUCTION.—Nothing in this
10 subsection shall be construed to affect or mod-
11 ify the responsibilities of the fiduciaries of a
12 group health plan under part 4 of subtitle B of
13 title I of the Employee Retirement Income Se-
14 curity Act of 1974.

15 “(7) STUDY AND REPORT.—

16 “(A) STUDY.—The Secretary shall analyze
17 cancer clinical research and its cost implications
18 for managed care, including differentiation in—

19 “(i) the cost of patient care in trials
20 versus standard care;

21 “(ii) the cost effectiveness achieved in
22 different sites of service;

23 “(iii) research outcomes;

24 “(iv) volume of research subjects
25 available in different sites of service;

1 “(v) access to research sites and clin-
2 ical trials by cancer patients;

3 “(vi) patient cost sharing or copay-
4 ment costs realized in different sites of
5 service;

6 “(vii) health outcomes experienced in
7 different sites of service;

8 “(viii) long term health care services
9 and costs experienced in different sites of
10 service;

11 “(ix) morbidity and mortality experi-
12 enced in different sites of service; and

13 “(x) patient satisfaction and pref-
14 erence of sites of service.

15 “(B) REPORT TO CONGRESS.—Not later
16 than January 1, 2005, the Secretary shall sub-
17 mit a report to Congress that contains—

18 “(i) an assessment of any incremental
19 cost to group health plans resulting from
20 the provisions of this section;

21 “(ii) a projection of expenditures to
22 such plans resulting from this section;

23 “(iii) an assessment of any impact on
24 premiums resulting from this section; and

1 “(iv) recommendations regarding ac-
2 tion on other diseases.”.

3 **SEC. 202. REQUIRING HEALTH MAINTENANCE ORGANIZA-**
4 **TIONS TO OFFER OPTION OF POINT-OF-SERV-**
5 **ICE COVERAGE.**

6 Title XXVII of the Public Health Service Act is
7 amended by inserting after section 2713 the following new
8 section:

9 **“SEC. 2714. REQUIRING OFFERING OF OPTION OF POINT-**
10 **OF-SERVICE COVERAGE.**

11 “(a) REQUIREMENT TO OFFER COVERAGE OPTION
12 TO CERTAIN EMPLOYERS.—Except as provided in sub-
13 section (c), any health insurance issuer which—

14 “(1) is a health maintenance organization (as
15 defined in section 2791(b)(3)); and

16 “(2) which provides for coverage of services of
17 one or more classes of health care professionals
18 under health insurance coverage offered in connec-
19 tion with a group health plan only if such services
20 are furnished exclusively through health care profes-
21 sionals within such class or classes who are members
22 of a closed panel of health care professionals,

23 the issuer shall make available to the plan sponsor in con-
24 nection with such a plan a coverage option which provides
25 for coverage of such services which are furnished through

1 such class (or classes) of health care professionals regard-
2 less of whether or not the professionals are members of
3 such panel.

4 “(b) REQUIREMENT TO OFFER SUPPLEMENTAL COV-
5 ERAGE TO PARTICIPANTS IN CERTAIN CASES.—Except as
6 provided in subsection (c), if a health insurance issuer
7 makes available a coverage option under and described in
8 subsection (a) to a plan sponsor of a group health plan
9 and the sponsor declines to contract for such coverage op-
10 tion, then the issuer shall make available in the individual
11 insurance market to each participant in the group health
12 plan optional separate supplemental health insurance cov-
13 erage in the individual health insurance market which con-
14 sists of services identical to those provided under such cov-
15 erage provided through the closed panel under the group
16 health plan but are furnished exclusively by health care
17 professionals who are not members of such a closed panel.

18 “(c) EXCEPTIONS.—

19 “(1) OFFERING OF NON-PANEL OPTION.—Sub-
20 sections (a) and (b) shall not apply with respect to
21 a group health plan if the plan offers a coverage op-
22 tion that provides coverage for services that may be
23 furnished by a class or classes of health care profes-
24 sionals who are not in a closed panel. This para-

1 graph shall be applied separately to distinguishable
2 groups of employees under the plan.

3 “(2) AVAILABILITY OF COVERAGE THROUGH
4 HEALTHMART.—Subsections (a) and (b) shall not
5 apply to a group health plan if the health insurance
6 coverage under the plan is made available through a
7 HealthMart (as defined in section 2801) and if any
8 health insurance coverage made available through
9 the HealthMart provides for coverage of the services
10 of any class of health care professionals other than
11 through a closed panel of professionals.

12 “(3) RELICENSURE EXEMPTION.—Subsections
13 (a) and (b) shall not apply to a health maintenance
14 organization in a State in any case in which—

15 “(A) the organization demonstrates to the
16 applicable authority that the organization has
17 made a good faith effort to obtain (but has
18 failed to obtain) a contract between the organi-
19 zation and any other health insurance issuer
20 providing for the coverage option or supple-
21 mental coverage described in subsection (a) or
22 (b), as the case may be, within the applicable
23 service area of the organization; and

24 “(B) the State requires the organization to
25 receive or qualify for a separate license, as an

1 indemnity insurer or otherwise, in order to offer
2 such coverage option or supplemental coverage,
3 respectively.

4 The applicable authority may require that the orga-
5 nization demonstrate that it meets the requirements
6 of the previous sentence no more frequently than
7 once every 2 years.

8 “(4) COLLECTIVE BARGAINING AGREEMENTS.—
9 Subsections (a) and (b) shall not apply in connection
10 with a group health plan if the plan is established
11 or maintained pursuant to one or more collective
12 bargaining agreements.

13 “(5) SMALL ISSUERS.—Subsections (a) and (b)
14 shall not apply in the case of a health insurance
15 issuer with 25,000 or fewer covered lives.

16 “(d) APPLICABILITY.—The requirements of this sec-
17 tion shall apply only in connection with included group
18 health plan benefits.

19 “(e) DEFINITIONS.—For purposes of this section:

20 “(1) COVERAGE THROUGH CLOSED PANEL.—
21 Health insurance coverage for a class of health care
22 professionals shall be treated as provided through a
23 closed panel of such professionals only if such cov-
24 erage consists of coverage of items or services con-
25 sisting of professionals services which are reim-

1 bursed for or provided only within a limited network
2 of such professionals.

3 “(2) HEALTH CARE PROFESSIONAL.—The term
4 ‘health care professional’ has the meaning given
5 such term in section 2707(a)(2).

6 “(3) INCLUDED GROUP HEALTH PLAN BEN-
7 EFIT.—The term ‘included group health plan ben-
8 efit’ means a benefit which is not an excepted ben-
9 efit (as defined in section 2791(c)).”.

10 **SEC. 203. EFFECTIVE DATE AND RELATED RULES.**

11 (a) IN GENERAL.—The amendments made by this
12 title shall apply with respect to plan years beginning on
13 or after January 1 of the second calendar year following
14 the date of the enactment of this Act, except that the Sec-
15 retary of Health and Human Services may issue regula-
16 tions before such date under such amendments. The Sec-
17 retary shall first issue regulations necessary to carry out
18 the amendments made by this title before the effective
19 date thereof.

20 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
21 enforcement action shall be taken, pursuant to the amend-
22 ments made by this title, against a group health plan or
23 health insurance issuer with respect to a violation of a re-
24 quirement imposed by such amendments before the date
25 of issuance of regulations issued in connection with such

1 requirement, if the plan or issuer has sought to comply
2 in good faith with such requirement.

3 (c) SPECIAL RULE FOR COLLECTIVE BARGAINING
4 AGREEMENTS.—In the case of a group health plan main-
5 tained pursuant to one or more collective bargaining
6 agreements between employee representatives and one or
7 more employers ratified before the date of the enactment
8 of this Act, the amendments made by this title shall not
9 apply with respect to plan years beginning before the later
10 of—

11 (1) the date on which the last of the collective
12 bargaining agreements relating to the plan termi-
13 nates (determined without regard to any extension
14 thereof agreed to after the date of the enactment of
15 this Act); or

16 (2) January 1, 2002.

17 For purposes of this subsection, any plan amendment
18 made pursuant to a collective bargaining agreement relat-
19 ing to the plan which amends the plan solely to conform
20 to any requirement added by this title shall not be treated
21 as a termination of such collective bargaining agreement.

