

105TH CONGRESS
1ST SESSION

S. 353

To amend title XXVII of the Public Health Service Act and part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 to establish standards for protection of consumers in managed care plans and other health plans.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 25, 1997

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend title XXVII of the Public Health Service Act and part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 to establish standards for protection of consumers in managed care plans and other health plans.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Health Insurance Bill of Rights Act of 1997”.

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

- Sec. 1. Short title; table of contents.
 Sec. 2. Amendments to the Public Health Service Act.

“PART C—PATIENT PROTECTION STANDARDS

“Sec. 2770. Notice; additional definitions.

“SUBPART 1—ACCESS TO CARE

- “Sec. 2771. Access to emergency care.
 “Sec. 2772. Access to specialty care.
 “Sec. 2773. Continuity of care.
 “Sec. 2774. Choice of provider.
 “Sec. 2775. Coverage for individuals participating in approved clinical trials.
 “Sec. 2776. Access to needed prescription drugs.

“SUBPART 2—QUALITY ASSURANCE

- “Sec. 2777. Internal quality assurance program.
 “Sec. 2778. Collection of standardized data.
 “Sec. 2779. Process for selection of providers.
 “Sec. 2780. Drug utilization program.
 “Sec. 2781. Standards for utilization review activities.

“SUBPART 3—PATIENT INFORMATION

- “Sec. 2782. Patient information.
 “Sec. 2783. Protection of patient confidentiality.

“SUBPART 4—GRIEVANCE PROCEDURES

- “Sec. 2784. Establishment of complaint and appeals process.
 “Sec. 2785. Provisions relating to appeals of utilization review determinations and similar determinations.
 “Sec. 2786. State health insurance ombudsmen.

“SUBPART 5—PROTECTION OF PROVIDERS AGAINST INTERFERENCE WITH MEDICAL COMMUNICATIONS AND IMPROPER INCENTIVE ARRANGEMENTS

- “Sec. 2787. Prohibition of interference with certain medical communications.
 “Sec. 2788. Prohibition against transfer of indemnification or improper incentive arrangements.

“SUBPART 6—PROMOTING GOOD MEDICAL PRACTICE AND PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

- “Sec. 2789. Promoting good medical practice.
 Sec. 3. Amendments to the Employee Retirement Income Security Act of 1974.
 “Sec. 713. Patient protection standards”.

1 **SEC. 2. AMENDMENTS TO THE PUBLIC HEALTH SERVICE**
 2 **ACT.**

3 (a) PATIENT PROTECTION STANDARDS.—Title
 4 XXVII of the Public Health Service Act is amended—

5 (1) by redesignating part C as part D, and

6 (2) by inserting after part B the following new
 7 part:

8 “PART C—PATIENT PROTECTION STANDARDS

9 “**SEC. 2770. NOTICE; ADDITIONAL DEFINITIONS.**

10 “(a) NOTICE.—A health insurance issuer under this
 11 part shall comply with the notice requirement under sec-
 12 tion 711(d) of the Employee Retirement Income Security
 13 Act of 1974 with respect to the requirements of this part
 14 as if such section applied to such issuer and such issuer
 15 were a group health plan.

16 “(b) ADDITIONAL DEFINITIONS.—For purposes of
 17 this part:

18 “(1) NONPARTICIPATING PHYSICIAN OR PRO-
 19 VIDER.—The term ‘nonparticipating physician or
 20 provider’ means, with respect to health care items
 21 and services furnished to an enrollee under health
 22 insurance coverage, a physician or provider that is
 23 not a participating physician or provider for such
 24 services.

1 “(2) PARTICIPATING PHYSICIAN OR PRO-
 2 VIDER.—The term ‘participating physician or pro-
 3 vider’ means, with respect to health care items and
 4 services furnished to an enrollee under health insur-
 5 ance coverage, a physician or provider that furnishes
 6 such items and services under a contract or other
 7 arrangement with the health insurance issuer offer-
 8 ing such coverage.

9 “SUBPART 1—ACCESS TO CARE

10 **“SEC. 2771. ACCESS TO EMERGENCY CARE.**

11 “(a) PROHIBITION OF CERTAIN RESTRICTIONS ON
 12 COVERAGE OF EMERGENCY SERVICES.

13 “(1) IN GENERAL.—If health insurance cov-
 14 erage provides any benefits with respect to emer-
 15 gency services (as defined in paragraph (2)(B)), the
 16 health insurance issuer offering such coverage shall
 17 cover emergency services furnished to an enrollee—

18 “(A) without the need for any prior au-
 19 thorization determination,

20 “(B) subject to paragraph (3), whether or
 21 not the physician or provider furnishing such
 22 services is a participating physician or provider
 23 with respect to such services, and

“(C) subject to paragraph (3), without regard to any other term or condition of such coverage (other than an exclusion of benefits, or an affiliation or waiting period, permitted under section 2701).

“(2) EMERGENCY SERVICES; EMERGENCY MEDICAL CONDITION.—For purposes of this section—

“(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON.—The term ‘emergency medical condition’ means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

“(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

“(ii) serious impairment to bodily functions, or

“(iii) serious dysfunction of any bodily organ or part.

1 “(B) EMERGENCY SERVICES.—The term
2 ‘emergency services’ means—

3 “(i) a medical screening examination
4 (as required under section 1867 of the So-
5 cial Security Act) that is within the capa-
6 bility of the emergency department of a
7 hospital, including ancillary services rou-
8 tinely available to the emergency depart-
9 ment, to evaluate an emergency medical
10 condition (as defined in subparagraph
11 (A)), and

12 “(ii) within the capabilities of the
13 staff and facilities available at the hospital,
14 such further medical examination and
15 treatment as are required under section
16 1867 of the Social Security Act to stabilize
17 the patient.

18 “(C) TRAUMA AND BURN CENTERS.—The
19 provisions of clause (ii) of subparagraph (B)
20 apply to a trauma or burn center, in a hospital,
21 that—

22 “(i) is designated by the State, a re-
23 gional authority of the State, or by the
24 designee of the State, or

1 “(ii) is in a State that has not made
 2 such designations and meets medically rec-
 3 ognized national standards.

4 “(3) APPLICATION OF NETWORK RESTRICTION
 5 PERMITTED IN CERTAIN CASES.—

6 “(A) IN GENERAL.—Except as provided in
 7 subparagraph (B), if a health insurance issuer
 8 in relation to health insurance coverage denies,
 9 limits, or otherwise differentiates in coverage or
 10 payment for benefits other than emergency
 11 services on the basis that the physician or pro-
 12 vider of such services is a nonparticipating phy-
 13 sician or provider, the issuer may deny, limit, or
 14 differentiate in coverage or payment for emer-
 15 gency services on such basis.

16 “(B) NETWORK RESTRICTIONS NOT PER-
 17 MITTED IN CERTAIN EXCEPTIONAL CASES.—
 18 The denial or limitation of, or differentiation in,
 19 coverage or payment of benefits for emergency
 20 services under subparagraph (A) shall not apply
 21 in the following cases:

22 “(i) CIRCUMSTANCES BEYOND CON-
 23 TROL OF ENROLLEE.—The enrollee is un-
 24 able to go to a participating hospital for
 25 such services due to circumstances beyond

the control of the enrollee (as determined consistent with guidelines and subparagraph (C)).

“(ii) LIKELIHOOD OF AN ADVERSE HEALTH CONSEQUENCE BASED ON LAYPERSON’S JUDGMENT.—A prudent layperson possessing an average knowledge of health and medicine could reasonably believe that, under the circumstances and consistent with guidelines, the time required to go to a participating hospital for such services could result in any of the adverse health consequences described in a clause of subsection (a)(2)(A).

“(iii) PHYSICIAN REFERRAL.—A participating physician or other person authorized by the plan refers the enrollee to an emergency department of a hospital and does not specify an emergency department of a hospital that is a participating hospital with respect to such services.

“(C) APPLICATION OF ‘BEYOND CONTROL’ STANDARDS.—For purposes of applying subparagraph (B)(i), receipt of emergency services

1 from a nonparticipating hospital shall be treat-
2 ed under the guidelines as being ‘due to cir-
3 cumstances beyond the control of the enrollee’
4 if any of the following conditions are met:

5 “(i) UNCONSCIOUS.—The enrollee was
6 unconscious or in an otherwise altered
7 mental state at the time of initiation of the
8 services.

9 “(ii) AMBULANCE DELIVERY.—The
10 enrollee was transported by an ambulance
11 or other emergency vehicle directed by a
12 person other than the enrollee to the non-
13 participating hospital in which the services
14 were provided.

15 “(iii) NATURAL DISASTER.—A natural
16 disaster or civil disturbance prevented the
17 enrollee from presenting to a participating
18 hospital for the provision of such services.

19 “(iv) NO GOOD FAITH EFFORT TO IN-
20 FORM OF CHANGE IN PARTICIPATION DUR-
21 ING A CONTRACT YEAR.—The status of the
22 hospital changed from a participating hos-
23 pital to a nonparticipating hospital with re-
24 spect to emergency services during a con-
25 tract year and the plan or issuer failed to

1 make a good faith effort to notify the en-
 2 rollee involved of such change.

3 “(v) OTHER CONDITIONS.—There
 4 were other factors (such as those identified
 5 in guidelines) that prevented the enrollee
 6 from controlling selection of the hospital in
 7 which the services were provided.

8 “(b) ASSURING COORDINATED COVERAGE OF MAIN-
 9 TENANCE CARE AND POST-STABILIZATION CARE.—

10 “(1) IN GENERAL.—In the case of an enrollee
 11 who is covered under health insurance coverage is-
 12 sued by a health insurance issuer and who has re-
 13 ceived emergency services pursuant to a screening
 14 evaluation conducted (or supervised) by a treating
 15 physician at a hospital that is a nonparticipating
 16 provider with respect to emergency services, if—

17 “(A) pursuant to such evaluation, the phy-
 18 sician identifies post-stabilization care (as de-
 19 fined in paragraph (3)(B)) that is required by
 20 the enrollee,

21 “(B) the coverage provides benefits with
 22 respect to the care so identified and the cov-
 23 erage requires (but for this subsection) an af-
 24 firmative prior authorization determination as a
 25 condition of coverage of such care, and

1 “(C) the treating physician (or another in-
2 dividual acting on behalf of such physician) ini-
3 tiates, not later than 30 minutes after the time
4 the treating physician determines that the con-
5 dition of the enrollee is stabilized, a good faith
6 effort to contact a physician or other person au-
7 thorized by the issuer (by telephone or other
8 means) to obtain an affirmative prior authoriza-
9 tion determination with respect to the care,
10 then, without regard to terms and conditions speci-
11 fied in paragraph (2) the issuer shall cover mainte-
12 nance care (as defined in paragraph (3)(A)) fur-
13 nished to the enrollee during the period specified in
14 paragraph (4) and shall cover post-stabilization care
15 furnished to the enrollee during the period beginning
16 under paragraph (5) and ending under paragraph
17 (6).

18 “(2) TERMS AND CONDITIONS WAIVED.—The
19 terms and conditions (of coverage) described in this
20 paragraph that are waived under paragraph (1) are
21 as follows:

22 “(A) The need for any prior authorization
23 determination.

1 “(B) Any limitation on coverage based on
 2 whether or not the physician or provider fur-
 3 nishing the care is a participating physician or
 4 provider with respect to such care.

