

105TH CONGRESS
1ST SESSION

H. R. 820

To amend title XXVII of the Public Health Service Act to establish standards for protection of consumers in managed care plans and other health insurance coverage.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 1997

Mr. DINGELL introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend title XXVII of the Public Health Service Act to establish standards for protection of consumers in managed care plans and other health insurance coverage.

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.

“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.

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

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

3 “PART C—PATIENT PROTECTION STANDARDS

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

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

11 “(b) ADDITIONAL DEFINITIONS.—For purposes of
12 this part:

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

20 “(2) PARTICIPATING PHYSICIAN OR PRO-
21 VIDER.—The term ‘participating physician or pro-
22 vider’ means, with respect to health care items and
23 services furnished to an enrollee under health insur-
24 ance coverage, a physician or provider that furnishes
25 such items and services under a contract or other

1 arrangement with the health insurance issuer offer-
2 ing such coverage.

3 “SUBPART 1—ACCESS TO CARE

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

5 “(a) PROHIBITION OF CERTAIN RESTRICTIONS ON
6 COVERAGE OF EMERGENCY SERVICES.

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

12 “(A) without the need for any prior au-
13 thorization determination,

14 “(B) subject to paragraph (3), whether or
15 not the physician or provider furnishing such
16 services is a participating physician or provider
17 with respect to such services, and

18 “(C) subject to paragraph (3), without re-
19 gard to any other term or condition of such cov-
20 erage (other than an exclusion of benefits, or an
21 affiliation or waiting period, permitted under
22 section 2701).

23 “(2) EMERGENCY SERVICES; EMERGENCY MEDI-
24 CAL CONDITION.—For purposes of this section—

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

10 “(i) placing the health of the individ-
11 ual (or, with respect to a pregnant woman,
12 the health of the woman or her unborn
13 child) in serious jeopardy,

14 “(ii) serious impairment to bodily
15 functions, or

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

18 “(B) EMERGENCY SERVICES.—The term
19 ‘emergency services’ means—

20 “(i) a medical screening examination
21 (as required under section 1867 of the So-
22 cial Security Act) that is within the capa-
23 bility of the emergency department of a

1 hospital, including ancillary services rou-
2 tinely available to the emergency depart-
3 ment, to evaluate an emergency medical
4 condition (as defined in subparagraph
5 (A)), and

6 “(ii) within the capabilities of the
7 staff and facilities available at the hospital,
8 such further medical examination and
9 treatment as are required under section
10 1867 of the Social Security Act to stabilize
11 the patient.

12 “(C) TRAUMA AND BURN CENTERS.—The
13 provisions of clause (ii) of subparagraph (B)
14 apply to a trauma or burn center, in a hospital,
15 that—

16 “(i) is designated by the State, a re-
17 gional authority of the State, or by the
18 designee of the State, or

19 “(ii) is in a State that has not made
20 such designations and meets medically rec-
21 ognized national standards.

22 “(3) APPLICATION OF NETWORK RESTRICTION
23 PERMITTED IN CERTAIN CASES.—

24 “(A) IN GENERAL.—Except as provided in
25 subparagraph (B), if a health insurance issuer

1 in relation to health insurance coverage denies,
2 limits, or otherwise differentiates in coverage or
3 payment for benefits other than emergency
4 services on the basis that the physician or pro-
5 vider of such services is a nonparticipating phy-
6 sician or provider, the issuer may deny, limit, or
7 differentiate in coverage or payment for emer-
8 gency services on such basis.

9 “(B) NETWORK RESTRICTIONS NOT PER-
10 MITTED IN CERTAIN EXCEPTIONAL CASES.—
11 The denial or limitation of, or differentiation in,
12 coverage or payment of benefits for emergency
13 services under subparagraph (A) shall not apply
14 in the following cases:

15 “(i) CIRCUMSTANCES BEYOND CON-
16 TROL OF ENROLLEE.—The enrollee is un-
17 able to go to a participating hospital for
18 such services due to circumstances beyond
19 the control of the enrollee (as determined
20 consistent with guidelines and subpara-
21 graph (C)).

22 “(ii) LIKELIHOOD OF AN ADVERSE
23 HEALTH CONSEQUENCE BASED ON
24 LAYPERSON’S JUDGMENT.—A prudent
25 layperson possessing an average knowledge

1 of health and medicine could reasonably
2 believe that, under the circumstances and
3 consistent with guidelines, the time re-
4 quired to go to a participating hospital for
5 such services could result in any of the ad-
6 verse health consequences described in a
7 clause of subsection (a)(2)(A).