1 **Subtitle B—Patient Access to**
2 **Information**

3 **SEC. 111. PATIENT ACCESS TO INFORMATION REGARDING**
4 **PLAN COVERAGE, MANAGED CARE PROCE-**
5 **DURES, HEALTH CARE PROVIDERS, AND**
6 **QUALITY OF MEDICAL CARE.**

7 (a) IN GENERAL.—Subpart 2 of part A of title
8 XXVII of the Public Health Service Act (as amended by
9 subtitle A) is amended further by adding at the end the
10 following new section:

11 **“SEC. 2708. DISCLOSURE BY GROUP HEALTH PLANS.**

12 “(a) DISCLOSURE REQUIREMENT.—Each health in-
13 surance issuer offering health insurance coverage in con-
14 nection with a group health plan shall provide the plan
15 administrator on a timely basis with the information nec-
16 essary to enable the administrator to provide participants
17 and beneficiaries with information in a manner and to an
18 extent consistent with the requirements of section 111 of
19 the Employee Retirement Income Security Act of 1974.
20 To the extent that any such issuer provides such informa-
21 tion on a timely basis to plan participants and bene-
22 ficiaries, the requirements of this subsection shall be
23 deemed satisfied in the case of such plan with respect to
24 such information.

1 “(b) PLAN BENEFITS.—The information required
2 under subsection (a) includes the following:

3 “(1) COVERED ITEMS AND SERVICES.—

4 “(A) CATEGORIZATION OF INCLUDED BEN-
5 EFITS.—A description of covered benefits, cat-
6 egorized by—

7 “(i) types of items and services (in-
8 cluding any special disease management
9 program); and

10 “(ii) types of health care professionals
11 providing such items and services.

12 “(B) EMERGENCY MEDICAL CARE.—A de-
13 scription of the extent to which the plan covers
14 emergency medical care (including the extent to
15 which the plan provides for access to urgent
16 care centers), and any definitions provided
17 under the plan for the relevant plan termi-
18 nology referring to such care.

19 “(C) PREVENTATIVE SERVICES.—A de-
20 scription of the extent to which the plan pro-
21 vides benefits for preventative services.

22 “(D) DRUG FORMULARIES.—A description
23 of the extent to which covered benefits are de-
24 termined by the use or application of a drug

1 formulary and a summary of the process for de-
2 termining what is included in such formulary.

3 “(E) COBRA CONTINUATION COV-
4 ERAGE.—A description of the benefits available
5 under the plan pursuant to part 6.

6 “(2) LIMITATIONS, EXCLUSIONS, AND RESTRIC-
7 TIONS ON COVERED BENEFITS.—

8 “(A) CATEGORIZATION OF EXCLUDED
9 BENEFITS.—A description of benefits specifi-
10 cally excluded from coverage, categorized by
11 types of items and services.

12 “(B) UTILIZATION REVIEW AND
13 PREAUTHORIZATION REQUIREMENTS.—Whether
14 coverage for medical care is limited or excluded
15 on the basis of utilization review or
16 preauthorization requirements.

17 “(C) LIFETIME, ANNUAL, OR OTHER PE-
18 RIOD LIMITATIONS.—A description of the cir-
19 cumstances under which, and the extent to
20 which, coverage is subject to lifetime, annual, or
21 other period limitations, categorized by types of
22 benefits.

23 “(D) CUSTODIAL CARE.—A description of
24 the circumstances under which, and the extent
25 to which, the coverage of benefits for custodial

1 care is limited or excluded, and a statement of
2 the definition used by the plan for custodial
3 care.

4 “(E) EXPERIMENTAL TREATMENTS.—
5 Whether coverage for any medical care is lim-
6 ited or excluded because it constitutes an inves-
7 tigational item or experimental treatment or
8 technology, and any definitions provided under
9 the plan for the relevant plan terminology refer-
10 ring to such limited or excluded care.

11 “(F) MEDICAL APPROPRIATENESS OR NE-
12 CESSITY.—Whether coverage for medical care
13 may be limited or excluded by reason of a fail-
14 ure to meet the plan’s requirements for medical
15 appropriateness or necessity, and any defini-
16 tions provided under the plan for the relevant
17 plan terminology referring to such limited or
18 excluded care.

19 “(G) SECOND OR SUBSEQUENT OPIN-
20 IONS.—A description of the circumstances
21 under which, and the extent to which, coverage
22 for second or subsequent opinions is limited or
23 excluded.

24 “(H) SPECIALTY CARE.—A description of
25 the circumstances under which, and the extent

1 to which, coverage of benefits for specialty care
2 is conditioned on referral from a primary care
3 provider.

4 “(I) CONTINUITY OF CARE.—A description
5 of the circumstances under which, and the ex-
6 tent to which, coverage of items and services
7 provided by any health care professional is lim-
8 ited or excluded by reason of the departure by
9 the professional from any defined set of pro-
10 viders.

11 “(J) RESTRICTIONS ON COVERAGE OF
12 EMERGENCY SERVICES.—A description of the
13 circumstances under which, and the extent to
14 which, the plan, in covering emergency medical
15 care furnished to a participant or beneficiary of
16 the plan imposes any financial responsibility de-
17 scribed in subsection (c) on participants or
18 beneficiaries or limits or conditions benefits for
19 such care subject to any other term or condition
20 of such plan.

21 “(3) NETWORK CHARACTERISTICS.—If the plan
22 (or issuer) utilizes a defined set of providers under
23 contract with the plan (or issuer), a detailed list of
24 the names of such providers and their geographic lo-

1 cation, set forth separately with respect to primary
2 care providers and with respect to specialists.

3 “(c) PARTICIPANT’S FINANCIAL RESPONSIBIL-
4 ITIES.—The information required under subsection (a) in-
5 cludes an explanation of—

6 “(1) a participant’s financial responsibility for
7 payment of premiums, coinsurance, copayments,
8 deductibles, and any other charges; and

9 “(2) the circumstances under which, and the
10 extent to which, the participant’s financial responsi-
11 bility described in paragraph (1) may vary, including
12 any distinctions based on whether a health care pro-
13 vider from whom covered benefits are obtained is in-
14 cluded in a defined set of providers.

15 “(d) DISPUTE RESOLUTION PROCEDURES.—The in-
16 formation required under subsection (a) includes a de-
17 scription of the processes adopted by the plan of the type
18 described in section 503 of the Employee Retirement In-
19 come Security Act of 1974, including—

20 “(1) descriptions thereof relating specifically
21 to—

22 “(A) coverage decisions;

23 “(B) internal review of coverage decisions;

24 and

1 “(C) any external review of coverage deci-
2 sions; and

3 “(2) the procedures and time frames applicable
4 to each step of the processes referred to in subpara-
5 graphs (A), (B), and (C) of paragraph (1).

6 “(e) INFORMATION ON PLAN PERFORMANCE.—Any
7 information required under subsection (a) shall include in-
8 formation concerning the number of external reviews of
9 the type described in section 503 of the Employee Retire-
10 ment Income Security Act of 1974 that have been com-
11 pleted during the prior plan year and the number of such
12 reviews in which a recommendation is made for modifica-
13 tion or reversal of an internal review decision under the
14 plan.

15 “(f) INFORMATION INCLUDED WITH ADVERSE COV-
16 ERAGE DECISIONS.—A health insurance issuer offering
17 health insurance coverage in connection with a group
18 health plan shall provide to each participant and bene-
19 ficiary, together with any notification of the participant
20 or beneficiary of an adverse coverage decision, the fol-
21 lowing information:

22 “(1) PREAUTHORIZATION AND UTILIZATION RE-
23 VIEW PROCEDURES.—A description of the basis on
24 which any preauthorization requirement or any utili-

1 zation review requirement has resulted in the ad-
2 verse coverage decision.

3 “(2) PROCEDURES FOR DETERMINING EXCLU-
4 SIONS BASED ON MEDICAL NECESSITY OR ON INVES-
5 TIGATIONAL ITEMS OR EXPERIMENTAL TREAT-
6 MENTS.—If the adverse coverage decision is based
7 on a determination relating to medical necessity or
8 to an investigational item or an experimental treat-
9 ment or technology, a description of the procedures
10 and medically-based criteria used in such decision.

11 “(g) INFORMATION AVAILABLE ON REQUEST.—

12 “(1) ACCESS TO PLAN BENEFIT INFORMATION
13 IN ELECTRONIC FORM.—

14 “(A) IN GENERAL.—A health insurance
15 issuer offering health insurance coverage in
16 connection with a group health plan may, upon
17 written request (made not more frequently than
18 annually), make available to participants and
19 beneficiaries, in a generally recognized elec-
20 tronic format—

21 “(i) the latest summary plan descrip-
22 tion, including the latest summary of ma-
23 terial modifications, and

24 “(ii) the actual plan provisions setting
25 forth the benefits available under the plan,

1 to the extent such information relates to the
2 coverage options under the plan available to the
3 participant or beneficiary. A reasonable charge
4 may be made to cover the cost of providing
5 such information in such generally recognized
6 electronic format. The Secretary may by regula-
7 tion prescribe a maximum amount which will
8 constitute a reasonable charge under the pre-
9 ceding sentence.

10 “(B) ALTERNATIVE ACCESS.—The require-
11 ments of this paragraph may be met by making
12 such information generally available (rather
13 than upon request) on the Internet or on a pro-
14 prietary computer network in a format which is
15 readily accessible to participants and bene-
16 ficiaries.