5 “(C) Any other term or condition of the
 6 coverage (other than an exclusion of benefits, or
 7 an affiliation or waiting period, permitted under
 8 section 2701 and other than a requirement re-
 9 lating to medical necessity for coverage of bene-
 10 fits).

11 “(3) MAINTENANCE CARE AND POST-STA-
 12 BILIZATION CARE DEFINED.—In this subsection:

13 “(A) MAINTENANCE CARE.—The term
 14 ‘maintenance care’ means, with respect to an
 15 individual who is stabilized after provision of
 16 emergency services, medically necessary items
 17 and services (other than emergency services)
 18 that are required by the individual to ensure
 19 that the individual remains stabilized during
 20 the period described in paragraph (4).

21 “(B) POST-STABILIZATION CARE.—The
 22 term ‘post-stabilization care’ means, with re-
 23 spect to an individual who is determined to be

1 stable pursuant to a medical screening examina-
2 tion or who is stabilized after provision of emer-
3 gency services, medically necessary items and
4 services (other than emergency services and
5 other than maintenance care) that are required
6 by the individual.

7 “(4) PERIOD OF REQUIRED COVERAGE OF
8 MAINTENANCE CARE.—The period of required cov-
9 erage of maintenance care of an individual under
10 this subsection begins at the time of the request (or
11 the initiation of the good faith effort to make the re-
12 quest) under paragraph (1)(C) and ends when—

13 “(A) the individual is discharged from the
14 hospital;

15 “(B) a physician (designated by the issuer
16 involved) and with privileges at the hospital in-
17 volved arrives at the emergency department of
18 the hospital and assumes responsibility with re-
19 spect to the treatment of the individual; or

20 “(C) the treating physician and the issuer
21 agree to another arrangement with respect to
22 the care of the individual.

23 “(5) WHEN POST-STABILIZATION CARE RE-
24 QUIRED TO BE COVERED.—

1 “(A) WHEN TREATING PHYSICIAN UNABLE
2 TO COMMUNICATE REQUEST.—If the treating
3 physician or other individual makes the good
4 faith effort to request authorization under para-
5 graph (1)(C) but is unable to communicate the
6 request directly with an authorized person re-
7 ferred to in such paragraph within 30 minutes
8 after the time of initiating such effort, then
9 post-stabilization care is required to be covered
10 under this subsection beginning at the end of
11 such 30-minute period.

12 “(B) WHEN ABLE TO COMMUNICATE RE-
13 QUEST, AND NO TIMELY RESPONSE.—

14 “(i) IN GENERAL.—If the treating
15 physician or other individual under para-
16 graph (1)(C) is able to communicate the
17 request within the 30-minute period de-
18 scribed in subparagraph (A), the post-sta-
19 bilization care requested is required to be
20 covered under this subsection beginning 30
21 minutes after the time when the issuer re-
22 ceives the request unless a person author-
23 ized by the plan or issuer involved commu-
24 nicates (or makes a good faith effort to
25 communicate) a denial of the request for

the prior authorization determination within 30 minutes of the time when the issuer receives the request and the treating physician does not request under clause (ii) to communicate directly with an authorized physician concerning the denial.

“(ii) REQUEST FOR DIRECT PHYSICIAN-TO-PHYSICIAN COMMUNICATION CONCERNING DENIAL.—If a denial of a request is communicated under clause (i), the treating physician may request to communicate respecting the denial directly with a physician who is authorized by the issuer to deny or affirm such a denial.

“(C) WHEN NO TIMELY RESPONSE TO REQUEST FOR PHYSICIAN-TO-PHYSICIAN COMMUNICATION.—If a request for physician-to-physician communication is made under subparagraph (B)(ii), the post-stabilization care requested is required to be covered under this subsection beginning 30 minutes after the time when the issuer receives the request from a treating physician unless a physician, who is authorized by the issuer to reverse or affirm the initial denial of the care, communicates (or

1 makes a good faith effort to communicate) di-
 2 rectly with the treating physician within such
 3 30-minute period.

4 “(D) DISAGREEMENTS OVER POST-STA-
 5 BILIZATION CARE.—If, after a direct physician-
 6 to-physician communication under subpara-
 7 graph (C), the denial of the request for the
 8 post-stabilization care is not reversed and the
 9 treating physician communicates to the issuer
 10 involved a disagreement with such decision, the
 11 post-stabilization care requested is required to
 12 be covered under this subsection beginning as
 13 follows:

14 “(i) DELAY TO ALLOW FOR PROMPT
 15 ARRIVAL OF PHYSICIAN ASSUMING RE-
 16 SPONSIBILITY.—If the issuer commu-
 17 nicates that a physician (designated by the
 18 plan or issuer) with privileges at the hos-
 19 pital involved will arrive promptly (as de-
 20 termined under guidelines) at the emer-
 21 gency department of the hospital in order
 22 to assume responsibility with respect to the
 23 treatment of the enrollee involved, the re-
 24 quired coverage of the post-stabilization
 25 care begins after the passage of such time

1 period as would allow the prompt arrival of
2 such a physician.

3 “(ii) OTHER CASES.—If the issuer
4 does not so communicate, the required cov-
5 erage of the post-stabilization care begins
6 immediately.

7 “(6) NO REQUIREMENT OF COVERAGE OF POST-
8 STABILIZATION CARE IF ALTERNATE PLAN OF
9 TREATMENT.—

10 “(A) IN GENERAL.—Coverage of post-sta-
11 bilization care is not required under this sub-
12 section with respect to an individual when—

13 “(i) subject to subparagraph (B), a
14 physician (designated by the plan or issuer
15 involved) and with privileges at the hos-
16 pital involved arrives at the emergency de-
17 partment of the hospital and assumes re-
18 sponsibility with respect to the treatment
19 of the individual; or

20 “(ii) the treating physician and the is-
21 suer agree to another arrangement with re-
22 spect to the post-stabilization care (such as
23 an appropriate transfer of the individual

1 involved to another facility or an appoint-
 2 ment for timely followup treatment for the
 3 individual).

4 “(B) SPECIAL RULE WHERE ONCE CARE
 5 INITIATED.—Required coverage of requested
 6 post-stabilization care shall not end by reason
 7 of subparagraph (A)(i) during an episode of
 8 care (as determined by guidelines) if the treat-
 9 ing physician initiated such care (consistent
 10 with a previous paragraph) before the arrival of
 11 a physician described in such subparagraph.

12 “(7) CONSTRUCTION.—Nothing in this sub-
 13 section shall be construed as—

14 “(A) preventing an issuer from authorizing
 15 coverage of maintenance care or post-stabiliza-
 16 tion care in advance or at any time; or

17 “(B) preventing a treating physician or
 18 other individual described in paragraph (1)(C)
 19 and an issuer from agreeing to modify any of
 20 the time periods specified in paragraphs (5) as
 21 it relates to cases involving such persons.

22 “(c) LIMITS ON COST-SHARING FOR SERVICES FUR-
 23 NISHED IN EMERGENCY DEPARTMENTS.—If health insur-
 24 ance coverage provides any benefits with respect to emer-
 25 gency services, the health insurance issuer offering such

1 coverage may impose cost sharing with respect to such
 2 services only if the following conditions are met:

3 “(1) LIMITATIONS ON COST-SHARING DIF-
 4 FERENTIAL FOR NONPARTICIPATING PROVIDERS.—

5 “(A) NO DIFFERENTIAL FOR CERTAIN
 6 SERVICES.—In the case of services furnished
 7 under the circumstances described in clause (i),
 8 (ii), or (iii) of subsection (a)(3)(B) (relating to
 9 circumstances beyond the control of the en-
 10 rollee, the likelihood of an adverse health con-
 11 sequence based on layperson’s judgment, and
 12 physician referral), the cost-sharing for such
 13 services provided by a nonparticipating provider
 14 or physician does not exceed the cost-sharing
 15 for such services provided by a participating
 16 provider or physician.

17 “(B) ONLY REASONABLE DIFFERENTIAL
 18 FOR OTHER SERVICES.—In the case of other
 19 emergency services, any differential by which
 20 the cost-sharing for such services provided by a
 21 nonparticipating provider or physician exceeds
 22 the cost-sharing for such services provided by a
 23 participating provider or physician is reasonable
 24 (as determined under guidelines).

1 “(2) ONLY REASONABLE DIFFERENTIAL BE-
 2 TWEEN EMERGENCY SERVICES AND OTHER SERV-
 3 ICES.—Any differential by which the cost-sharing for
 4 services furnished in an emergency department ex-
 5 ceeds the cost-sharing for such services furnished in
 6 another setting is reasonable (as determined under
 7 guidelines).

8 “(3) CONSTRUCTION.—Nothing in paragraph
 9 (1)(B) or (2) shall be construed as authorizing
 10 guidelines other than guidelines that establish maxi-
 11 mum cost-sharing differentials.

12 “(d) INFORMATION ON ACCESS TO EMERGENCY
 13 SERVICES.—A health insurance issuer, to the extent a
 14 health insurance issuer offers health insurance coverage,
 15 shall provide education to enrollees on—

16 “(1) coverage of emergency services (as defined
 17 in subsection (a)(2)(B)) by the issuer in accordance
 18 with the provisions of this section,

19 “(2) the appropriate use of emergency services,
 20 including use of the 911 telephone system or its
 21 local equivalent,

22 “(3) any cost sharing applicable to emergency
 23 services,

24 “(4) the process and procedures of the plan for
 25 obtaining emergency services, and

1 “(5) the locations of—

2 “(A) emergency departments, and

3 “(B) other settings,

4 in which participating physicians and hospitals pro-
5 vide emergency services and post-stabilization care.

6 “(e) GENERAL DEFINITIONS.—For purposes of this
7 section:

8 “(1) COST SHARING.—The term ‘cost sharing’
9 means any deductible, coinsurance amount, copay-
10 ment or other out-of-pocket payment (other than
11 premiums or enrollment fees) that a health insur-
12 ance issuer offering health insurance issuer imposes
13 on enrollees with respect to the coverage of benefits.

14 “(2) GOOD FAITH EFFORT.—The term ‘good
15 faith effort’ has the meaning given such term in
16 guidelines and requires such appropriate documenta-
17 tion as is specified under such guidelines.

18 “(3) GUIDELINES.—The term ‘guidelines’
19 means guidelines established by the Secretary after
20 consultation with an advisory panel that includes in-
21 dividuals representing emergency physicians, health
22 insurance issuers, including at least one health
23 maintenance organization, hospitals, employers, the
24 States, and consumers.

1 “(4) PRIOR AUTHORIZATION DETERMINA-
2 TION.—The term ‘prior authorization determination’
3 means, with respect to items and services for which
4 coverage may be provided under health insurance
5 coverage, a determination (before the provision of
6 the items and services and as a condition of coverage
7 of the items and services under the coverage) of
8 whether or not such items and services will be cov-
9 ered under the coverage.

10 “(5) STABILIZE.—The term ‘to stabilize’
11 means, with respect to an emergency medical condi-
12 tion, to provide (in complying with section 1867 of
13 the Social Security Act) such medical treatment of
14 the condition as may be necessary to assure, within
15 reasonable medical probability, that no material de-
16 terioration of the condition is likely to result from or
17 occur during the transfer of the individual from the
18 facility.