8 “(iii) PHYSICIAN REFERRAL.—A par-
9 ticipating physician or other person au-
10 thorized by the plan refers the enrollee to
11 an emergency department of a hospital and
12 does not specify an emergency department
13 of a hospital that is a participating hos-
14 pital with respect to such services.

15 “(C) APPLICATION OF ‘BEYOND CONTROL’
16 STANDARDS.—For purposes of applying sub-
17 paragraph (B)(i), receipt of emergency services
18 from a nonparticipating hospital shall be treat-
19 ed under the guidelines as being ‘due to cir-
20 cumstances beyond the control of the enrollee’
21 if any of the following conditions are met:

22 “(i) UNCONSCIOUS.—The enrollee was
23 unconscious or in an otherwise altered
24 mental state at the time of initiation of the
25 services.

1 “(ii) AMBULANCE DELIVERY.—The
2 enrollee was transported by an ambulance
3 or other emergency vehicle directed by a
4 person other than the enrollee to the non-
5 participating hospital in which the services
6 were provided.

7 “(iii) NATURAL DISASTER.—A natural
8 disaster or civil disturbance prevented the
9 enrollee from presenting to a participating
10 hospital for the provision of such services.

11 “(iv) NO GOOD FAITH EFFORT TO IN-
12 FORM OF CHANGE IN PARTICIPATION DUR-
13 ING A CONTRACT YEAR.—The status of the
14 hospital changed from a participating hos-
15 pital to a nonparticipating hospital with re-
16 spect to emergency services during a con-
17 tract year and the plan or issuer failed to
18 make a good faith effort to notify the en-
19 rollee involved of such change.

20 “(v) OTHER CONDITIONS.—There
21 were other factors (such as those identified
22 in guidelines) that prevented the enrollee
23 from controlling selection of the hospital in
24 which the services were provided.

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

3 “(1) IN GENERAL.—In the case of an enrollee
4 who is covered under health insurance coverage is-
5 sued by a health insurance issuer and who has re-
6 ceived emergency services pursuant to a screening
7 evaluation conducted (or supervised) by a treating
8 physician at a hospital that is a nonparticipating
9 provider with respect to emergency services, if—

10 “(A) pursuant to such evaluation, the phy-
11 sician identifies post-stabilization care (as de-
12 fined in paragraph (3)(B)) that is required by
13 the enrollee,

14 “(B) the coverage provides benefits with
15 respect to the care so identified and the cov-
16 erage requires (but for this subsection) an af-
17 firmative prior authorization determination as a
18 condition of coverage of such care, and

19 “(C) the treating physician (or another in-
20 dividual acting on behalf of such physician) ini-
21 tiates, not later than 30 minutes after the time
22 the treating physician determines that the con-
23 dition of the enrollee is stabilized, a good faith
24 effort to contact a physician or other person au-
25 thorized by the issuer (by telephone or other

1 means) to obtain an affirmative prior authoriza-
2 tion determination with respect to the care,
3 then, without regard to terms and conditions speci-
4 fied in paragraph (2) the issuer shall cover mainte-
5 nance care (as defined in paragraph (3)(A)) fur-
6 nished to the enrollee during the period specified in
7 paragraph (4) and shall cover post-stabilization care
8 furnished to the enrollee during the period beginning
9 under paragraph (5) and ending under paragraph
10 (6).

11 “(2) TERMS AND CONDITIONS WAIVED.—The
12 terms and conditions (of coverage) described in this
13 paragraph that are waived under paragraph (1) are
14 as follows:

15 “(A) The need for any prior authorization
16 determination.

17 “(B) Any limitation on coverage based on
18 whether or not the physician or provider fur-
19 nishing the care is a participating physician or
20 provider with respect to such care.

21 “(C) Any other term or condition of the
22 coverage (other than an exclusion of benefits, or
23 an affiliation or waiting period, permitted under

1 section 2701 and other than a requirement re-
2 lating to medical necessity for coverage of bene-
3 fits).

4 “(3) MAINTENANCE CARE AND POST-STABILIZATION CARE DEFINED.—In this subsection:
5

6 “(A) MAINTENANCE CARE.—The term
7 ‘maintenance care’ means, with respect to an
8 individual who is stabilized after provision of
9 emergency services, medically necessary items
10 and services (other than emergency services)
11 that are required by the individual to ensure
12 that the individual remains stabilized during
13 the period described in paragraph (4).