17 “(2) ADDITIONAL INFORMATION TO BE PRO-
18 VIDED ON REQUEST.—

19 “(A) INCLUSION IN SUMMARY PLAN DE-
20 SCRPTION OF SUMMARY OF ADDITIONAL IN-
21 FORMATION.—The information required under
22 subsection (a) includes a summary description
23 of the types of information required by this
24 subsection to be made available to participants
25 and beneficiaries on request.

1 “(B) INFORMATION REQUIRED FROM
2 PLANS AND ISSUERS ON REQUEST.—In addition
3 to information otherwise required to be pro-
4 vided under this subsection, a health insurance
5 issuer offering health insurance coverage in
6 connection with a group health plan shall pro-
7 vide the following information to a participant
8 or beneficiary on request:

9 “(i) CARE MANAGEMENT INFORMA-
10 TION.—A description of the circumstances
11 under which, and the extent to which, the
12 plan has special disease management pro-
13 grams or programs for persons with dis-
14 abilities, indicating whether these pro-
15 grams are voluntary or mandatory and
16 whether a significant benefit differential
17 results from participation in such pro-
18 grams.

19 “(ii) INCLUSION OF DRUGS AND
20 BIOLOGICALS IN FORMULARIES.—A state-
21 ment of whether a specific drug or biologi-
22 cal is included in a formulary used to de-
23 termine benefits under the plan and a de-
24 scription of the procedures for considering
25 requests for any patient-specific waivers.

1 “(iii) ACCREDITATION STATUS OF
2 HEALTH INSURANCE ISSUERS AND SERV-
3 ICE PROVIDERS.—A description of the ac-
4 creditation and licensing status (if any) of
5 each health insurance issuer offering
6 health insurance coverage in connection
7 with the plan and of any utilization review
8 organization utilized by the issuer or the
9 plan, together with the name and address
10 of the accrediting or licensing authority.

11 “(iv) QUALITY PERFORMANCE MEAS-
12 URES.—The latest information (if any)
13 maintained by the health insurance issuer
14 relating to quality of performance of the
15 delivery of medical care with respect to
16 coverage options offered under the plan
17 and of health care professionals and facili-
18 ties providing medical care under the plan.

19 “(C) INFORMATION REQUIRED FROM
20 HEALTH CARE PROFESSIONALS.—

21 “(i) QUALIFICATIONS, PRIVILEGES,
22 AND METHOD OF COMPENSATION.—Any
23 health care professional treating a partici-
24 pant or beneficiary under a group health
25 plan shall provide to the participant or

1 beneficiary, on request, a description of his
2 or her professional qualifications (including
3 board certification status, licensing status,
4 and accreditation status, if any), privileges,
5 and experience and a general description
6 by category (including salary, fee-for-service,
7 capitation, and such other categories
8 as may be specified in regulations of the
9 Secretary) of the applicable method by
10 which such professional is compensated in
11 connection with the provision of such medical
12 care.

13 “(ii) COST OF PROCEDURES.—Any
14 health care professional who recommends
15 an elective procedure or treatment while
16 treating a participant or beneficiary under
17 a group health plan that requires a participant
18 or beneficiary to share in the cost of
19 treatment shall inform such participant or
20 beneficiary of each cost associated with the
21 procedure or treatment and an estimate of
22 the magnitude of such costs.

23 “(D) INFORMATION REQUIRED FROM
24 HEALTH CARE FACILITIES ON REQUEST.—Any
25 health care facility from which a participant or

1 beneficiary has sought treatment under a group
2 health plan shall provide to the participant or
3 beneficiary, on request, a description of the fa-
4 cility's corporate form or other organizational
5 form and all forms of licensing and accredita-
6 tion status (if any) assigned to the facility by
7 standard-setting organizations.

8 “(h) ACCESS TO INFORMATION RELEVANT TO THE
9 COVERAGE OPTIONS UNDER WHICH THE PARTICIPANT OR
10 BENEFICIARY IS ELIGIBLE TO ENROLL.—In addition to
11 information otherwise required to be made available under
12 this section, a health insurance issuer offering health in-
13 surance coverage in connection with a group health plan
14 shall, upon written request (made not more frequently
15 than annually), make available to a participant (and an
16 employee who, under the terms of the plan, is eligible for
17 coverage but not enrolled) in connection with a period of
18 enrollment the summary plan description for any coverage
19 option under the plan under which the participant is eligi-
20 ble to enroll and any information described in clauses (i),
21 (ii), (iii), (vi), (vii), and (viii) of subsection (e)(2)(B).

22 “(i) ADVANCE NOTICE OF CHANGES IN DRUG
23 FORMULARIES.—Not later than 30 days before the effec-
24 tive of date of any exclusion of a specific drug or biological
25 from any drug formulary under health insurance coverage

1 offered by a health insurance issuer in connection with a
2 group health plan that is used in the treatment of a chron-
3 ic illness or disease, the issuer shall take such actions as
4 are necessary to reasonably ensure that plan participants
5 are informed of such exclusion. The requirements of this
6 subsection may be satisfied—

7 “(1) by inclusion of information in publications
8 broadly distributed by plan sponsors, employers, or
9 employee organizations;

10 “(2) by electronic means of communication (in-
11 cluding the Internet or proprietary computer net-
12 works in a format which is readily accessible to par-
13 ticipants);

14 “(3) by timely informing participants who,
15 under an ongoing program maintained under the
16 plan, have submitted their names for such notifica-
17 tion; or

18 “(4) by any other reasonable means of timely
19 informing plan participants.

20 “(j) DEFINITIONS AND RELATED RULES.—

21 “(1) IN GENERAL.—For purposes of this
22 section—

23 “(A) GROUP HEALTH PLAN.—The term
24 ‘group health plan’ has the meaning provided
25 such term under section 733(a)(1).

1 “(B) MEDICAL CARE.—The term ‘medical
2 care’ has the meaning provided such term
3 under section 733(a)(2).

4 “(C) HEALTH INSURANCE COVERAGE.—
5 The term ‘health insurance coverage’ has the
6 meaning provided such term under section
7 733(b)(1).

8 “(D) HEALTH INSURANCE ISSUER.—The
9 term ‘health insurance issuer’ has the meaning
10 provided such term under section 733(b)(2).

11 “(2) APPLICABILITY ONLY IN CONNECTION
12 WITH INCLUDED GROUP HEALTH PLAN BENEFITS.—

13 “(A) IN GENERAL.—The requirements of
14 this section shall apply only in connection with
15 included group health plan benefits.

16 “(B) INCLUDED GROUP HEALTH PLAN
17 BENEFIT.—For purposes of subparagraph (A),
18 the term ‘included group health plan benefit’
19 means a benefit which is not an excepted ben-
20 efit (as defined in section 2791(c)).”.

21 **SEC. 212. EFFECTIVE DATE AND RELATED RULES.**

22 (a) IN GENERAL.—The amendments made by section
23 211 shall apply with respect to plan years beginning on
24 or after January 1 of the second calendar year following
25 the date of the enactment of this Act. The Secretary of

1 Labor shall first issue all regulations necessary to carry
2 out the amendments made by this title before such date.

3 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
4 enforcement action shall be taken, pursuant to the amend-
5 ments made by this title, against a health insurance issuer
6 with respect to a violation of a requirement imposed by
7 such amendments before the date of issuance of final regu-
8 lations issued in connection with such requirement, if the
9 issuer has sought to comply in good faith with such re-
10 quirement.

11 **TITLE III—AMENDMENTS TO**
12 **THE INTERNAL REVENUE**
13 **CODE OF 1986**

14 **SEC. 301. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
15 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
16 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
17 **ATRIC CARE, AND CONTINUITY OF CARE.**

18 Subchapter B of chapter 100 of the Internal Revenue
19 Code of 1986 is amended—

20 (1) in the table of sections, by inserting after
21 the item relating to section 9812 the following new
22 item:

“Sec. 9813. Patient access to unrestricted medical advice,
emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.”; and

1 (2) by inserting after section 9812 the fol-
2 lowing:

3 **“SEC. 9813. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
4 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
5 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
6 **ATRIC CARE, AND CONTINUITY OF CARE.**

7 **“(a) PATIENT ACCESS TO UNRESTRICTED MEDICAL**
8 **ADVICE.—**

9 **“(1) IN GENERAL.—**In the case of any health
10 care professional acting within the lawful scope of
11 practice in the course of carrying out a contractual
12 employment arrangement or other direct contractual
13 arrangement between such professional and a group
14 health plan, the plan with which such contractual
15 employment arrangement or other direct contractual
16 arrangement is maintained by the professional may
17 not impose on such professional under such arrange-
18 ment any prohibition or restriction with respect to
19 advice, provided to a participant or beneficiary
20 under the plan who is a patient, about the health
21 status of the participant or beneficiary or the med-
22 ical care or treatment for the condition or disease of
23 the participant or beneficiary, regardless of whether
24 benefits for such care or treatment are provided
25 under the plan.