19 “(6) STABILIZED.—The term ‘stabilized’
20 means, with respect to an emergency medical condi-
21 tion, that no material deterioration of the condition

1 is likely, within reasonable medical probability, to re-
 2 sult from or occur before an individual can be trans-
 3 ferred from the facility, in compliance with the re-
 4 quirements of section 1867 of the Social Security
 5 Act.

6 “(7) TREATING PHYSICIAN.—The term ‘treat-
 7 ing physician’ includes a treating health care profes-
 8 sional who is licensed under State law to provide
 9 emergency services other than under the supervision
 10 of a physician.

11 **“SEC. 2772. ACCESS TO SPECIALTY CARE.**

12 “(a) OBSTETRICAL AND GYNECOLOGICAL CARE.—

13 “(1) IN GENERAL.—If a health insurance is-
 14 suer, in connection with the provision of health in-
 15 surance coverage, requires or provides for an en-
 16 rollee to designate a participating primary care pro-
 17 vider—

18 “(A) the issuer shall permit a female en-
 19 rollee to designate a physician who specializes
 20 in obstetrics and gynecology as the enrollee’s
 21 primary care provider; and

22 “(B) if such an enrollee has not designated
 23 such a provider as a primary care provider, the
 24 issuer—

1 “(i) may not require prior authoriza-
 2 tion by the enrollee’s primary care provider
 3 or otherwise for coverage of routine gyne-
 4 cological care (such as preventive women’s
 5 health examinations) and pregnancy-relat-
 6 ed services provided by a participating phy-
 7 sician who specializes in obstetrics and
 8 gynecology to the extent such care is other-
 9 wise covered, and

10 “(ii) may treat the ordering of other
 11 gynecological care by such a participating
 12 physician as the prior authorization of the
 13 primary care provider with respect to such
 14 care under the coverage.

15 “(2) CONSTRUCTION.—Nothing in paragraph
 16 (1)(B)(ii) shall waive any requirements of coverage
 17 relating to medical necessity or appropriateness with
 18 respect to coverage of gynecological care so ordered.

19 “(b) SPECIALTY CARE.—

20 “(1) REFERRAL TO SPECIALTY CARE FOR EN-
 21 ROLLEES REQUIRING TREATMENT BY SPECIAL-
 22 ISTS.—

23 “(A) IN GENERAL.—In the case of an en-
 24 rollee who is covered under health insurance
 25 coverage offered by a health insurance issuer

1 and who has a condition or disease of sufficient
2 seriousness and complexity to require treatment
3 by a specialist, the issuer shall make or provide
4 for a referral to a specialist who is available
5 and accessible to provide the treatment for such
6 condition or disease.

7 “(B) SPECIALIST DEFINED.—For purposes
8 of this subsection, the term ‘specialist’ means,
9 with respect to a condition, a health care practi-
10 tioner, facility, or center (such as a center of
11 excellence) that has adequate expertise through
12 appropriate training and experience (including,
13 in the case of a child, appropriate pediatric ex-
14 pertise) to provide high quality care in treating
15 the condition.

16 “(C) CARE UNDER REFERRAL.—Care pro-
17 vided pursuant to such referral under subpara-
18 graph (A) shall be—

19 “(i) pursuant to a treatment plan (if
20 any) developed by the specialist and ap-
21 proved by the issuer, in consultation with
22 the designated primary care provider or
23 specialist and the enrollee (or the enrollee’s
24 designee), and

1 “(ii) in accordance with applicable
2 quality assurance and utilization review
3 standards of the issuer.

4 Nothing in this subsection shall be construed as
5 preventing such a treatment plan for an en-
6 rollee from requiring a specialist to provide the
7 primary care provider with regular updates on
8 the specialty care provided, as well as all nec-
9 essary medical information.

10 “(D) REFERRALS TO PARTICIPATING PRO-
11 VIDERS.—An issuer is not required under sub-
12 paragraph (A) to provide for a referral to a spe-
13 cialist that is not a participating provider, un-
14 less the issuer does not have an appropriate
15 specialist that is available and accessible to
16 treat the enrollee’s condition and that is a par-
17 ticipating provider with respect to such treat-
18 ment.

19 “(E) TREATMENT OF NONPARTICIPATING
20 PROVIDERS.—If an issuer refers an enrollee to
21 a nonparticipating specialist, services provided
22 pursuant to the approved treatment plan shall
23 be provided at no additional cost to the enrollee
24 beyond what the enrollee would otherwise pay

1 for services received by such a specialist that is
2 a participating provider.

3 “(2) SPECIALISTS AS PRIMARY CARE PROVID-
4 ERS.—

5 “(A) IN GENERAL.—A health insurance is-
6 suer, in connection with the provision of health
7 insurance coverage, shall have a procedure by
8 which a new enrollee upon enrollment, or an en-
9 rollee upon diagnosis, with an ongoing special
10 condition (as defined in subparagraph (C)) may
11 receive a referral to a specialist for such condi-
12 tion who shall be responsible for and capable of
13 providing and coordinating the enrollee’s pri-
14 mary and specialty care. If such an enrollee’s
15 care would most appropriately be coordinated
16 by such a specialist, the issuer shall refer the
17 enrollee to such specialist.

18 “(B) TREATMENT AS PRIMARY CARE PRO-
19 VIDER.—Such specialist shall be permitted to
20 treat the enrollee without a referral from the
21 enrollee’s primary care provider and may au-
22 thorize such referrals, procedures, tests, and
23 other medical services as the enrollee’s primary
24 care provider would otherwise be permitted to
25 provide or authorize, subject to the terms of the

1 treatment plan (referred to in paragraph
2 (1)(C)(i)).

3 “(C) ONGOING SPECIAL CONDITION DE-
4 FINED.—In this paragraph, the term ‘special
5 condition’ means a condition or disease that—

6 “(i) is life-threatening, degenerative,
7 or disabling, and

8 “(ii) requires specialized medical care
9 over a prolonged period of time.

10 “(D) TERMS OF REFERRAL.—The provi-
11 sions of subparagraphs (C) through (E) of
12 paragraph (1) shall apply with respect to refer-
13 rals under subparagraph (A) of this paragraph
14 in the same manner as they apply to referrals
15 under paragraph (1)(A).

16 “(3) STANDING REFERRALS.—

17 “(A) IN GENERAL.—A health insurance is-
18 suer, in connection with the provision of health
19 insurance coverage, shall have a procedure by
20 which an enrollee who has a condition that re-
21 quires ongoing care from a specialist may re-
22 ceive a standing referral to such specialist for
23 treatment of such condition. If the issuer, or
24 the primary care provider in consultation with

1 the medical director of the issuer and the spe-
 2 cialist (if any), determines that such a standing
 3 referral is appropriate, the issuer shall make
 4 such a referral to such a specialist.

5 “(B) TERMS OF REFERRAL.—The provi-
 6 sions of subparagraphs (C) through (E) of
 7 paragraph (1) shall apply with respect to refer-
 8 rals under subparagraph (A) of this paragraph
 9 in the same manner as they apply to referrals
 10 under paragraph (1)(A).

11 **“SEC. 2773. CONTINUITY OF CARE.**

12 “(a) IN GENERAL.—If a contract between a health
 13 insurance issuer, in connection with the provision of health
 14 insurance coverage, and a health care provider is termi-
 15 nated (other than by the issuer for failure to meet applica-
 16 ble quality standards or for fraud) and an enrollee is un-
 17 dergoing a course of treatment from the provider at the
 18 time of such termination, the issuer shall—

19 “(1) notify the enrollee of such termination,
 20 and

21 “(2) subject to subsection (c), permit the en-
 22 rollee to continue the course of treatment with the
 23 provider during a transitional period (provided under
 24 subsection (b)).

25 “(b) TRANSITIONAL PERIOD.—

1 “(1) IN GENERAL.—Except as provided in para-
 2 graphs (2) through (4), the transitional period under
 3 this subsection shall extend for at least—

4 “(A) 60 days from the date of the notice
 5 to the enrollee of the provider’s termination in
 6 the case of a primary care provider, or

7 “(B) 120 days from such date in the case
 8 of another provider.

9 “(2) INSTITUTIONAL CARE.—The transitional
 10 period under this subsection for institutional or in-
 11 patient care from a provider shall extend until the
 12 discharge or termination of the period of institu-
 13 tionalization and shall include reasonable follow-up
 14 care related to the institutionalization and shall also
 15 include institutional care scheduled prior to the date
 16 of termination of the provider status.

17 “(3) PREGNANCY.—If—

18 “(A) an enrollee has entered the second
 19 trimester of pregnancy at the time of a provid-
 20 er’s termination of participation, and

21 “(B) the provider was treating the preg-
 22 nancy before date of the termination,
 23 the transitional period under this subsection with re-
 24 spect to provider’s treatment of the pregnancy shall

1 extend through the provision of post-partum care di-
 2 rectly related to the delivery.

3 “(4) TERMINAL ILLNESS.—

4 “(A) IN GENERAL.—If—

5 “(i) an enrollee was determined to be
 6 terminally ill (as defined in subparagraph
 7 (B)) at the time of a provider’s termi-
 8 nation 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 subsection
 13 shall extend for the remainder of the enrollee’s
 14 life for care directly related to the treatment of
 15 the terminal illness.

16 “(B) DEFINITION.—In subparagraph (A),
 17 an enrollee is considered to be ‘terminally ill’ if
 18 the enrollee has a medical prognosis that the
 19 enrollee’s life expectancy is 6 months or less.

20 “(c) PERMISSIBLE TERMS AND CONDITIONS.—An is-
 21 suer may condition coverage of continued treatment by a
 22 provider under subsection (a)(2) upon the provider agree-
 23 ing to the following terms and conditions:

1 “(1) The provider agrees to continue to accept
2 reimbursement from the issuer at the rates applica-
3 ble prior to the start of the transitional period as
4 payment in full.

5 “(2) The provider agrees to adhere to the issu-
6 er’s quality assurance standards and to provide to
7 the issuer necessary medical information related to
8 the care provided.

9 “(3) The provider agrees otherwise to adhere to
10 the issuer’s policies and procedures, including proce-
11 dures regarding referrals and obtaining prior au-
12 thorization and providing services pursuant to a
13 treatment plan approved by the issuer.

14 **“SEC. 2774. CHOICE OF PROVIDER.**

15 “(a) PRIMARY CARE.—A health insurance issuer that
16 offers health insurance coverage shall permit each enrollee
17 to receive primary care from any participating primary
18 care provider who is available to accept such enrollee.

19 “(b) SPECIALISTS.—

20 “(1) IN GENERAL.—Subject to paragraph (2), a
21 health insurance issuer that offers health insurance

1 coverage shall permit each enrollee to receive medi-
 2 cally necessary specialty care, pursuant to appro-
 3 priate referral procedures, from any qualified par-
 4 ticipating health care provider who is available to ac-
 5 cept such enrollee for such care.

6 “(2) LIMITATION.—Paragraph (1) shall not
 7 apply to speciality care if the issuer clearly informs
 8 enrollees of the limitations on choice of participating
 9 providers with respect to such care.

10 “(c) LIST OF PARTICIPATING PROVIDERS.—For dis-
 11 closure of information about participating primary care
 12 and specialty care providers, see section 2782(b)(3).