14 “(B) POST-STABILIZATION CARE.—The
15 term ‘post-stabilization care’ means, with re-
16 spect to an individual who is determined to be
17 stable pursuant to a medical screening examina-
18 tion or who is stabilized after provision of emer-
19 gency services, medically necessary items and
20 services (other than emergency services and
21 other than maintenance care) that are required
22 by the individual.

23 “(4) PERIOD OF REQUIRED COVERAGE OF
24 MAINTENANCE CARE.—The period of required cov-
25 erage of maintenance care of an individual under

1 this subsection begins at the time of the request (or
2 the initiation of the good faith effort to make the re-
3 quest) under paragraph (1)(C) and ends when—

4 “(A) the individual is discharged from the
5 hospital;

6 “(B) a physician (designated by the issuer
7 involved) and with privileges at the hospital in-
8 volved arrives at the emergency department of
9 the hospital and assumes responsibility with re-
10 spect to the treatment of the individual; or

11 “(C) the treating physician and the issuer
12 agree to another arrangement with respect to
13 the care of the individual.

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

16 “(A) WHEN TREATING PHYSICIAN UNABLE
17 TO COMMUNICATE REQUEST.—If the treating
18 physician or other individual makes the good
19 faith effort to request authorization under para-
20 graph (1)(C) but is unable to communicate the
21 request directly with an authorized person re-
22 ferred to in such paragraph within 30 minutes
23 after the time of initiating such effort, then
24 post-stabilization care is required to be covered

1 under this subsection beginning at the end of
2 such 30-minute period.

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

5 “(i) IN GENERAL.—If the treating
6 physician or other individual under para-
7 graph (1)(C) is able to communicate the
8 request within the 30-minute period de-
9 scribed in subparagraph (A), the post-sta-
10 bilization care requested is required to be
11 covered under this subsection beginning 30
12 minutes after the time when the issuer re-
13 ceives the request unless a person author-
14 ized by the plan or issuer involved commu-
15 nicates (or makes a good faith effort to
16 communicate) a denial of the request for
17 the prior authorization determination with-
18 in 30 minutes of the time when the issuer
19 receives the request and the treating physi-
20 cian does not request under clause (ii) to
21 communicate directly with an authorized
22 physician concerning the denial.

23 “(ii) REQUEST FOR DIRECT PHYSI-
24 CIAN-TO-PHYSICIAN COMMUNICATION CON-
25 CERNING DENIAL.—If a denial of a request

1 is communicated under clause (i), the
2 treating physician may request to commu-
3 nicate respecting the denial directly with a
4 physician who is authorized by the issuer
5 to deny or affirm such a denial.

6 “(C) WHEN NO TIMELY RESPONSE TO RE-
7 QUEST FOR PHYSICIAN-TO-PHYSICIAN COMMU-
8 NICATION.—If a request for physician-to-physi-
9 cian communication is made under subpara-
10 graph (B)(ii), the post-stabilization care re-
11 quested is required to be covered under this
12 subsection beginning 30 minutes after the time
13 when the issuer receives the request from a
14 treating physician unless a physician, who is
15 authorized by the issuer to reverse or affirm the
16 initial denial of the care, communicates (or
17 makes a good faith effort to communicate) di-
18 rectly with the treating physician within such
19 30-minute period.

20 “(D) DISAGREEMENTS OVER POST-STA-
21 BILIZATION CARE.—If, after a direct physician-
22 to-physician communication under subpara-
23 graph (C), the denial of the request for the
24 post-stabilization care is not reversed and the
25 treating physician communicates to the issuer

1 involved a disagreement with such decision, the
2 post-stabilization care requested is required to
3 be covered under this subsection beginning as
4 follows:

5 “(i) DELAY TO ALLOW FOR PROMPT
6 ARRIVAL OF PHYSICIAN ASSUMING RE-
7 SPONSIBILITY.—If the issuer commu-
8 nicates that a physician (designated by the
9 plan or issuer) with privileges at the hos-
10 pital involved will arrive promptly (as de-
11 termined under guidelines) at the emer-
12 gency department of the hospital in order
13 to assume responsibility with respect to the
14 treatment of the enrollee involved, the re-
15 quired coverage of the post-stabilization
16 care begins after the passage of such time
17 period as would allow the prompt arrival of
18 such a physician.