1 “(2) HEALTH CARE PROFESSIONAL DEFINED.—

2 For purposes of this paragraph, the term ‘health
3 care professional’ means a physician (as defined in
4 section 1861(r) of the Social Security Act) or other
5 health care professional if coverage for the profes-
6 sional’s services is provided under the group health
7 plan for the services of the professional. Such term
8 includes a podiatrist, optometrist, chiropractor, psy-
9 chologist, dentist, physician assistant, physical or oc-
10 cupational therapist and therapy assistant, speech-
11 language pathologist, audiologist, registered or li-
12 censed practical nurse (including nurse practitioner,
13 clinical nurse specialist, certified registered nurse
14 anesthetist, and certified nurse-midwife), licensed
15 certified social worker, registered respiratory thera-
16 pist, and certified respiratory therapy technician.

17 “(3) RULE OF CONSTRUCTION.—Nothing in
18 this subsection shall be construed to require the
19 sponsor of a group health plan to engage in any
20 practice that would violate its religious beliefs or
21 moral convictions.

22 “(b) PATIENT ACCESS TO EMERGENCY MEDICAL
23 CARE.—

24 “(1) COVERAGE OF EMERGENCY SERVICES.—

1 “(A) IN GENERAL.—If a group health plan
2 provides any benefits with respect to emergency
3 services (as defined in subparagraph (B)(ii)), or
4 ambulance services, the plan shall cover emer-
5 gency services (including emergency ambulance
6 services as defined in subparagraph (B)(iii))
7 furnished under the plan—

8 “(i) without the need for any prior
9 authorization determination;

10 “(ii) whether or not the health care
11 provider furnishing such services is a par-
12 ticipating provider with respect to such
13 services;

14 “(iii) in a manner so that, if such
15 services are provided to a participant or
16 beneficiary by a nonparticipating health
17 care provider, the participant or bene-
18 ficiary is not liable for amounts that ex-
19 ceed the amounts of liability that would be
20 incurred if the services were provided by a
21 participating provider; and

22 “(iv) without regard to any other term
23 or condition of such plan (other than ex-
24 clusion or coordination of benefits, or an
25 affiliation or waiting period, permitted

1 under section 701 and other than applica-
2 ble cost sharing).

3 “(B) DEFINITIONS.—In this subsection:

4 “(i) EMERGENCY MEDICAL CONDI-
5 TION.—The term ‘emergency medical con-
6 dition’ means—

7 “(I) a medical condition mani-
8 festing itself by acute symptoms of
9 sufficient severity (including severe
10 pain) such that a prudent layperson,
11 who possesses an average knowledge
12 of health and medicine, could reason-
13 ably expect the absence of immediate
14 medical attention to result in a condi-
15 tion described in clause (i), (ii), or
16 (iii) of section 1867(e)(1)(A) of the
17 Social Security Act (42 U.S.C.
18 1395dd(e)(1)(A)); and

19 “(II) a medical condition mani-
20 festing itself in a neonate by acute
21 symptoms of sufficient severity (in-
22 cluding severe pain) such that a pru-
23 dent health care professional could
24 reasonably expect the absence of im-
25 mediate medical attention to result in

1 a condition described in clause (i),
2 (ii), or (iii) of section 1867(e)(1)(A)
3 of the Social Security Act.

4 “(ii) EMERGENCY SERVICES.—The
5 term ‘emergency services’ means—

6 “(I) with respect to an emer-
7 gency medical condition described in
8 clause (i)(I), a medical screening ex-
9 amination (as required under section
10 1867 of the Social Security Act, 42
11 U.S.C. 1395dd) that is within the ca-
12 pability of the emergency department
13 of a hospital, including ancillary serv-
14 ices routinely available to the emer-
15 gency department to evaluate an
16 emergency medical condition (as de-
17 fined in clause (i)) and also, within
18 the capabilities of the staff and facili-
19 ties at the hospital, such further med-
20 ical examination and treatment as are
21 required under section 1867 of such
22 Act to stabilize the patient; or

23 “(II) with respect to an emer-
24 gency medical condition described in
25 clause (i)(II), medical treatment for

1 such condition rendered by a health
2 care provider in a hospital to a
3 neonate, including available hospital
4 ancillary services in response to an ur-
5 gent request of a health care profes-
6 sional and to the extent necessary to
7 stabilize the neonate.

8 “(iii) EMERGENCY AMBULANCE SERV-
9 ICES.—The term ‘emergency ambulance
10 services’ means ambulance services (as de-
11 fined for purposes of section 1861(s)(7) of
12 the Social Security Act) furnished to trans-
13 port an individual who has an emergency
14 medical condition (as defined in clause (i))
15 to a hospital for the receipt of emergency
16 services (as defined in clause (ii)) in a case
17 in which appropriate emergency medical
18 screening examinations are covered under
19 the plan pursuant to paragraph (1)(A) and
20 a prudent layperson, with an average
21 knowledge of health and medicine, could
22 reasonably expect that the absence of such
23 transport would result in placing the
24 health of the individual in serious jeopardy,
25 serious impairment of bodily function, or

1 serious dysfunction of any bodily organ or
2 part.

3 “(iv) STABILIZE.—The term ‘to sta-
4 bilize’ means, with respect to an emergency
5 medical condition, to provide such medical
6 treatment of the condition as may be nec-
7 essary to assure, within reasonable medical
8 probability, that no material deterioration
9 of the condition is likely to result from or
10 occur during the transfer of the individual
11 from a facility.

12 “(v) NONPARTICIPATING.—The term
13 ‘nonparticipating’ means, with respect to a
14 health care provider that provides health
15 care items and services to a participant or
16 beneficiary under group health plan, a
17 health care provider that is not a partici-
18 pating health care provider with respect to
19 such items and services.

20 “(vi) PARTICIPATING.—The term
21 ‘participating’ means, with respect to a
22 health care provider that provides health
23 care items and services to a participant or
24 beneficiary under group health plan, a
25 health care provider that furnishes such

1 items and services under a contract or
2 other arrangement with the plan.

3 “(c) PATIENT RIGHT TO OBSTETRIC AND GYNECO-
4 LOGICAL CARE.—

5 “(1) IN GENERAL.—In any case in which a
6 group health plan—

7 “(A) provides benefits under the terms of
8 the plan consisting of—

9 “(i) gynecological care (such as pre-
10 ventive women’s health examinations); or

11 “(ii) obstetric care (such as preg-
12 nancy-related services),

13 provided by a participating health care profes-
14 sional who specializes in such care (or provides
15 benefits consisting of payment for such care);
16 and

17 “(B) requires or provides for designation
18 by a participant or beneficiary of a partici-
19 pating primary care provider,

20 if the primary care provider designated by such a
21 participant or beneficiary is not such a health care
22 professional, then the plan shall meet the require-
23 ments of paragraph (2).

24 “(2) REQUIREMENTS.—A group health plan
25 meets the requirements of this paragraph, in connec-

1 tion with benefits described in paragraph (1) con-
2 sisting of care described in clause (i) or (ii) of para-
3 graph (1)(A) (or consisting of payment therefor), if
4 the plan—

5 “(A) does not require authorization or a
6 referral by the primary care provider in order
7 to obtain such benefits; and

8 “(B) treats the ordering of other care of
9 the same type, by the participating health care
10 professional providing the care described in
11 clause (i) or (ii) of paragraph (1)(A), as the au-
12 thorization of the primary care provider with
13 respect to such care.

14 “(3) HEALTH CARE PROFESSIONAL DEFINED.—
15 For purposes of this subsection, the term ‘health
16 care professional’ means an individual (including,
17 but not limited to, a nurse midwife or nurse practi-
18 tioner) who is licensed, accredited, or certified under
19 State law to provide obstetric and gynecological
20 health care services and who is operating within the
21 scope of such licensure, accreditation, or certifi-
22 cation.

23 “(4) CONSTRUCTION.—Nothing in paragraph
24 (1) shall be construed as preventing a plan from of-
25 fering (but not requiring a participant or beneficiary

1 to accept) a health care professional trained,
2 credentialed, and operating within the scope of their
3 licensure to perform obstetric and gynecological
4 health care services. Nothing in paragraph (2)(B)
5 shall waive any requirements of coverage relating to
6 medical necessity or appropriateness with respect to
7 coverage of gynecological or obstetric care so or-
8 dered.

9 “(5) TREATMENT OF MULTIPLE COVERAGE OP-
10 TIONS.—In the case of a plan providing benefits
11 under two or more coverage options, the require-
12 ments of this subsection shall apply separately with
13 respect to each coverage option.