13 **“SEC. 2775. COVERAGE FOR INDIVIDUALS PARTICIPATING**
 14 **IN APPROVED CLINICAL TRIALS.**

15 “(a) IN GENERAL.—If a health insurance issuer of-
 16 fers health insurance coverage to a qualified enrollee (as
 17 defined in subsection (b)), the issuer—

18 “(1) may not deny the enrollee participation in
 19 the clinical trial referred to in subsection (b)(2);

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

1 “(3) may not discriminate against the enrollee
2 on the basis of the enrollee’s participation in such
3 trial.

4 “(b) QUALIFIED ENROLLEE DEFINED.—For pur-
5 poses of subsection (a), the term ‘qualified enrollee’ means
6 an enrollee under health insurance coverage who meets the
7 following conditions:

8 “(1) The enrollee has a life-threatening or seri-
9 ous illness for which no standard treatment is effec-
10 tive.

11 “(2) The enrollee is eligible to participate in an
12 approved clinical trial with respect to treatment of
13 such illness.

14 “(3) The enrollee and the referring physician
15 conclude that the enrollee’s participation in such
16 trial would be appropriate.

17 “(4) The enrollee’s participation in the trial of-
18 fers potential for significant clinical benefit for the
19 enrollee.

20 “(c) PAYMENT.—

21 “(1) IN GENERAL.—Under this section an is-
22 suer shall provide for payment for routine patient
23 costs described in subsection (a)(2) but is not re-
24 quired to pay for costs of items and services that are

1 reasonably expected (as determined by the Sec-
 2 retary) to be paid for by the sponsors of an ap-
 3 proved clinical trial.

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

6 “(A) a participating provider, the payment
 7 rate shall be at the agreed upon rate, or

8 “(B) a nonparticipating provider, the pay-
 9 ment rate shall be at the rate the issuer would
 10 normally pay for comparable services under
 11 subparagraph (A).

12 “(d) APPROVED CLINICAL TRIAL DEFINED.—In this
 13 section, the term ‘approved clinical trial’ means a clinical
 14 research study or clinical investigation approved and fund-
 15 ed by one or more of the following:

16 “(1) The National Institutes of Health.

17 “(2) A cooperative group or center of the Na-
 18 tional Institutes of Health.

19 “(3) The Department of Veterans Affairs.

20 “(4) The Department of Defense.

21 **“SEC. 2776. ACCESS TO NEEDED PRESCRIPTION DRUGS.**

22 “If a health insurance issuer offers health insurance
 23 coverage that provides benefits with respect to prescription
 24 drugs but the coverage limits such benefits to drugs in-
 25 cluded in a formulary, the issuer shall—

1 “(1) ensure participation of participating physi-
 2 cians in the development of the formulary;

3 “(2) disclose the nature of the formulary re-
 4 strictions; and

5 “(3) provide for exceptions from the formulary
 6 limitation when medical necessity, as determined by
 7 the enrollee’s physician subject to reasonable review
 8 by the issuer, dictates that a non-formulary alter-
 9 native is indicated.

10 “SUBPART 2—QUALITY ASSURANCE

11 **“SEC. 2777. INTERNAL QUALITY ASSURANCE PROGRAM.**

12 “(a) REQUIREMENT.—A health insurance issuer that
 13 offers health insurance coverage shall establish and main-
 14 tain an ongoing, internal quality assurance and continuous
 15 quality improvement program that meets the requirements
 16 of subsection (b).

17 “(b) PROGRAM REQUIREMENTS.—The requirements
 18 of this subsection for a quality improvement program of
 19 an issuer are as follows:

20 “(1) ADMINISTRATION.—The issuer has a sepa-
 21 rate identifiable unit with responsibility for adminis-
 22 tration of the program.

23 “(2) WRITTEN PLAN.—The issuer has a written
 24 plan for the program that is updated annually and
 25 that specifies at least the following:

1 “(A) The activities to be conducted.

2 “(B) The organizational structure.

3 “(C) The duties of the medical director.

4 “(D) Criteria and procedures for the as-
5 sessment of quality.

6 “(E) Systems for ongoing and focussed
7 evaluation activities.

8 “(3) SYSTEMATIC REVIEW.—The program pro-
9 vides for systematic review of the type of health
10 services provided, consistency of services provided
11 with good medical practice, and patient outcomes.

12 “(4) QUALITY CRITERIA.—The program—

13 “(A) uses criteria that are based on per-
14 formance and clinical outcomes where feasible
15 and appropriate, and

16 “(B) includes criteria that are directed
17 specifically at meeting the needs of at-risk pop-
18 ulations and enrollees with chronic or severe ill-
19 nesses.

20 “(5) SYSTEM FOR REPORTING.—The program
21 has procedures for reporting of possible quality con-
22 cerns by providers and enrollees and for remedial ac-
23 tions to correct quality problems, including written
24 procedures for responding to concerns and taking
25 appropriate corrective action.

1 “(6) DATA COLLECTION.—The program pro-
 2 vides for the collection of systematic, scientifically
 3 based data to be used in the measure of quality.

4 “(c) DEEMING.—For purposes of subsection (a), the
 5 requirements of subsection (b) are deemed to be met with
 6 respect to a health insurance issuer if the issuer—

7 “(1) is a qualified health maintenance organiza-
 8 tion (as defined in section 1310(d)), or

9 “(2) is accredited by a national accreditation
 10 organization that is certified by the Secretary.

11 **“SEC. 2778. COLLECTION OF STANDARDIZED DATA.**

12 “(a) IN GENERAL.—A health insurance issuer that
 13 offers health insurance coverage shall collect uniform qual-
 14 ity data that include—

15 “(1) a minimum uniform data set described in
 16 subsection (b), and

17 “(2) additional data that are consistent with
 18 the requirements of a nationally recognized body
 19 identified by the Secretary.

20 “(b) MINIMUM UNIFORM DATA SET.—The Secretary
 21 shall specify the data required to be included in the mini-
 22 mum uniform data set under subsection (a)(1) and the
 23 standard format for such data. Such data shall include
 24 at least—

25 “(1) aggregate utilization data;

1 “(2) data on the demographic characteristics of
2 enrollees;

3 “(3) data on disease-specific and age-specific
4 mortality rates of enrollees;

5 “(4) data on enrollee satisfaction, including
6 data on enrollee disenrollment and grievances; and

7 “(5) data on quality indicators.

8 “(c) AVAILABILITY.—A summary of the data col-
9 lected under subsection (a) shall be disclosed under section
10 2782(b)(4).

11 **“SEC. 2779. PROCESS FOR SELECTION OF PROVIDERS.**

12 “(a) IN GENERAL.—A health insurance issuer that
13 offers health insurance coverage shall have a written proc-
14 ess for the selection of participating health care profes-
15 sionals, including minimum professional requirements.

16 “(b) VERIFICATION OF BACKGROUND.—Such process
17 shall include verification of a health care provider’s li-
18 cense, a history of suspension or revocation, and liability
19 claim history.

20 “(c) RESTRICTION.—Such process shall not use a
21 high-risk patient base or location of a provider in an area
22 with residents with poorer health status as a basis for ex-
23 cluding providers from participation.

1 **“SEC. 2780. DRUG UTILIZATION PROGRAM.**

2 “A health insurance issuer that provides health insur-
 3 ance coverage that includes benefits for prescription drugs
 4 shall establish and maintain a drug utilization program
 5 which—

6 “(1) encourages appropriate use of prescription
 7 drugs by enrollees and providers,

8 “(2) monitors illnesses arising from improper
 9 drug use or from adverse drug reactions or inter-
 10 actions, and

11 “(3) takes appropriate action to reduce the inci-
 12 dence of improper drug use and adverse drug reac-
 13 tions and interactions.

14 **“SEC. 2781. STANDARDS FOR UTILIZATION REVIEW ACTIVI-**
 15 **TIES.**

16 “(a) COMPLIANCE WITH REQUIREMENTS.—

17 “(1) IN GENERAL.—A health insurance issuer
 18 shall conduct utilization review activities in connec-
 19 tion with the provision of health insurance coverage
 20 only in accordance with a utilization review program
 21 that meets the requirements of this section.

22 “(2) USE OF OUTSIDE AGENTS.—Nothing in
 23 this section shall be construed as preventing a health
 24 insurance issuer from arranging through a contract
 25 or otherwise for persons or entities to conduct utili-
 26 zation review activities on behalf of the issuer, so

1 long as such activities are conducted in accordance
 2 with a utilization review program that meets the re-
 3 quirements of this section.

4 “(3) UTILIZATION REVIEW DEFINED.—For pur-
 5 poses of this section, the terms ‘utilization review’
 6 and ‘utilization review activities’ mean procedures
 7 used to monitor or evaluate the clinical necessity,
 8 appropriateness, efficacy, or efficiency of health care
 9 services, procedures or settings, and includes ambu-
 10 latory review, prospective review, concurrent review,
 11 second opinions, case management, discharge plan-
 12 ning, or retrospective review.

13 “(b) WRITTEN POLICIES AND CRITERIA.—

14 “(1) WRITTEN POLICIES.—A utilization review
 15 program shall be conducted consistent with written
 16 policies and procedures that govern all aspects of the
 17 program.

18 “(2) USE OF WRITTEN CRITERIA.—

19 “(A) IN GENERAL.—Such a program shall
 20 utilize written clinical review criteria developed
 21 pursuant to the program with the input of ap-
 22 propriate physicians.

23 “(B) CONTINUING USE OF STANDARDS IN
 24 RETROSPECTIVE REVIEW.—If a health care
 25 service has been specifically pre-authorized or

1 approved for an enrollee under such a program,
 2 the program shall not, pursuant to retrospective
 3 review, revise or modify the specific standards,
 4 criteria, or procedures used for the utilization
 5 review for procedures, treatment, and services
 6 delivered to the enrollee during the same course
 7 of treatment.

8 “(C) NO ADVERSE DETERMINATION BASED
 9 ON REFUSAL TO OBSERVE SERVICE.—Such a
 10 program shall not base an adverse determina-
 11 tion on—

12 “(i) a refusal to consent to observing
 13 any health care service, or

14 “(ii) lack of reasonable access to a
 15 health care provider’s medical or treatment
 16 records, unless the program has provided
 17 reasonable notice to the enrollee.

18 “(c) CONDUCT OF PROGRAM ACTIVITIES.—

19 “(1) ADMINISTRATION BY HEALTH CARE PRO-
 20 FESSIONALS.—A utilization review program shall be
 21 administered by qualified health care professionals
 22 who shall oversee review decisions. In this sub-
 23 section, the term ‘health care professional’ means a
 24 physician or other health care practitioner licensed,

1 accredited, or certified to perform specified health
2 services consistent with State law.

3 “(2) USE OF QUALIFIED, INDEPENDENT PER-
4 SONNEL.—

5 “(A) IN GENERAL.—A utilization review
6 program shall provide for the conduct of utiliza-
7 tion review activities only through personnel
8 who are qualified and, to the extent required,
9 who have received appropriate training in the
10 conduct of such activities under the program.

11 “(B) PEER REVIEW OF ADVERSE CLINICAL
12 DETERMINATIONS.—Such a program shall pro-
13 vide that clinical peers shall evaluate the clinical
14 appropriateness of adverse clinical determina-
15 tions. In this subsection, the term ‘clinical peer’
16 means, with respect to a review, a physician or
17 other health care professional who holds a non-
18 restricted license in a State and in the same or
19 similar specialty as typically manages the medi-
20 cal condition, procedure, or treatment under re-
21 view.