19 “(ii) OTHER CASES.—If the issuer
20 does not so communicate, the required cov-
21 erage of the post-stabilization care begins
22 immediately.

23 “(6) NO REQUIREMENT OF COVERAGE OF POST-
24 STABILIZATION CARE IF ALTERNATE PLAN OF
25 TREATMENT.—

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

4 “(i) subject to subparagraph (B), a
5 physician (designated by the plan or issuer
6 involved) and with privileges at the hos-
7 pital involved arrives at the emergency de-
8 partment of the hospital and assumes re-
9 sponsibility with respect to the treatment
10 of the individual; or

11 “(ii) the treating physician and the is-
12 suer agree to another arrangement with re-
13 spect to the post-stabilization care (such as
14 an appropriate transfer of the individual
15 involved to another facility or an appoint-
16 ment for timely followup treatment for the
17 individual).

18 “(B) SPECIAL RULE WHERE ONCE CARE
19 INITIATED.—Required coverage of requested
20 post-stabilization care shall not end by reason
21 of subparagraph (A)(i) during an episode of
22 care (as determined by guidelines) if the treat-
23 ing physician initiated such care (consistent
24 with a previous paragraph) before the arrival of
25 a physician described in such subparagraph.

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

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

6 “(B) preventing a treating physician or
7 other individual described in paragraph (1)(C)
8 and an issuer from agreeing to modify any of
9 the time periods specified in paragraphs (5) as
10 it relates to cases involving such persons.

11 “(c) LIMITS ON COST-SHARING FOR SERVICES FUR-
12 NISHED IN EMERGENCY DEPARTMENTS.—If health insur-
13 ance coverage provides any benefits with respect to emer-
14 gency services, the health insurance issuer offering such
15 coverage may impose cost sharing with respect to such
16 services only if the following conditions are met:

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

19 “(A) NO DIFFERENTIAL FOR CERTAIN
20 SERVICES.—In the case of services furnished
21 under the circumstances described in clause (i),
22 (ii), or (iii) of subsection (a)(3)(B) (relating to
23 circumstances beyond the control of the en-
24 rollee, the likelihood of an adverse health con-
25 sequence based on layperson’s judgment, and

1 physician referral), the cost-sharing for such
2 services provided by a nonparticipating provider
3 or physician does not exceed the cost-sharing
4 for such services provided by a participating
5 provider or physician.

6 “(B) ONLY REASONABLE DIFFERENTIAL
7 FOR OTHER SERVICES.—In the case of other
8 emergency services, any differential by which
9 the cost-sharing for such services provided by a
10 nonparticipating provider or physician exceeds
11 the cost-sharing for such services provided by a
12 participating provider or physician is reasonable
13 (as determined under guidelines).

14 “(2) ONLY REASONABLE DIFFERENTIAL BE-
15 TWEEN EMERGENCY SERVICES AND OTHER SERV-
16 ICES.—Any differential by which the cost-sharing for
17 services furnished in an emergency department ex-
18 ceeds the cost-sharing for such services furnished in
19 another setting is reasonable (as determined under
20 guidelines).

21 “(3) CONSTRUCTION.—Nothing in paragraph
22 (1)(B) or (2) shall be construed as authorizing
23 guidelines other than guidelines that establish maxi-
24 mum cost-sharing differentials.

1 “(d) INFORMATION ON ACCESS TO EMERGENCY
2 SERVICES.—A health insurance issuer, to the extent a
3 health insurance issuer offers health insurance coverage,
4 shall provide education to enrollees on—

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

8 “(2) the appropriate use of emergency services,
9 including use of the 911 telephone system or its
10 local equivalent,

11 “(3) any cost sharing applicable to emergency
12 services,

13 “(4) the process and procedures of the plan for
14 obtaining emergency services, and

15 “(5) the locations of—

16 “(A) emergency departments, and

17 “(B) other settings,

18 in which participating physicians and hospitals pro-
19 vide emergency services and post-stabilization care.

20 “(e) GENERAL DEFINITIONS.—For purposes of this
21 section:

22 “(1) COST SHARING.—The term ‘cost sharing’
23 means any deductible, coinsurance amount, copay-
24 ment or other out-of-pocket payment (other than

1 premiums or enrollment fees) that a health insur-
2 ance offering health insurance issuer imposes on en-
3 rollees with respect to the coverage of benefits.