14 “(d) PATIENT RIGHT TO PEDIATRIC CARE.—

15 “(1) IN GENERAL.—In any case in which a
16 group health plan provides benefits consisting of
17 routine pediatric care provided by a participating
18 health care professional who specializes in pediatrics
19 (or consisting of payment for such care) and the
20 plan requires or provides for designation by a partic-
21 ipant or beneficiary of a participating primary care
22 provider, the plan shall provide that such a partici-
23 pating health care professional may be designated, if
24 available, by a parent or guardian of any beneficiary
25 under the plan is who under 18 years of age, as the

1 primary care provider with respect to any such bene-
2 fits.

3 “(2) HEALTH CARE PROFESSIONAL DEFINED.—
4 For purposes of this subsection, the term ‘health
5 care professional’ means an individual (including,
6 but not limited to, a nurse practitioner) who is li-
7 censed, accredited, or certified under State law to
8 provide pediatric health care services and who is op-
9 erating within the scope of such licensure, accredita-
10 tion, or certification.

11 “(3) CONSTRUCTION.—Nothing in paragraph
12 (1) shall be construed as preventing a plan from of-
13 fering (but not requiring a participant or beneficiary
14 to accept) a health care professional trained,
15 credentialed, and operating within the scope of their
16 licensure to perform pediatric health care services.
17 Nothing in paragraph (1) shall waive any require-
18 ments of coverage relating to medical necessity or
19 appropriateness with respect to coverage of pediatric
20 care so ordered.

21 “(4) TREATMENT OF MULTIPLE COVERAGE OP-
22 TIONS.—In the case of a plan providing benefits
23 under two or more coverage options, the require-
24 ments of this subsection shall apply separately with
25 respect to each coverage option.

1 “(e) CONTINUITY OF CARE.—

2 “(1) IN GENERAL.—

3 “(A) TERMINATION OF PROVIDER.—If a
4 contract between a group health plan and a
5 health care provider is terminated (as defined
6 in subparagraph (D)(ii)), or benefits provided
7 by a health care provider are terminated be-
8 cause of a change in the terms of provider par-
9 ticipation in a group health plan, and an indi-
10 vidual who, at the time of such termination, is
11 a participant or beneficiary in the plan and is
12 scheduled to undergo surgery (including an
13 organ transplantation), is undergoing treatment
14 for pregnancy, or is determined to be terminally
15 ill (as defined in section 1861(dd)(3)(A) of the
16 Social Security Act) and is undergoing treat-
17 ment for the terminal illness, the plan shall—

18 “(i) notify the individual on a timely
19 basis of such termination and of the right
20 to elect continuation of coverage of treat-
21 ment by the provider under this sub-
22 section; and

23 “(ii) subject to paragraph (3), permit
24 the individual to elect to continue to be
25 covered with respect to treatment by the

1 provider for such surgery, pregnancy, or
2 illness during a transitional period (pro-
3 vided under paragraph (2)).

4 “(B) TREATMENT OF TERMINATION OF
5 CONTRACT WITH HEALTH INSURANCE
6 ISSUER.—If a contract for the provision of
7 health insurance coverage between a group
8 health plan and a health insurance issuer is ter-
9 minated and, as a result of such termination,
10 coverage of services of a health care provider is
11 terminated with respect to an individual, the
12 provisions of subparagraph (A) (and the suc-
13 ceeding provisions of this subsection) shall
14 apply under the plan in the same manner as if
15 there had been a contract between the plan and
16 the provider that had been terminated, but only
17 with respect to benefits that are covered under
18 the plan after the contract termination.

19 “(C) TERMINATION DEFINED.—For pur-
20 poses of this subsection, the term ‘terminated’
21 includes, with respect to a contract, the expira-
22 tion or nonrenewal of the contract, but does not
23 include a termination of the contract by the
24 plan for failure to meet applicable quality
25 standards or for fraud.

1 “(2) TRANSITIONAL PERIOD.—

2 “(A) IN GENERAL.—Except as provided in
3 subparagraphs (B) through (D), the transi-
4 tional period under this paragraph shall extend
5 up to 90 days (as determined by the treating
6 health care professional) after the date of the
7 notice described in paragraph (1)(A)(i) of the
8 provider’s termination.

9 “(B) SCHEDULED SURGERY.—If surgery
10 was scheduled for an individual before the date
11 of the announcement of the termination of the
12 provider status under paragraph (1)(A)(i), the
13 transitional period under this paragraph with
14 respect to the surgery or transplantation.

15 “(C) PREGNANCY.—If—

16 “(i) a participant or beneficiary was
17 determined to be pregnant at the time of
18 a provider’s termination of participation,
19 and

20 “(ii) the provider was treating the
21 pregnancy before date of the termination,
22 the transitional period under this paragraph
23 with respect to provider’s treatment of the
24 pregnancy shall extend through the provision of

1 post-partum care directly related to the deliv-
2 ery.

3 “(D) TERMINAL ILLNESS.—If—

4 “(i) a participant or beneficiary was
5 determined to be terminally ill (as deter-
6 mined under section 1861(dd)(3)(A) of the
7 Social Security Act) at the time of a pro-
8 vider’s termination of participation, and

9 “(ii) the provider was treating the ter-
10 minal illness before the date of termi-
11 nation,

12 the transitional period under this paragraph
13 shall extend for the remainder of the individ-
14 ual’s life for care directly related to the treat-
15 ment of the terminal illness or its medical
16 manifestations.

17 “(3) PERMISSIBLE TERMS AND CONDITIONS.—

18 A group health plan may condition coverage of con-
19 tinued treatment by a provider under paragraph
20 (1)(A)(i) upon the individual notifying the plan of
21 the election of continued coverage and upon the pro-
22 vider agreeing to the following terms and conditions:

23 “(A) The provider agrees to accept reim-
24 bursement from the plan and individual in-
25 volved (with respect to cost-sharing) at the

1 rates applicable prior to the start of the transi-
2 tional period as payment in full (or, in the case
3 described in paragraph (1)(B), at the rates ap-
4 plicable under the replacement plan after the
5 date of the termination of the contract with the
6 health insurance issuer) and not to impose cost-
7 sharing with respect to the individual in an
8 amount that would exceed the cost-sharing that
9 could have been imposed if the contract referred
10 to in paragraph (1)(A) had not been termi-
11 nated.

12 “(B) The provider agrees to adhere to the
13 quality assurance standards of the plan respon-
14 sible for payment under subparagraph (A) and
15 to provide to such plan necessary medical infor-
16 mation related to the care provided.

17 “(C) The provider agrees otherwise to ad-
18 here to such plan’s policies and procedures, in-
19 cluding procedures regarding referrals and ob-
20 taining prior authorization and providing serv-
21 ices pursuant to a treatment plan (if any) ap-
22 proved by the plan.

23 “(D) The provider agrees to provide tran-
24 sitional care to all participants and beneficiaries

1 who are eligible for and elect to have coverage
2 of such care from such provider.

3 “(E) If the provider initiates the termi-
4 nation, the provider has notified the plan within
5 30 days prior to the effective date of the termi-
6 nation of—

7 “(i) whether the provider agrees to
8 permissible terms and conditions (as set
9 forth in this paragraph) required by the
10 plan, and

11 “(ii) if the provider agrees to the
12 terms and conditions, the specific plan
13 beneficiaries and participants undergoing a
14 course of treatment from the provider who
15 the provider believes, at the time of the no-
16 tification, would be eligible for transitional
17 care under this subsection.

18 “(4) CONSTRUCTION.—Nothing in this sub-
19 section shall be construed to—

20 “(A) require the coverage of benefits which
21 would not have been covered if the provider in-
22 volved remained a participating provider, or

23 “(B) prohibit a group health plan from
24 conditioning a provider’s participation on the
25 provider’s agreement to provide transitional

1 care to all participants and beneficiaries eligible
2 to obtain coverage of such care furnished by the
3 provider as set forth under this subsection.

4 “(f) COVERAGE FOR INDIVIDUALS PARTICIPATING IN
5 APPROVED CANCER CLINICAL TRIALS.—

6 “(1) COVERAGE.—

7 “(A) IN GENERAL.—If a group health plan
8 provides coverage to a qualified individual (as
9 defined in paragraph (2)), the plan—

10 “(i) may not deny the individual par-
11 ticipation in the clinical trial referred to in
12 paragraph (2)(B);

13 “(ii) subject to paragraphs (2), (3),
14 and (4), may not deny (or limit or impose
15 additional conditions on) the coverage of
16 routine patient costs for items and services
17 furnished in connection with participation
18 in the trial; and

19 “(iii) may not discriminate against the
20 individual on the basis of the participation
21 of the participant or beneficiary in such
22 trial.

23 “(B) EXCLUSION OF CERTAIN COSTS.—

24 For purposes of subparagraph (A)(ii), routine
25 patient costs do not include the cost of the tests

1 or measurements conducted primarily for the
2 purpose of the clinical trial involved.