22 “(C) PROHIBITION OF CONTINGENT COM-
23 PENSATION ARRANGEMENTS.—Such a program

1 shall not, with respect to utilization review ac-
 2 tivities, permit or provide compensation or any-
 3 thing of value to its employees, agents, or con-
 4 tractors in a manner that—

5 “(i) provides incentives, direct or indi-
 6 rect, for such persons to make inappropri-
 7 ate review decisions, or

8 “(ii) is based, directly or indirectly, on
 9 the quantity or type of adverse determina-
 10 tions rendered.

11 “(D) PROHIBITION OF CONFLICTS.—Such
 12 a program shall not permit a health care pro-
 13 fessional who provides health care services to an
 14 enrollee to perform utilization review activities
 15 in connection with the health care services
 16 being provided to the enrollee.

17 “(3) TOLL-FREE TELEPHONE NUMBER.—Such
 18 a program shall provide that—

19 “(A) appropriate personnel performing uti-
 20 lization review activities under the program are
 21 reasonably accessible by toll-free telephone not
 22 less than 40 hours per week during normal
 23 business hours to discuss patient care and allow
 24 response to telephone requests, and

1 “(B) the program has a telephone system
2 capable of accepting, recording, or providing in-
3 struction to incoming telephone calls during
4 other than normal business hours and to ensure
5 response to accepted or recorded messages not
6 less than one business day after the date on
7 which the call was received.

8 “(4) LIMITS ON FREQUENCY.—Such a program
9 shall not provide for the performance of utilization
10 review activities with respect to a class of services
11 furnished to an enrollee more frequently than is rea-
12 sonably required to assess whether the services
13 under review are medically necessary.

14 “(5) LIMITATION ON INFORMATION RE-
15 QUESTS.—Under such a program, information shall
16 be required to be provided by health care providers
17 only to the extent it is necessary to perform the uti-
18 lization review activity involved.

19 “(d) DEADLINE FOR DETERMINATIONS.—

20 “(1) PRIOR AUTHORIZATION SERVICES.—Ex-
21 cept as provided in paragraph (2), in the case of a
22 utilization review activity involving the prior author-
23 ization of health care items and services, the utiliza-
24 tion review program shall make a determination con-
25 cerning such authorization, and provide notice of the

1 determination to the enrollee or the enrollee's des-
2 ignee and the enrollee's health care provider by tele-
3 phone and in writing, as soon as possible in accord-
4 ance with the medical exigencies of the cases, and in
5 no event later than 3 business days after the date
6 of receipt of the necessary information respecting
7 such determination.

8 “(2) CONTINUED CARE.—In the case of a utili-
9 zation review activity involving authorization for con-
10 tinued or extended health care services, or additional
11 services for an enrollee undergoing a course of con-
12 tinued treatment prescribed by a health care pro-
13 vider, the utilization review program shall make a
14 determination concerning such authorization, and
15 provide notice of the determination to the enrollee or
16 the enrollee's designee and the enrollee's health care
17 provider by telephone and in writing, within 1 busi-
18 ness day of the date of receipt of the necessary in-
19 formation respecting such determination. Such no-
20 tice shall include, with respect to continued or ex-
21 tended health care services, the number of extended
22 services approved, the new total of approved serv-
23 ices, the date of onset of services, and the next re-
24 view date.

1 “(3) PREVIOUSLY PROVIDED SERVICES.—In the
 2 case of a utilization review activity involving retro-
 3 spective review of health care services previously pro-
 4 vided, the utilization review program shall make a
 5 determination concerning such services, and provide
 6 notice of the determination to the enrollee or the en-
 7 rollee’s designee and the enrollee’s health care pro-
 8 vider by telephone and in writing, within 30 days of
 9 the date of receipt of the necessary information re-
 10 specting such determination.

11 “(4) REFERENCE TO SPECIAL RULES FOR
 12 EMERGENCY SERVICES, MAINTENANCE CARE, AND
 13 POST-STABILIZATION CARE.—For waiver of prior au-
 14 thorization requirements in certain cases involving
 15 emergency services and maintenance care and post-
 16 stabilization care, see sections 2771(a)(1)(A) and
 17 2771(a)(2)(A), respectively.

18 “(e) NOTICE OF ADVERSE DETERMINATIONS.—

19 “(1) IN GENERAL.—Notice of an adverse deter-
 20 mination under a utilization review program (includ-
 21 ing as a result of a reconsideration under subsection
 22 (f)) shall be in writing and shall include—

23 “(A) the reasons for the determination (in-
 24 cluding the clinical rationale);

1 “(B) instructions on how to initiate an ap-
 2 peal under section 2785; and

3 “(C) notice of the availability, upon re-
 4 quest of the enrollee (or the enrollee’s designee)
 5 of the clinical review criteria relied upon to
 6 make such determination.

7 “(2) SPECIFICATION OF ANY ADDITIONAL IN-
 8 FORMATION.—Such a notice shall also specify what
 9 (if any) additional necessary information must be
 10 provided to, or obtained by, person making the de-
 11 termination in order to make a decision on such an
 12 appeal.

13 “(f) RECONSIDERATION.—

14 “(1) AT REQUEST OF PROVIDER.—In the event
 15 that a utilization review program provides for an ad-
 16 verse determination without attempting to discuss
 17 such matter with the enrollee’s health care provider
 18 who specifically recommended the health care serv-
 19 ice, procedure, or treatment under review, such
 20 health care provider shall have the opportunity to re-
 21 quest a reconsideration of the adverse determination
 22 under this subsection.

23 “(2) TIMING AND CONDUCT.—Except in cases
 24 of retrospective reviews, such reconsideration shall
 25 occur as soon as possible in accordance with the

1 medical exigencies of the cases, and in no event later
 2 than 1 business day after the date of receipt of the
 3 request and shall be conducted by the enrollee’s
 4 health care provider and the health care professional
 5 making the initial determination or a designated
 6 qualified health care professional if the original pro-
 7 fessional cannot be available.

8 “(3) NOTICE.—In the event that the adverse
 9 determination is upheld after reconsideration, the
 10 utilization review program shall provide notice as re-
 11 quired under subsection (e).

12 “(4) CONSTRUCTION.—Nothing in this sub-
 13 section shall preclude the enrollee from initiating an
 14 appeal from an adverse determination under section
 15 2785.

16 “SUBPART 3—PATIENT INFORMATION

17 **“SEC. 2782. PATIENT INFORMATION.**

18 “(a) DISCLOSURE REQUIREMENT.—A health insur-
 19 ance issuer in connection with the provision of health in-
 20 surance coverage shall submit to the applicable State au-
 21 thority, provide to enrollees (and prospective enrollees),
 22 and make available to the public, in writing the informa-
 23 tion described in subsection (b).

24 “(b) INFORMATION.—The information described in
 25 this subsection includes the following:

1 “(1) DESCRIPTION OF COVERAGE.—A descrip-
 2 tion of coverage provisions, including health care
 3 benefits, benefit limits, coverage exclusions, coverage
 4 of emergency care, and the definition of medical ne-
 5 cessity used in determining whether benefits will be
 6 covered.

7 “(2) ENROLLEE FINANCIAL RESPONSIBILITY.—
 8 An explanation of an enrollee’s financial responsibil-
 9 ity for payment of premiums, coinsurance, copay-
 10 ments, deductibles, and any other charges, including
 11 limits on such responsibility and responsibility for
 12 health care services that are provided by nonpartici-
 13 pating providers or are furnished without meeting
 14 applicable utilization review requirements.

15 “(3) INFORMATION ON PROVIDERS.—A descrip-
 16 tion—

17 “(A) of procedures for enrollees to select,
 18 access, and change participating primary and
 19 specialty providers,

20 “(B) of the rights and procedures for ob-
 21 taining referrals (including standing referrals)
 22 to participating and nonparticipating providers,
 23 and

1 “(C) in the case of each participating pro-
2 vider, of the name, address, and telephone num-
3 ber of the provider, the credentials of the pro-
4 vider, and the provider’s availability to accept
5 new patients.

6 “(4) UTILIZATION REVIEW ACTIVITIES.—A de-
7 scription of procedures used and requirements (in-
8 cluding circumstances, time frames, and rights to re-
9 consideration and appeal) under any utilization re-
10 view program under section 2781 or any drug utili-
11 zation program under section 2780, as well as a
12 summary of the minimum uniform data collected
13 under section 2778(a)(1).

14 “(5) GRIEVANCE PROCEDURES.—Information
15 on the grievance procedures under sections 2784 and
16 2785, including information describing—

17 “(A) the grievance procedures used by the
18 issuer to process and resolve disputes between
19 the issuer and an enrollee (including method for
20 filing grievances and the time frames and cir-
21 cumstances for acting on grievances);

22 “(B) written complaints and appeals, by
23 type of complaint or appeal, received by the is-
24 suer relating to its coverage; and

1 “(C) the disposition of such complaints
2 and appeals.

3 “(6) PAYMENT METHODOLOGY.—A description
4 of the types of methodologies the issuer uses to re-
5 imburse different classes of providers and, as speci-
6 fied by the Secretary, the financial arrangements or
7 contractual provisions with providers.

8 “(7) INFORMATION ON ISSUER.—Notice of ap-
9 propriate mailing addresses and telephone numbers
10 to be used by enrollees in seeking information or au-
11 thorization for treatment.

12 “(8) ASSURING COMMUNICATIONS WITH EN-
13 ROLLEES.—A description of how the issuer address-
14 es the needs of non-English-speaking enrollees and
15 others with special communications needs, including
16 the provision of information described in this sub-
17 section to such enrollees.

18 “(c) FORM OF DISCLOSURE.—

19 “(1) UNIFORMITY.—Information required to be
20 disclosed under this section shall be provided in ac-
21 cordance with uniform, national reporting standards
22 specified by the Secretary, after consultation with
23 applicable State authorities, so that prospective en-
24 rollees may compare the attributes of different issu-
25 ers and coverage offered within an area.

1 “(2) INFORMATION INTO HANDBOOK.—Nothing
 2 in this section shall be construed as preventing an
 3 issuer from making the information under sub-
 4 section (b) available to enrollees through an enrollee
 5 handbook or similar publication.

6 “(3) UPDATING.—The information on partici-
 7 pating providers described in subsection (a)(3)(C)
 8 shall be updated not less frequently than monthly.
 9 Nothing in this section shall prevent an issuer from
 10 changing or updating other information made avail-
 11 able under this section.

12 “(4) CONSTRUCTION.—Nothing in subsection
 13 (a)(6) shall be construed as requiring disclosure of
 14 individual contracts or financial arrangements be-
 15 tween an issuer and any provider. Nothing in this
 16 subsection shall be construed as preventing the in-
 17 formation described in subsection (a)(3)(C) from
 18 being provided in a separate document.

19 **“SEC. 2783. PROTECTION OF PATIENT CONFIDENTIALITY.**

20 “A health insurance issuer that offers health insur-
 21 ance coverage shall establish appropriate policies and pro-
 22 cedures to ensure that all applicable State and Federal
 23 laws to protect the confidentiality of individually identifi-
 24 able medical information are followed.

1 “SUBPART 4—GRIEVANCE PROCEDURES

2 **“SEC. 2784. ESTABLISHMENT OF COMPLAINT AND APPEALS**

3 **PROCESS.**

4 “(a) ESTABLISHMENT OF SYSTEM.—A health insur-
 5 ance issuer in connection with the provision of health in-
 6 surance coverage shall establish and maintain a system to
 7 provide for the presentation and resolution of complaints
 8 and appeals brought by enrollees, designees of enrollees,
 9 or by health care providers acting on behalf of an enrollee
 10 and with the enrollee’s consent, regarding any aspect of
 11 the issuer’s health care services, including complaints re-
 12 garding quality of care, choice and accessibility of provid-
 13 ers, network adequacy, and compliance with the require-
 14 ments of this part.

15 “(b) COMPONENTS OF SYSTEM.—Such system shall
 16 include the following components (which shall be consist-
 17 ent with applicable requirements of section 2785):

18 “(1) Written notification to all enrollees and
 19 providers of the telephone numbers and business ad-
 20 dresses of the issuer employees responsible for reso-
 21 lution of complaints and appeals.

22 “(2) A system to record and document, over a
 23 period of at least 3 years, all complaints and appeals
 24 made and their status.

1 “(3) The availability of an enrollee services rep-
2 resentative to assist enrollees, as requested, with
3 complaint and appeal procedures.

4 “(4) Establishment of a specified deadline (not
5 to exceed 30 days after the date of receipt of a com-
6 plaint or appeal) for the issuer to respond to com-
7 plaints or appeals.

8 “(5) A process describing how complaints and
9 appeals are processed and resolved.

10 “(6) Procedures for follow-up action, including
11 the methods to inform the complainant or appellant
12 of the resolution of a complaint or appeal.

13 “(7) Notification to the continuous quality im-
14 provement program under section 2777(a) of all
15 complaints and appeals relating to quality of care.

16 “(c) NO REPRISAL FOR EXERCISE OF RIGHTS.—A
17 health insurance issuer shall not take any action with re-
18 spect to an enrollee or a health care provider that is in-
19 tended to penalize the enrollee, a designee of the enrollee,
20 or the health care provider for discussing or exercising any
21 rights provided under this part (including the filing of a
22 complaint or appeal pursuant to this section).

1 **“SEC. 2785. PROVISIONS RELATING TO APPEALS OF UTILI-**
2 **ZATION REVIEW DETERMINATIONS AND SIMI-**
3 **LAR DETERMINATIONS.**

4 “(a) RIGHT OF APPEAL.—

5 “(1) IN GENERAL.—An enrollee in health insur-
6 ance coverage offered by a health insurance issuer,
7 and any provider acting on behalf of the enrollee
8 with the enrollee’s consent, may appeal any appeal-
9 able decision (as defined in paragraph (2)) under the
10 procedures described in this section and (to the ex-
11 tent applicable) section 2784. Such enrollees and
12 providers shall be provided with a written expla-
13 nation of the appeal process upon the conclusion of
14 each stage in the appeal process and as provided in
15 section 2782(a)(5)

16 “(2) APPEALABLE DECISION DEFINED.—In this
17 section, the term ‘appealable decision’ means any of
18 the following:

19 “(A) An adverse determination under a
20 utilization review program under section 2781.

21 “(B) Denial of access to specialty and
22 other care under section 2772.

23 “(C) Denial of continuation of care under
24 section 2773.

25 “(D) Denial of a choice of provider under
26 section 2774.

1 “(E) Denial of coverage of routine patient
2 costs in connection with an approval clinical
3 trial under section 2775.

4 “(F) Denial of access to needed drugs
5 under section 2776(3).

6 “(G) The imposition of a limitation that is
7 prohibited under section 2789.

8 “(H) Denial of payment for a benefit,

9 “(b) INFORMAL INTERNAL APPEAL PROCESS (STAGE
10 1) .—

11 “(1) IN GENERAL.—Each issuer shall establish
12 and maintain an informal internal appeal process
13 (an appeal under such process in this section re-
14 ferred to as a ‘stage 1 appeal’) under which any en-
15 rollee or any provider acting on behalf of an enrollee
16 with the enrollee’s consent, who is dissatisfied with
17 any appealable decision has the opportunity to dis-
18 cuss and appeal that decision with the medical direc-
19 tor of the issuer or the health care professional who
20 made the decision.

21 “(2) TIMING.—All appeals under this para-
22 graph shall be concluded as soon as possible in ac-
23 cordance with the medical exigencies of the cases,
24 and in no event later than 72 hours in the case of

1 appeals from decisions regarding urgent care and 5
2 days in the case of all other appeals.

3 “(3) FURTHER REVIEW.—If the appeal is not
4 resolved to the satisfaction of the enrollee at this
5 level by the deadline under paragraph (2), the issuer
6 shall provide the enrollee and provider (if any) with
7 a written explanation of the decision and the right
8 to proceed to a stage 2 appeal under subsection (c).
9 “(c) FORMAL INTERNAL APPEAL PROCESS (STAGE
10 2).—

11 “(1) IN GENERAL.—Each issuer shall establish
12 and maintain a formal internal appeal process (an
13 appeal under such process in this section referred to
14 as a ‘stage 2 appeal’) under which any enrollee or
15 provider acting on behalf of an enrollee with the en-
16 rollee’s consent, who is dissatisfied with the results
17 of a stage 1 appeal has the opportunity to appeal
18 the results before a panel that includes a physician
19 or other health care professional (or professionals)
20 selected by the issuer who have not been involved in
21 the appealable decision at issue in the appeal.

22 “(2) AVAILABILITY OF CLINICAL PEERS.—The
23 panel under subparagraph (A) shall have available
24 either clinical peers (as defined in section
25 2781(c)(2)(B)) who have not been involved in the

1 appealable decision at issue in the appeal or others
2 who are mutually agreed upon by the parties. If re-
3 quested by the enrollee or enrollee’s provider with
4 the enrollee’s consent, such a peer shall participate
5 in the panel’s review of the case.

6 “(3) TIMELY ACKNOWLEDGMENT.—The issuer
7 shall acknowledge the enrollee or provider involved
8 of the receipt of a stage 2 appeals upon receipt of
9 the appeal.

10 “(4) DEADLINE.—

11 “(A) IN GENERAL.—The issuer shall con-
12 clude each stage 2 appeal as soon as possible
13 after the date of the receipt of the appeal in ac-
14 cordance with medical exigencies of the case in-
15 volved, but in no event later than 72 hours in
16 the case of appeals from decisions regarding ur-
17 gent care and (except as provided in subpara-
18 graph (B)) 20 business days in the case of all
19 other appeals.

20 “(B) EXTENSION.—An issuer may extend
21 the deadline for an appeal that does not relate
22 to a decision regarding urgent or emergency
23 care up to an additional 20 business days where
24 it can demonstrate to the applicable State au-
25 thority reasonable cause for the delay beyond

1 its control and where it provides, within the
2 original deadline under subparagraph (A), a
3 written progress report and explanation for the
4 delay to such authority and to the enrollee and
5 provider involved.

6 “(5) NOTICE.—If an issuer denies a stage 2 ap-
7 peal, the issuer shall provide the enrollee and pro-
8 vider involved with written notification of the denial
9 and the reasons therefore, together with a written
10 notification of rights to any further appeal

11 “(d) DIRECT USE OF FURTHER APPEALS.—In the
12 event that the issuer fails to comply with any of the dead-
13 lines for completion of appeals under this section or in
14 the event that the issuer for any reason expressly waives
15 its rights to an internal review of an appeal under sub-
16 section (b) or (c), the enrollee and provider involved shall
17 be relieved of any obligation to complete the appeal stage
18 involved and may, at the enrollee’s or provider’s option,
19 proceed directly to seek further appeal through any appli-
20 cable external appeals process.

21 “(e) EXTERNAL APPEAL PROCESS IN CASE OF USE
22 OF EXPERIMENTAL TREATMENT TO SAVE LIFE OF PA-
23 TIENT.—

1 “(1) IN GENERAL.—In the case of an enrollee
2 described in paragraph (2), the health insurance is-
3 suer shall provide for an external independent review
4 process respecting the issuer’s decision not to cover
5 the experimental therapy (described in paragraph
6 (2)(B)(ii)).

7 “(2) ENROLLEE DESCRIBED.—An enrollee de-
8 scribed in this paragraph is an enrollee who meets
9 the following requirements:

10 “(A) The enrollee has a terminal condition
11 that is highly likely to cause death within 2
12 years.

13 “(B) The enrollee’s physician certifies
14 that—

15 “(i) there is no standard, medically
16 appropriate therapy for successfully treat-
17 ing such terminal condition, but

18 “(ii) based on medical and scientific
19 evidence, there is a drug, device, proce-
20 dure, or therapy (in this section referred to
21 as the ‘experimental therapy’) that is more
22 beneficial than any available standard ther-
23 apy.

1 “(C) The issuer has denied coverage of the
2 experimental therapy on the basis that it is ex-
3 perimental or investigational.

4 “(3) DESCRIPTION OF PROCESS AND DECISION.—The process under this subsection shall pro-
5 vide for a determination on a timely basis, by a
6 panel of independent, impartial physicians appointed
7 by a State authority or by an independent review or-
8 ganization certified by the State, of the medical ap-
9 propriateness of the experimental therapy. The deci-
10 sion of the panel shall be in writing and shall be ac-
11 companied by an explanation of the basis for the de-
12 cision. A decision of the panel that is favorable to
13 the enrollee may not be appealed by the issuer ex-
14 cept in the case of misrepresentation of a material
15 fact by the enrollee or a provider. A decision of the
16 panel that is not favorable to the enrollee may be
17 appealed by the enrollee.

18 “(4) ISSUER COVERING PROCESS COSTS.—Di-
19 rect costs of the process under this subsection shall
20 be borne by the issuer, and not by the enrollee.

21 “(f) OTHER INDEPENDENT OR EXTERNAL RE-
22 VIEW.—
23

1 “(1) IN GENERAL.—In the case of appealable
2 decision described in paragraph (2), the health in-
3 surance issuer shall provide for—

4 “(A) an external review process for such
5 decisions consistent with the requirements of
6 paragraph (3), or

7 “(B) an internal independent review proc-
8 ess for such decisions consistent with the re-
9 quirements of paragraph (4).

10 “(2) APPEALABLE DECISION DESCRIBED.—An
11 appealable decision described in this paragraph is
12 decision that does not involve a decision described in
13 subsection (e)(1) but involves—

14 “(A) a claim for benefits involving costs
15 over a significant threshold, or

16 “(B) assuring access to care for a serious
17 condition.

18 “(3) EXTERNAL REVIEW PROCESS.—The re-
19 quirements of this subsection for an external review
20 process are as follows:

21 “(A) The process is established under
22 State law and provides for review of decisions
23 on stage 2 appeals by an independent review or-
24 ganization certified by the State.

1 “(B) If the process provides that decisions
 2 in such process are not binding on issuers, the
 3 process must provide for public methods of dis-
 4 closing frequency of noncompliance with such
 5 decisions and for sanctioning issuers that con-
 6 sistently refuse to take appropriate actions in
 7 response to such decisions.

8 “(C) Results of all such reviews under the
 9 process are disclosed to the public, along with
 10 at least annual disclosure of information on is-
 11 suer compliance.

12 “(D) All decisions under the process shall
 13 be in writing and shall be accompanied by an
 14 explanation of the basis for the decision.

15 “(E) Direct costs of the process shall be
 16 borne by the issuer, and not by the enrollee.