3 “(C) USE OF IN-NETWORK PROVIDERS.—If
4 one or more participating providers is partici-
5 pating in a clinical trial, nothing in subpara-
6 graph (A) shall be construed as preventing a
7 plan from requiring that a qualified individual
8 participate in the trial through such a partici-
9 pating provider if the provider will accept the
10 individual as a participant in the trial.

11 “(2) QUALIFIED INDIVIDUAL DEFINED.—For
12 purposes of paragraph (1), the term ‘qualified indi-
13 vidual’ means an individual who is a participant or
14 beneficiary in a group health plan and who meets
15 the following conditions:

16 “(A)(i) The individual has been diagnosed
17 with cancer.

18 “(ii) The individual is eligible to partici-
19 pate in an approved clinical trial according to
20 the trial protocol with respect to treatment of
21 cancer.

22 “(iii) The individual’s participation in the
23 trial offers meaningful potential for significant
24 clinical benefit for the individual.

25 “(B) Either—

1 “(i) the referring physician is a par-
2 ticipating health care professional and has
3 concluded that the individual’s participa-
4 tion in such trial would be appropriate
5 based upon satisfaction by the individual of
6 the conditions described in subparagraph
7 (A); or

8 “(ii) the individual provides medical
9 and scientific information establishing that
10 the individual’s participation in such trial
11 would be appropriate based upon the satis-
12 faction by the individual of the conditions
13 described in subparagraph (A).

14 “(3) PAYMENT.—

15 “(A) IN GENERAL.—A group health plan
16 shall provide for payment for routine patient
17 costs described in paragraph (1)(B) but is not
18 required to pay for costs of items and services
19 that are reasonably expected to be paid for by
20 the sponsors of an approved clinical trial.

21 “(B) ROUTINE PATIENT CARE COSTS.—

22 “(i) IN GENERAL.—For purposes of
23 this paragraph, the term ‘routine patient
24 care costs’ shall include the costs associ-

1 ated with the provision of items and serv-
2 ices that—

3 “(I) would otherwise be covered
4 under the group health plan if such
5 items and services were not provided
6 in connection with an approved clin-
7 ical trial program; and

8 “(II) are furnished according to
9 the protocol of an approved clinical
10 trial program.

11 “(ii) EXCLUSION.—For purposes of
12 this paragraph, ‘routine patient care costs’
13 shall not include the costs associated with
14 the provision of—

15 (I) an investigational drug or de-
16 vice, unless the Secretary has author-
17 ized the manufacturer of such drug or
18 device to charge for such drug or de-
19 vice; or

20 (II) any item or service supplied
21 without charge by the sponsor of the
22 approved clinical trial program.

23 “(C) PAYMENT RATE.—For purposes of
24 this subsection—

1 “(i) PARTICIPATING PROVIDERS.—In
2 the case of covered items and services pro-
3 vided by a participating provider, the pay-
4 ment rate shall be at the agreed upon rate.

5 “(ii) NONPARTICIPATING PRO-
6 VIDERS.—In the case of covered items and
7 services provided by a nonparticipating pro-
8 vider, the payment rate shall be at the rate
9 the plan would normally pay for com-
10 parable items or services under clause (i).

11 “(4) APPROVED CLINICAL TRIAL DEFINED.—

12 “(A) IN GENERAL.—For purposes of this
13 subsection, the term ‘approved clinical trial’
14 means a cancer clinical research study or can-
15 cer clinical investigation approved by an Institu-
16 tional Review Board.

17 “(B) CONDITIONS FOR DEPARTMENTS.—
18 The conditions described in this paragraph, for
19 a study or investigation conducted by a Depart-
20 ment, are that the study or investigation has
21 been reviewed and approved through a system
22 of peer review that the Secretary determines—

23 “(i) to be comparable to the system of
24 peer review of studies and investigations

1 used by the National Institutes of Health,
2 and

3 “(ii) assures unbiased review of the
4 highest scientific standards by qualified in-
5 dividuals who have no interest in the out-
6 come of the review.

7 “(5) CONSTRUCTION.—Nothing in this sub-
8 section shall be construed to limit a plan’s coverage
9 with respect to clinical trials.

10 “(6) PLAN SATISFACTION OF CERTAIN RE-
11 QUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

12 “(A) IN GENERAL.—For purposes of this
13 subsection, insofar as a group health plan pro-
14 vides benefits in the form of health insurance
15 coverage through a health insurance issuer, the
16 plan shall be treated as meeting the require-
17 ments of this subsection with respect to such
18 benefits and not be considered as failing to
19 meet such requirements because of a failure of
20 the issuer to meet such requirements so long as
21 the plan sponsor or its representatives did not
22 cause such failure by the issuer.

23 “(B) CONSTRUCTION.—Nothing in this
24 subsection shall be construed to affect or mod-
25 ify the responsibilities of the fiduciaries of a

1 group health plan under part 4 of subtitle B of
2 title I of the Employee Retirement Income Se-
3 curity Act of 1974.

4 “(7) STUDY AND REPORT.—

5 “(A) STUDY.—The Secretary shall analyze
6 cancer clinical research and its cost implications
7 for managed care, including differentiation in—

8 “(i) the cost of patient care in trials
9 versus standard care;

10 “(ii) the cost effectiveness achieved in
11 different sites of service;

12 “(iii) research outcomes;

13 “(iv) volume of research subjects
14 available in different sites of service;

15 “(v) access to research sites and clin-
16 ical trials by cancer patients;

17 “(vi) patient cost sharing or
18 copyment costs realized in different sites
19 of service;

20 “(vii) health outcomes experienced in
21 different sites of service;

22 “(viii) long term health care services
23 and costs experienced in different sites of
24 service;

1 “(ix) morbidity and mortality experi-
2 enced in different sites of service; and

3 “(x) patient satisfaction and pref-
4 erence of sites of service.

5 “(B) REPORT TO CONGRESS.—Not later
6 than January 1, 2005, the Secretary shall sub-
7 mit a report to Congress that contains—

8 “(i) an assessment of any incremental
9 cost to group health plans resulting from
10 the provisions of this section;

11 “(ii) a projection of expenditures to
12 such plans resulting from this section;

13 “(iii) an assessment of any impact on
14 premiums resulting from this section; and

15 “(iv) recommendations regarding ac-
16 tion on other diseases.”.

17 **SEC. 302. EFFECTIVE DATE AND RELATED RULES.**

18 (a) IN GENERAL.—The amendments made by this
19 title shall apply with respect to plan years beginning on
20 or after January 1 of the second calendar year following
21 the date of the enactment of this Act, except that the Sec-
22 retary of the Treasury may issue regulations before such
23 date under such amendments. The Secretary shall first
24 issue regulations necessary to carry out the amendments
25 made by this title before the effective date thereof.

1 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
2 enforcement action shall be taken, pursuant to the amend-
3 ments made by this title, against a group health plan with
4 respect to a violation of a requirement imposed by such
5 amendments before the date of issuance of regulations
6 issued in connection with such requirement, if the plan
7 has sought to comply in good faith with such requirement.

8 (c) SPECIAL RULE FOR COLLECTIVE BARGAINING
9 AGREEMENTS.—In the case of a group health plan main-
10 tained pursuant to one or more collective bargaining
11 agreements between employee representatives and one or
12 more employers ratified before the date of the enactment
13 of this Act, the amendments made by this title shall not
14 apply with respect to plan years beginning before the later
15 of—

16 (1) the date on which the last of the collective
17 bargaining agreements relating to the plan termi-
18 nates (determined without regard to any extension
19 thereof agreed to after the date of the enactment of
20 this Act); or

21 (2) January 1, 2002.

22 For purposes of this subsection, any plan amendment
23 made pursuant to a collective bargaining agreement relat-
24 ing to the plan which amends the plan solely to conform

1 to any requirement added by this title shall not be treated
2 as a termination of such collective bargaining agreement.

3 **TITLE IV—HEALTH CARE**

4 **LAWSUIT REFORM**

5 **Subtitle A—General Provisions**

6 **SEC. 401. FEDERAL REFORM OF HEALTH CARE LIABILITY**

7 **ACTIONS.**

8 (a) **APPLICABILITY.**—This title shall apply with re-
9 spect to any health care liability action brought in any
10 State or Federal court, except that this title shall not
11 apply to—

12 (1) an action for damages arising from a vac-
13 cine-related injury or death to the extent that title
14 XXI of the Public Health Service Act applies to the
15 action;

16 (2) an action under the Employee Retirement
17 Income Security Act of 1974 (29 U.S.C. 1001 et
18 seq.); or

19 (3) an action in connection with benefits which
20 are not included group health plan benefits (as de-
21 fined in section 402(14)).