17 “(F) The issuer shall provide for publica-
 18 tion at least annually of information on the
 19 numbers of appeals and decisions considered
 20 under the process.

21 “(4) INTERNAL, INDEPENDENT REVIEW PROC-
 22 ESS.—The requirements of this subsection for an in-
 23 ternal, independent review process are as follows:

24 “(A)(i) The process must provide for the
 25 participation of persons who are independent of

1 the issuer in conducting reviews and (ii) the
2 Secretary must have found (through reviews
3 conducted no less often than biannually) the
4 process to be fair and impartial.

5 “(B) If the process provides that decisions
6 in such process are not binding on issuers, the
7 process must provide for public methods of dis-
8 closing frequency of noncompliance with such
9 decisions and for sanctioning issuers that con-
10 sistently refuse to take appropriate actions in
11 response to such decisions.

12 “(C) Results of all such reviews under the
13 process are disclosed to the public, along with
14 at least annual disclosure of information on is-
15 suer compliance.

16 “(D) All decisions under the process shall
17 be in writing and shall be accompanied by an
18 explanation of the basis for the decision.

19 “(E) Direct costs of the process shall be
20 borne by the issuer, and not by the enrollee.

21 “(F) The issuer shall provide for publica-
22 tion at least annually of information on the
23 numbers of appeals and decisions considered
24 under the process.

1 The Secretary may delegate the authority under sub-
 2 paragraph (A)(ii) to applicable State authorities.

3 “(5) OVERSIGHT.—The Secretary (and applica-
 4 ble State authorities in the case of delegation of Sec-
 5 retarial authority under paragraph (4)) shall con-
 6 duct reviews not less often than biannually of the
 7 fairness and impartiality issuers who desired to use
 8 an internal, independent review process described in
 9 paragraph (4) to satisfy the requirement of para-
 10 graph (1).

11 “(6) REPORT.—The Secretary shall provide for
 12 periodic reports on the effectiveness of this sub-
 13 section in assuring fair and impartial reviews of
 14 stage 2 appeals. Such reports shall include informa-
 15 tion on the number of stage 2 appeals (and deci-
 16 sions), for each of the types of review processes de-
 17 scribed in paragraph (2), by health insurance cov-
 18 erage.

19 “(g) CONSTRUCTION.—Nothing in this part shall be
 20 construed as removing any legal rights of enrollees under
 21 State or Federal law, including the right to file judicial
 22 actions to enforce rights.

23 **“SEC. 2786. STATE HEALTH INSURANCE OMBUDSMEN.**

24 “(a) IN GENERAL.—Each State that obtains a grant
 25 under subsection (c) shall establish and maintain a Health

1 Insurance Ombudsman. Such Ombudsman may be part of
2 a independent, nonprofit entity, and shall be responsible
3 for at least the following:

4 “(1) To assist consumers in the State in choos-
5 ing among health insurance coverage.

6 “(2) To provide counseling and assistance to
7 enrollees dissatisfied with their treatment by health
8 insurance issuers in regard to such coverage and in
9 the filing of complaints and appeals regarding deter-
10 minations under such coverage.

11 “(3) To investigate instances of poor quality or
12 improper treatment of enrollees by health insurance
13 issuers in regard to such coverage and to bring such
14 instances to the attention of the applicable State au-
15 thority.

16 “(b) FEDERAL ROLE.—In the case of any State that
17 does not establish and maintain such an Ombudsman
18 under subsection (a), the Secretary shall provide for the
19 establishment and maintenance of such an official as will
20 carry out with respect to that State the functions other-
21 wise provided under subsection (a) by a Health Insurance
22 Ombudsman.

23 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated to the Secretary such
25 amounts as may be necessary to provide for grants to

1 States to establish and operate Health Insurance Ombuds-
 2 men under subsection (a) or for the operation of Ombuds-
 3 men under subsection (b).

4 “SUBPART 5—PROTECTION OF PROVIDERS AGAINST IN-
 5 TERFERENCE WITH MEDICAL COMMUNICATIONS
 6 AND IMPROPER INCENTIVE ARRANGEMENTS

7 **“SEC. 2787. PROHIBITION OF INTERFERENCE WITH CER-**
 8 **TAIN MEDICAL COMMUNICATIONS.**

9 “(a) PROHIBITION.—

10 “(1) GENERAL RULE.—The provisions of any
 11 contract or agreement, or the operation of any con-
 12 tract or agreement, between a health insurance is-
 13 suer in relation to health insurance coverage (includ-
 14 ing any partnership, association, or other organiza-
 15 tion that enters into or administers such a contract
 16 or agreement) and a health care provider (or group
 17 of health care providers) shall not prohibit or re-
 18 strict the provider from engaging in medical commu-
 19 nications with the provider’s patient.

20 “(2) NULLIFICATION.—Any contract provision
 21 or agreement described in paragraph (1) shall be
 22 null and void.

23 “(3) PROHIBITION ON PROVISIONS.—A contract
 24 or agreement described in paragraph (1) shall not
 25 include a provision that violates paragraph (1).

1 “(b) RULES OF CONSTRUCTION.—Nothing in this
2 section shall be construed—

3 “(1) to prohibit the enforcement, as part of a
4 contract or agreement to which a health care pro-
5 vider is a party, of any mutually agreed upon terms
6 and conditions, including terms and conditions re-
7 quiring a health care provider to participate in, and
8 cooperate with, all programs, policies, and proce-
9 dures developed or operated by a health insurance
10 issuer to assure, review, or improve the quality and
11 effective utilization of health care services (if such
12 utilization is according to guidelines or protocols
13 that are based on clinical or scientific evidence and
14 the professional judgment of the provider) but only
15 if the guidelines or protocols under such utilization
16 do not prohibit or restrict medical communications
17 between providers and their patients; or

18 “(2) to permit a health care provider to mis-
19 represent the scope of benefits covered under health
20 insurance coverage or to otherwise require a health
21 insurance issuer to reimburse providers for benefits
22 not covered under the coverage.

23 “(c) PROTECTION OF RELIGIOUS OR MORAL EX-
24 pression.—

1 “(1) IN GENERAL.—An health insurance issuer
2 may fully advise—

3 “(A) licensed or certified health care pro-
4 viders at the time of their employment with the
5 issuer or at any time during such employment,
6 or

7 “(B) enrollees at the time of their enroll-
8 ment for health insurance coverage with the is-
9 suer or at any time during which such enrollees
10 have such coverage,
11 of the coverage’s limitations on providing particular
12 medical services (including limitations on referrals
13 for care provided outside of the coverage) based on
14 the religious or moral convictions of the issuer.

15 “(2) HEALTH CARE PROVIDERS.—Nothing in
16 this section shall be construed to alter the rights and
17 duties of a health care provider to determine what
18 medical communications are appropriate with re-
19 spect to each patient, except as provided for in sub-
20 section (a).

21 “(d) MEDICAL COMMUNICATION DEFINED.—

22 “(1) IN GENERAL.—In this section, the term
23 ‘medical communication’ means any communication
24 made by a health care provider with a patient of the

1 health care provider (or the guardian or legal rep-
 2 resentative of such patient) with respect to—

3 “(A) the patient’s health status, medical
 4 care, or treatment options;

5 “(B) any utilization review requirements
 6 that may affect treatment options for the pa-
 7 tient; or

8 “(C) any financial incentives that may af-
 9 fect the treatment of the patient.

10 “(2) MISREPRESENTATION.—The term ‘medical
 11 communication’ does not include a communication
 12 by a health care provider with a patient of the
 13 health care provider (or the guardian or legal rep-
 14 resentative of such patient) if the communication in-
 15 volves a knowing or willful misrepresentation by
 16 such provider.

17 **“SEC. 2788. PROHIBITION AGAINST TRANSFER OF INDEM-**
 18 **NIFICATION OR IMPROPER INCENTIVE AR-**
 19 **RANGEMENTS.**

20 “(a) PROHIBITION OF TRANSFER OF INDEMNIFICA-
 21 TION.—No contract or agreement between a health insur-
 22 ance issuer (or any agent acting on behalf of such an is-
 23 suer) and a health care provider shall contain any clause

1 purporting to transfer to the health care provider by in-
 2 demnification or otherwise any liability relating to activi-
 3 ties, actions, or omissions of the issuer or agent (as op-
 4 posed to the provider).

5 “(b) PROHIBITION OF IMPROPER PHYSICIAN INCEN-
 6 TIVE PLANS.—

7 “(1) IN GENERAL.—A health insurance issuer
 8 offering health insurance coverage may not operate
 9 any physician incentive plan unless the following re-
 10 quirements are met:

11 “(A) No specific payment is made directly
 12 or indirectly by the issuer to a physician or
 13 physician group as an inducement to reduce or
 14 limit medically necessary services provided with
 15 respect to a specific individual enrolled with the
 16 issuer.

17 “(B) If the plan places a physician or phy-
 18 sician group at substantial financial risk (as de-
 19 termined by the Secretary) for services not pro-
 20 vided by the physician or physician group, the
 21 issuer—

22 “(i) provides stop-loss protection for
 23 the physician or group that is adequate

1 and appropriate, based on standards devel-
2 oped by the Secretary that take into ac-
3 count the number of physicians placed at
4 such substantial financial risk in the group
5 or under the plan and the number of indi-
6 viduals enrolled with the issuer who receive
7 services from the physician or the physi-
8 cian group, and

9 “(ii) conducts periodic surveys of both
10 individuals enrolled and individuals pre-
11 viously enrolled with the issuer to deter-
12 mine the degree of access of such individ-
13 uals to services provided by the issuer and
14 satisfaction with the quality of such serv-
15 ices.

16 “(C) The issuer provides the applicable
17 State authority (or the Secretary if such au-
18 thority is implementing this section) with de-
19 scriptive information regarding the plan, suffi-
20 cient to permit the authority (or the Secretary
21 in such case) to determine whether the plan is
22 in compliance with the requirements of this
23 paragraph.

24 “(2) PHYSICIAN INCENTIVE PLAN DEFINED.—

25 In this section, the term ‘physician incentive plan’

1 means any compensation arrangement between a
 2 health insurance issuer and a physician or physician
 3 group that may directly or indirectly have the effect
 4 of reducing or limiting services provided with respect
 5 to individuals enrolled with the issuer.

6 “(3) APPLICATION OF MEDICARE RULES.—The
 7 Secretary shall provide for the application of rules
 8 under this subsection that are substantially the same
 9 as the rules established to carry out section
 10 1876(i)(8) of the Social Security Act.

11 “SUBPART 6—PROMOTING GOOD MEDICAL PRACTICE
 12 AND PROTECTING THE DOCTOR-PATIENT RELATIONSHIP
 13 **“SEC. 2789. PROMOTING GOOD MEDICAL PRACTICE.**

14 “(a) PROHIBITING ARBITRARY LIMITATIONS OR
 15 CONDITIONS FOR THE PROVISION OF SERVICES.—A
 16 health insurance issuer, in connection with the provision
 17 of health insurance coverage, may not impose limits on
 18 the manner in which particular services are delivered if
 19 the services are medically necessary and appropriate for
 20 the treatment or diagnosis of an illness or injury to the
 21 extent that such treatment or diagnosis is otherwise a cov-
 22 ered benefit.