22 (b) **PREEMPTION.**—This title shall preempt any State
23 law to the extent such law is inconsistent with the limita-
24 tions contained in this title. This title shall not preempt
25 any State law that provides for defenses or places limita-

1 tions on a person's liability in addition to those contained
2 in this title or otherwise imposes greater restrictions than
3 those provided in this title.

4 (c) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE
5 OF LAW OR VENUE.—Nothing in subsection (b) shall be
6 construed to—

7 (1) waive or affect any defense of sovereign im-
8 munity asserted by any State under any provision of
9 law;

10 (2) waive or affect any defense of sovereign im-
11 munity asserted by the United States;

12 (3) affect the applicability of any provision of
13 the Foreign Sovereign Immunities Act of 1976;

14 (4) preempt State choice-of-law rules with re-
15 spect to claims brought by a foreign nation or a cit-
16 izen of a foreign nation; or

17 (5) affect the right of any court to transfer
18 venue or to apply the law of a foreign nation or to
19 dismiss a claim of a foreign nation or of a citizen
20 of a foreign nation on the ground of inconvenient
21 forum.

22 (d) AMOUNT IN CONTROVERSY.—In an action to
23 which this title applies and which is brought under section
24 1332 of title 28, United States Code, the amount of non-
25 economic damages or punitive damages, and attorneys'

1 fees or costs, shall not be included in determining whether
2 the matter in controversy exceeds the sum or value of
3 \$50,000.

4 (e) FEDERAL COURT JURISDICTION NOT ESTAB-
5 LISHED ON FEDERAL QUESTION GROUNDS.—Nothing in
6 this title shall be construed to establish any jurisdiction
7 in the district courts of the United States over health care
8 liability actions on the basis of section 1331 or 1337 of
9 title 28, United States Code.

10 **SEC. 402. DEFINITIONS.**

11 As used in this title:

12 (1) ACTUAL DAMAGES.—The term “actual dam-
13 ages” means damages awarded to pay for economic
14 loss.

15 (2) ALTERNATIVE DISPUTE RESOLUTION SYS-
16 TEM; ADR.—The term “alternative dispute resolution
17 system” or “ADR” means a system established
18 under Federal or State law that provides for the res-
19 olution of health care liability claims in a manner
20 other than through health care liability actions.

21 (3) CLAIMANT.—The term “claimant” means
22 any person who brings a health care liability action
23 and any person on whose behalf such an action is
24 brought. If such action is brought through or on be-
25 half of an estate, the term includes the claimant’s

1 decedent. If such action is brought through or on be-
2 half of a minor or incompetent, the term includes
3 the claimant's legal guardian.

4 (4) CLEAR AND CONVINCING EVIDENCE.—The
5 term “clear and convincing evidence” is that meas-
6 ure or degree of proof that will produce in the mind
7 of the trier of fact a firm belief or conviction as to
8 the truth of the allegations sought to be established.
9 Such measure or degree of proof is more than that
10 required under preponderance of the evidence but
11 less than that required for proof beyond a reason-
12 able doubt.

13 (5) COLLATERAL SOURCE PAYMENTS.—The
14 term “collateral source payments” means any
15 amount paid or reasonably likely to be paid in the
16 future to or on behalf of a claimant, or any service,
17 product, or other benefit provided or reasonably like-
18 ly to be provided in the future to or on behalf of a
19 claimant, as a result of an injury or wrongful death,
20 pursuant to—

21 (A) any State or Federal health, sickness,
22 income-disability, accident or workers' com-
23 pensation Act;

1 (B) any health, sickness, income-disability,
2 or accident insurance that provides health bene-
3 fits or income-disability coverage;

4 (C) any contract or agreement of any
5 group, organization, partnership, or corporation
6 to provide, pay for, or reimburse the cost of
7 medical, hospital, dental, or income disability
8 benefits; and

9 (D) any other publicly or privately funded
10 program.

11 (6) DRUG.—The term “drug” has the meaning
12 given such term in section 201(g)(1) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C.
14 321(g)(1)).

15 (7) ECONOMIC LOSS.—The term “economic
16 loss” means any pecuniary loss resulting from injury
17 (including the loss of earnings or other benefits re-
18 lated to employment, medical expense loss, replace-
19 ment services loss, loss due to death, burial costs,
20 and loss of business or employment opportunities),
21 to the extent recovery for such loss is allowed under
22 applicable State law.

23 (8) HARM.—The term “harm” means any le-
24 gally cognizable wrong or injury for which punitive
25 damages may be imposed.

1 (9) HEALTH BENEFIT PLAN.—The term
2 “health benefit plan” means—

3 (A) a hospital or medical expense incurred
4 policy or certificate;

5 (B) a hospital or medical service plan con-
6 tract;

7 (C) a health maintenance subscriber con-
8 tract; or

9 (D) a Medicare+ Choice plan (offered
10 under part C of title XVIII of the Social Secu-
11 rity Act),

12 that provides benefits with respect to health care
13 services.

14 (10) HEALTH CARE LIABILITY ACTION.—The
15 term “health care liability action” means a civil ac-
16 tion brought in a State or Federal court against—

17 (A) a health care provider;

18 (B) an entity which is obligated to provide
19 or pay for health benefits under any health ben-
20 efit plan (including any person or entity acting
21 under a contract or arrangement to provide or
22 administer any health benefit); or

23 (C) the manufacturer, distributor, supplier,
24 marketer, promoter, or seller of a medical prod-
25 uct,

1 in which the claimant alleges a claim (including third
2 party claims, cross claims, counter claims, or contribution
3 claims) based upon the provision of (or the failure to pro-
4 vide or pay for) health care services or the use of a medical
5 product, regardless of the theory of liability on which the
6 claim is based or the number of plaintiffs, defendants, or
7 causes of action.

8 (11) HEALTH CARE LIABILITY CLAIM.—The
9 term “health care liability claim” means a claim in
10 which the claimant alleges that injury was caused by
11 the provision of (or the failure to provide) health
12 care services.

13 (12) HEALTH CARE PROVIDER.—The term
14 “health care provider” means any person that is en-
15 gaged in the delivery of health care services in a
16 State and that is required by the laws or regulations
17 of the State to be licensed or certified by the State
18 to engage in the delivery of such services in the
19 State.

20 (13) HEALTH CARE SERVICE.—The term
21 “health care service” means any service eligible for
22 payment under a health benefit plan, including serv-
23 ices related to the delivery or administration of such
24 service.

1 (14) INCLUDED GROUP HEALTH PLAN BEN-
2 EFIT.—The term ‘included group health plan ben-
3 efit’ means a benefit under a group health plan
4 which is not an excepted benefit (as defined in sec-
5 tion 733(c) of the Employee Retirement Income Se-
6 curity Act of 1974).

7 (15) MEDICAL DEVICE.—The term “medical de-
8 vice” has the meaning given such term in section
9 201(h) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 321(h)).

11 (16) NON-ECONOMIC DAMAGES.—The term
12 “non-economic damages” means damages paid to an
13 individual for pain and suffering, inconvenience,
14 emotional distress, mental anguish, loss of consor-
15 tium, injury to reputation, humiliation, and other
16 nonpecuniary losses.

17 (17) PERSON.—The term “person” means any
18 individual, corporation, company, association, firm,
19 partnership, society, joint stock company, or any
20 other entity, including any governmental entity.

21 (18) PRODUCT SELLER.—

22 (A) IN GENERAL.—Subject to subpara-
23 graph (B), the term “product seller” means a
24 person who, in the course of a business con-
25 ducted for that purpose—

1 (i) sells, distributes, rents, leases, pre-
2 pares, blends, packages, labels, or is other-
3 wise involved in placing, a product in the
4 stream of commerce; or

5 (ii) installs, repairs, or maintains the
6 harm-causing aspect of a product.

7 (B) EXCLUSION.—Such term does not
8 include—

9 (i) a seller or lessor of real property;

10 (ii) a provider of professional services
11 in any case in which the sale or use of a
12 product is incidental to the transaction and
13 the essence of the transaction is the fur-
14 nishing of judgment, skill, or services; or

15 (iii) any person who—

16 (I) acts in only a financial capac-
17 ity with respect to the sale of a prod-
18 uct; or

19 (II) leases a product under a
20 lease arrangement in which the selec-
21 tion, possession, maintenance, and op-
22 eration of the product are controlled
23 by a person other than the lessor.

24 (19) PUNITIVE DAMAGES.—The term “punitive
25 damages” means damages awarded against any per-

1 son not to compensate for actual injury suffered, but
2 to punish or deter such person or others from en-
3 gaging in similar behavior in the future.

4 (20) STATE.—The term “State” means each of
5 the several States, the District of Columbia, Puerto
6 Rico, the Virgin Islands, Guam, American Samoa,
7 the Northern Mariana Islands, and any other terri-
8 tory or possession of the United States.