23 “(b) MEDICAL NECESSITY AND APPROPRIATENESS
 24 DEFINED.—In subsection (a), the term ‘medically nec-
 25 essary and appropriate’ means, with respect to a service

1 or benefit, a service or benefit determined by the treating
 2 physician participating in the health insurance coverage
 3 after consultation with the enrollee, to be required, accord-
 4 ingly to generally accepted principles of good medical prac-
 5 tice, for the diagnosis or direct care and treatment of an
 6 illness or injury of the enrollee.

7 “(c) CONSTRUCTION.—Subsection (a) shall not be
 8 construed as requiring coverage of particular services the
 9 coverage of which is otherwise not covered under the terms
 10 of the coverage.”.

11 (b) APPLICATION TO GROUP HEALTH INSURANCE
 12 COVERAGE.—

13 (1) Subpart 2 of part A of title XXVII of the
 14 Public Health Service Act is amended by adding at
 15 the end the following new section:

16 **“SEC. 2706. PATIENT PROTECTION STANDARDS.**

17 “(a) IN GENERAL.—Each health insurance issuer
 18 shall comply with patient protection requirements under
 19 part C with respect to group health insurance coverage
 20 it offers.

21 “(b) ASSURING COORDINATION.—The Secretary of
 22 Health and Human Services and the Secretary of Labor
 23 shall ensure, through the execution of an interagency
 24 memorandum of understanding between such Secretaries,
 25 that—

1 “(1) regulations, rulings, and interpretations is-
 2 sued by such Secretaries relating to the same matter
 3 over which such Secretaries have responsibility
 4 under part C (and this section) and section 713 of
 5 the Employee Retirement Income Security Act of
 6 1974 are administered so as to have the same effect
 7 at all times; and

8 “(2) coordination of policies relating to enforce-
 9 ing the same requirements through such Secretaries
 10 in order to have a coordinated enforcement strategy
 11 that avoids duplication of enforcement efforts and
 12 assigns priorities in enforcement.”.

13 (2) Section 2792 of such Act (42 U.S.C.
 14 300gg-92) is amended by inserting “and section
 15 2706(b)” after “of 1996”.

16 (c) APPLICATION TO INDIVIDUAL HEALTH INSUR-
 17 ANCE COVERAGE.—Part B of title XXVII of the Public
 18 Health Service Act is amended by inserting after section
 19 2751 the following new section:

20 **“SEC. 2752. PATIENT PROTECTION STANDARDS.**

21 “Each health insurance issuer shall comply with pa-
 22 tient protection requirements under part C with respect
 23 to individual health insurance coverage it offers.”.

24 (d) MODIFICATION OF PREEMPTION STANDARDS.—

1 (1) GROUP HEALTH INSURANCE COVERAGE.—

2 Section 2723 of such Act (42 U.S.C. 300gg–23) is
3 amended—

4 (A) in subsection (a)(1), by striking “sub-
5 section (b)” and inserting “subsections (b) and
6 (c)”;

7 (B) by redesignating subsections (c) and
8 (d) as subsections (d) and (e), respectively; and

9 (C) by inserting after subsection (b) the
10 following new subsection:

11 “(c) SPECIAL RULES IN CASE OF PATIENT PROTEC-
12 TION REQUIREMENTS.—Subject to subsection (a)(2), the
13 provisions of section 2706 and part C (other than section
14 2771), and part D insofar as it applies to section 2706
15 or part C, shall not prevent a State from establishing re-
16 quirements relating to the subject matter of such provi-
17 sions (other than section 2771) so long as such require-
18 ments are at least as stringent on health insurance issuers
19 as the requirements imposed under such provisions. Sub-
20 section (a) shall apply to the provisions of section 2771
21 (and section 2706 insofar as it relates to such section).”.

22 (2) INDIVIDUAL HEALTH INSURANCE COV-
23 ERAGE.—Section 2762 of such Act (42 U.S.C.
24 300gg–62), as added by section 605(b)(3)(B) of
25 Public Law 104–204, is amended—

1 (A) in subsection (a), by striking “sub-
 2 section (b), nothing in this part” and inserting
 3 “subsections (b) and (c)”, and

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

6 “(c) SPECIAL RULES IN CASE OF MANAGED CARE
 7 REQUIREMENTS.—Subject to subsection (b), the provi-
 8 sions of section 2752 and part C (other than section
 9 2771), and part D insofar as it applies to section 2752
 10 or part C, shall not prevent a State from establishing re-
 11 quirements relating to the subject matter of such provi-
 12 sions so long as such requirements are at least as strin-
 13 gent on health insurance issuers as the requirements im-
 14 posed under such section. Subsection (a) shall apply to
 15 the provisions of section 2771 (and section 2752 insofar
 16 as it relates to such section).”.

17 (e) ADDITIONAL CONFORMING AMENDMENTS.—

18 (1) Section 2723(a)(1) of such Act (42 U.S.C.
 19 300gg-23(a)(1)) is amended by striking “part C”
 20 and inserting “parts C and D”.

21 (2) Section 2762(b)(1) of such Act (42 U.S.C.
 22 300gg-62(b)(1)) is amended by striking “part C”
 23 and inserting “part D”.

24 (f) EFFECTIVE DATES.—(1)(A) Subject to subpara-
 25 graph (B), the amendments made by subsections (a), (b),

1 (d)(1), and (e) shall apply with respect to group health
2 insurance coverage for group health plan years beginning
3 on or after July 1, 1998 (in this subsection referred to
4 as the “general effective date”) and also shall apply to
5 portions of plan years occurring on and after January 1,
6 1999.

7 (B) In the case of group health insurance coverage
8 provided pursuant to a group health plan maintained pur-
9 suant to 1 or more collective bargaining agreements be-
10 tween employee representatives and 1 or more employers
11 ratified before the date of enactment of this Act, the
12 amendments made by subsections (a), (b), (d)(1), and (e)
13 shall not apply to plan years beginning before the later
14 of—

15 (i) the date on which the last collective bargain-
16 ing agreements relating to the plan terminates (de-
17 termined without regard to any extension thereof
18 agreed to after the date of enactment of this Act),
19 or

20 (ii) the general effective date.

21 For purposes of clause (i), any plan amendment made pur-
22 suant to a collective bargaining agreement relating to the
23 plan which amends the plan solely to conform to any re-
24 quirement added by subsection (a) or (b) shall not be

1 treated as a termination of such collective bargaining
2 agreement.

3 (2) The amendments made by subsections (a), (c),
4 (d)(2), and (e) shall apply with respect to individual health
5 insurance coverage offered, sold, issued, renewed, in effect,
6 or operated in the individual market on or after the gen-
7 eral effective date.

8 **SEC. 3. AMENDMENTS TO THE EMPLOYEE RETIREMENT IN-**
9 **COME SECURITY ACT OF 1974.**

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

14 **“SEC. 713. PATIENT PROTECTION STANDARDS.**

15 “(a) IN GENERAL.—Subject to subsection (b), a
16 group health plan (and a health insurance issuer offering
17 group health insurance coverage in connection with such
18 a plan) shall comply with the requirements of part C
19 (other than section 2786) of title XXVII of the Public
20 Health Service Act.

21 “(b) APPLICATION.—In applying subsection (a)
22 under this part, any reference in such subpart C—

23 “(1) to a health insurance issuer and health in-
24 surance coverage offered by such an issuer is

1 deemed to include a reference to a group health plan
2 and coverage under such plan, respectively;

3 “(2) to the Secretary is deemed a reference to
4 the Secretary of Labor;

5 “(3) to an applicable State authority is deemed
6 a reference to the Secretary of Labor; and

7 “(4) to an enrollee with respect to health insur-
8 ance coverage is deemed to include a reference to a
9 participant or beneficiary with respect to a group
10 health plan.

11 “(c) GROUP HEALTH PLAN OMBUDSMAN.—With re-
12 spect to group health plans that provide benefits other
13 than through health insurance coverage, the Secretary
14 shall provide for the establishment and maintenance of
15 such a Federal Group Health Plan Ombudsman that will
16 carry out with respect to such plans the functions de-
17 scribed in section 2786(a) of the Public Health Service
18 Act with respect to health insurance issuers that offer
19 group health insurance coverage.

20 “(d) ASSURING COORDINATION.—The Secretary of
21 Health and Human Services and the Secretary of Labor
22 shall ensure, through the execution of an interagency
23 memorandum of understanding between such Secretaries,
24 that—

1 “(1) regulations, rulings, and interpretations is-
 2 sued by such Secretaries relating to the same matter
 3 over which such Secretaries have responsibility
 4 under such part C (and section 2706 of the Public
 5 Health Service Act) and this section are adminis-
 6 tered so as to have the same effect at all times; and

7 “(2) coordination of policies relating to enforce-
 8 ing the same requirements through such Secretaries
 9 in order to have a coordinated enforcement strategy
 10 that avoids duplication of enforcement efforts and
 11 assigns priorities in enforcement.”.

12 (b) MODIFICATION OF PREEMPTION STANDARDS.—
 13 Section 731 of such Act (42 U.S.C. 1191) is amended—

14 (1) in subsection (a)(1), by striking “subsection
 15 (b)” and inserting “subsections (b) and (c)”;

16 (2) by redesignating subsections (c) and (d) as
 17 subsections (d) and (e), respectively; and

18 (3) by inserting after subsection (b) the follow-
 19 ing new subsection:

20 “(c) SPECIAL RULES IN CASE OF PATIENT PROTEC-
 21 TION REQUIREMENTS.—Subject to subsection (a)(2), the
 22 provisions of section 713 and part C of title XXVII of
 23 the Public Health Service Act (other than section 2771
 24 of such Act), and subpart C insofar as it applies to section

1 713 or such part, shall not prevent a State from establish-
 2 ing requirements relating to the subject matter of such
 3 provisions (other than section 2771 of such Act) so long
 4 as such requirements are at least as stringent on health
 5 insurance issuers as the requirements imposed under such
 6 provisions. Subsection (a) shall apply to the provisions of
 7 section 2771 of such Act (and section 713 of this Act inso-
 8 far as it relates to such section).”.

9 (c) CONFORMING AMENDMENTS.—(1) Section 732(a)
 10 of such Act (29 U.S.C. 1185(a)) is amended by striking
 11 “section 711” and inserting “sections 711 and 713”.

12 (2) The table of contents in section 1 of such Act
 13 is amended by inserting after the item relating to section
 14 712 the following new item:

“Sec. 713. Patient protection standards.”.

15 (3) Section 734 of such Act (29 U.S.C. 1187) is
 16 amended by inserting “and section 713(d)” after “of
 17 1996”.

18 (d) EFFECTIVE DATE.—(1) Subject to paragraph
 19 (2), the amendments made by this section shall apply with
 20 respect to group health plans for plan years beginning on
 21 or after July 1, 1998 (in this subsection referred to as
 22 the “general effective date”) and also shall apply to por-
 23 tions of plan years occurring on and after January 1,
 24 1999.

1 (2) In the case of a group health plan maintained
2 pursuant to 1 or more collective bargaining agreements
3 between employee representatives and 1 or more employ-
4 ers ratified before the date of enactment of this Act, the
5 amendments made by this section shall not apply to plan
6 years beginning before the later of—

7 (A) the date on which the last collective bar-
8 gaining agreements relating to the plan terminates
9 (determined without regard to any extension thereof
10 agreed to after the date of enactment of this Act),
11 or

12 (B) the general effective date.

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

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