9 **SEC. 403. EFFECTIVE DATE.**

10 This title will apply to—

11 (1) any health care liability action brought in a
12 Federal or State court; and

13 (2) any health care liability claim subject to an
14 alternative dispute resolution system,

15 that is initiated on or after the date of enactment of this
16 title, except that any health care liability claim or action
17 arising from an injury occurring before the date of enact-
18 ment of this title shall be governed by the applicable stat-
19 ute of limitations provisions in effect at the time the injury
20 occurred.

21 **Subtitle B—Uniform Standards for**
22 **Health Care Liability Actions**

23 **SEC. 411. STATUTE OF LIMITATIONS.**

24 A health care liability action may not be brought
25 after the expiration of the 2-year period that begins on

1 the date on which the alleged injury that is the subject
2 of the action was discovered or should reasonably have
3 been discovered, but in no case after the expiration of the
4 5-year period that begins on the date the alleged injury
5 occurred.

6 **SEC. 412. CALCULATION AND PAYMENT OF DAMAGES.**

7 (a) TREATMENT OF NON-ECONOMIC DAMAGES.—

8 (1) LIMITATION ON NON-ECONOMIC DAM-
9 AGES.—The total amount of non-economic damages
10 that may be awarded to a claimant for losses result-
11 ing from the injury which is the subject of a health
12 care liability action may not exceed \$250,000, re-
13 gardless of the number of parties against whom the
14 action is brought or the number of actions brought
15 with respect to the injury. The limitation under this
16 paragraph shall not apply to an action for damages
17 based solely on intentional denial of medical treat-
18 ment necessary to preserve a patient's life that the
19 patient is otherwise qualified to receive, against the
20 wishes of a patient, or if the patient is incompetent,
21 against the wishes of the patient's guardian, on the
22 basis of the patient's present or predicated age, dis-
23 ability, degree of medical dependency, or quality of
24 life.

1 (2) LIMIT.—If, after the date of the enactment
2 of this Act, a State enacts a law which prescribes
3 the amount of non-economic damages which may be
4 awarded in a health care liability action which is dif-
5 ferent from the amount prescribed by section
6 412(a)(1), the State amount shall apply in lieu of
7 the amount prescribed by such section. If, after the
8 date of the enactment of this Act, a State enacts a
9 law which limits the amount of recovery in a health
10 care liability action without delineating between eco-
11 nomic and non-economic damages, the State amount
12 shall apply in lieu of the amount prescribed by such
13 section.

14 (3) JOINT AND SEVERAL LIABILITY.—In any
15 health care liability action brought in State or Fed-
16 eral court, a defendant shall be liable only for the
17 amount of non-economic damages attributable to
18 such defendant in direct proportion to such defend-
19 ant's share of fault or responsibility for the claim-
20 ant's actual damages, as determined by the trier of
21 fact. In all such cases, the liability of a defendant
22 for non-economic damages shall be several and not
23 joint and a separate judgment shall be rendered
24 against each defendant for the amount allocated to
25 such defendant.

1 (b) TREATMENT OF PUNITIVE DAMAGES.—

2 (1) GENERAL RULE.—Punitive damages may,
3 to the extent permitted by applicable State law, be
4 awarded in any health care liability action for harm
5 in any Federal or State court against a defendant if
6 the claimant establishes by clear and convincing evi-
7 dence that the harm suffered was the result of
8 conduct—

9 (A) specifically intended to cause harm; or

10 (B) conduct manifesting a conscious, fla-
11 grant indifference to the rights or safety of oth-
12 ers.

13 (2) APPLICABILITY.—This subsection shall
14 apply to any health care liability action brought in
15 any Federal or State court on any theory where pu-
16 nitive damages are sought. This subsection does not
17 create a cause of action for punitive damages.

18 (3) LIMITATION ON PUNITIVE DAMAGES.—The
19 total amount of punitive damages that may be
20 awarded to a claimant for losses resulting from the
21 injury which is the subject of a health care liability
22 action may not exceed the greater of—

23 (A) 2 times the amount of economic dam-
24 ages, or

25 (B) \$250,000,

1 regardless of the number of parties against whom
2 the action is brought or the number of actions
3 brought with respect to the injury. This subsection
4 does not preempt or supersede any State or Federal
5 law to the extent that such law would further limit
6 the award of punitive damages.

7 (4) BIFURCATION.—At the request of any
8 party, the trier of fact shall consider in a separate
9 proceeding whether punitive damages are to be
10 awarded and the amount of such award. If a sepa-
11 rate proceeding is requested, evidence relevant only
12 to the claim of punitive damages, as determined by
13 applicable State law, shall be inadmissible in any
14 proceeding to determine whether actual damages are
15 to be awarded.

16 (4) DRUGS AND DEVICES.—

17 (A) IN GENERAL.—

18 (i) PUNITIVE DAMAGES.—Punitive
19 damages shall not be awarded against a
20 manufacturer or product seller of a drug
21 or medical device which caused the claim-
22 ant's harm where—

23 (I) such drug or device was sub-
24 ject to premarket approval by the
25 Food and Drug Administration with

1 respect to the safety of the formula-
2 tion or performance of the aspect of
3 such drug or device which caused the
4 claimant's harm, or the adequacy of
5 the packaging or labeling of such drug
6 or device which caused the harm, and
7 such drug, device, packaging, or label-
8 ing was approved by the Food and
9 Drug Administration; or

10 (II) the drug is generally recog-
11 nized as safe and effective pursuant to
12 conditions established by the Food
13 and Drug Administration and applica-
14 ble regulations, including packaging
15 and labeling regulations.

16 (ii) APPLICATION.—Clause (i) shall
17 not apply in any case in which the defend-
18 ant, before or after premarket approval of
19 a drug or device—

20 (I) intentionally and wrongfully
21 withheld from or misrepresented to
22 the Food and Drug Administration in-
23 formation concerning such drug or de-
24 vice required to be submitted under
25 the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 301 et seq.) or
2 section 351 of the Public Health Serv-
3 ice Act (42 U.S.C. 262) that is mate-
4 rial and relevant to the harm suffered
5 by the claimant; or

6 (II) made an illegal payment to
7 an official or employee of the Food
8 and Drug Administration for the pur-
9 pose of securing or maintaining ap-
10 proval of such drug or device.

11 (B) PACKAGING.—In a health care liability
12 action for harm which is alleged to relate to the
13 adequacy of the packaging or labeling of a drug
14 which is required to have tamper-resistant
15 packaging under regulations of the Secretary of
16 Health and Human Services (including labeling
17 regulations related to such packaging), the
18 manufacturer or product seller of the drug shall
19 not be held liable for punitive damages unless
20 such packaging or labeling is found by the court
21 by clear and convincing evidence to be substan-
22 tially out of compliance with such regulations.

23 (c) PERIODIC PAYMENTS FOR FUTURE LOSSES.—

24 (1) GENERAL RULE.—In any health care liabil-
25 ity action in which the damages awarded for future

1 economic and non-economic loss exceeds \$50,000, a
2 person shall not be required to pay such damages in
3 a single, lump-sum payment, but shall be permitted
4 to make such payments periodically based on when
5 the damages are likely to occur, as such payments
6 are determined by the court.

7 (2) FINALITY OF JUDGMENT.—The judgment
8 of the court awarding periodic payments under this
9 subsection may not, in the absence of fraud, be re-
10 opened at any time to contest, amend, or modify the
11 schedule or amount of the payments.

12 (3) LUMP-SUM SETTLEMENTS.—This sub-
13 section shall not be construed to preclude a settle-
14 ment providing for a single, lump-sum payment.

15 (d) TREATMENT OF COLLATERAL SOURCE PAY-
16 MENTS.—

17 (1) INTRODUCTION INTO EVIDENCE.—In any
18 health care liability action, any defendant may intro-
19 duce evidence of collateral source payments. If any
20 defendant elects to introduce such evidence, the
21 claimant may introduce evidence of any amount paid
22 or contributed or reasonably likely to be paid or con-
23 tributed in the future by or on behalf of the claim-
24 ant to secure the right to such collateral source pay-
25 ments.

1 1998, including any revisions to that guideline;
2 and

3 (B) the compliance of the Office of the In-
4 specter General of the Department of Health
5 and Human Services with the protocols and
6 guidelines entitled “National Project Proto-
7 cols—Best Practice Guidelines” issued by the
8 Inspector General on June 3, 1998, including
9 any revisions to such protocols and guidelines;
10 and

11 (2) submit a report on such compliance to the
12 Committee on Commerce, the Committee on the Ju-
13 diciary, and the Committee on Ways and Means of
14 the House of Representatives and the Committee on
15 the Judiciary and the Committee on Finance of the
16 Senate not later than February 1, 2000, and every
17 year thereafter for a period of 4 years ending Feb-
18 ruary 1, 2003.