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

8 “(3) GUIDELINES.—The term ‘guidelines’
9 means guidelines established by the Secretary after
10 consultation with an advisory panel that includes in-
11 dividuals representing emergency physicians, health
12 insurance issuers, including at least one health
13 maintenance organization, hospitals, employers, the
14 States, and consumers.

15 “(4) PRIOR AUTHORIZATION DETERMINA-
16 TION.—The term ‘prior authorization determination’
17 means, with respect to items and services for which
18 coverage may be provided under health insurance
19 coverage, a determination (before the provision of
20 the items and services and as a condition of coverage
21 of the items and services under the coverage) of
22 whether or not such items and services will be cov-
23 ered under the coverage.

1 “(5) STABILIZE.—The term ‘to stabilize’
2 means, with respect to an emergency medical condi-
3 tion, to provide (in complying with section 1867 of
4 the Social Security Act) such medical treatment of
5 the condition as may be necessary to assure, within
6 reasonable medical probability, that no material de-
7 terioration of the condition is likely to result from or
8 occur during the transfer of the individual from the
9 facility.

10 “(6) STABILIZED.—The term ‘stabilized’
11 means, with respect to an emergency medical condi-
12 tion, that no material deterioration of the condition
13 is likely, within reasonable medical probability, to re-
14 sult from or occur before an individual can be trans-
15 ferred from the facility, in compliance with the re-
16 quirements of section 1867 of the Social Security
17 Act.

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

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

24 “(a) OBSTETRICAL AND GYNECOLOGICAL CARE.—

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

6 “(A) the issuer shall permit a female en-
7 rollee to designate a physician who specializes
8 in obstetrics and gynecology as the enrollee’s
9 primary care provider; and

10 “(B) if such an enrollee has not designated
11 such a provider as a primary care provider, the
12 issuer—

13 “(i) may not require prior authoriza-
14 tion by the enrollee’s primary care provider
15 or otherwise for coverage of routine gyne-
16 cological care (such as preventive women’s
17 health examinations) and pregnancy-relat-
18 ed services provided by a participating phy-
19 sician who specializes in obstetrics and
20 gynecology to the extent such care is other-
21 wise covered, and

22 “(ii) may treat the ordering of other
23 gynecological care by such a participating
24 physician as the prior authorization of the

1 primary care provider with respect to such
2 care under the coverage.

3 “(2) CONSTRUCTION.—Nothing in paragraph
4 (1)(B)(ii) shall waive any requirements of coverage
5 relating to medical necessity or appropriateness with
6 respect to coverage of gynecological care so ordered.

7 “(b) SPECIALTY CARE.—

8 “(1) REFERRAL TO SPECIALTY CARE FOR EN-
9 ROLLEES REQUIRING TREATMENT BY SPECIAL-
10 ISTS.—

11 “(A) IN GENERAL.—In the case of an en-
12 rollee who is covered under health insurance
13 coverage offered by a health insurance issuer
14 and who has a condition or disease of sufficient
15 seriousness and complexity to require treatment
16 by a specialist, the issuer shall make or provide
17 for a referral to a specialist who is available
18 and accessible to provide the treatment for such
19 condition or disease.

20 “(B) SPECIALIST DEFINED.—For purposes
21 of this subsection, the term ‘specialist’ means,
22 with respect to a condition, a health care practi-
23 tioner, facility, or center (such as a center of
24 excellence) that has adequate expertise through
25 appropriate training and experience (including,

1 in the case of a child, appropriate pediatric ex-
2 pertise) to provide high quality care in treating
3 the condition.

4 “(C) CARE UNDER REFERRAL.—Care pro-
5 vided pursuant to such referral under subpara-
6 graph (A) shall be—

7 “(i) pursuant to a treatment plan (if
8 any) developed by the specialist and ap-
9 proved by the issuer, in consultation with
10 the designated primary care provider or
11 specialist and the enrollee (or the enrollee’s
12 designee), and

13 “(ii) in accordance with applicable
14 quality assurance and utilization review
15 standards of the issuer.

16 Nothing in this subsection shall be construed as
17 preventing such a treatment plan for an en-
18 rollee from requiring a specialist to provide the
19 primary care provider with regular updates on
20 the specialty care provided, as well as all nec-
21 essary medical information.

1 “(D) REFERRALS TO PARTICIPATING PRO-
2 VIDERS.—An issuer is not required under sub-
3 paragraph (A) to provide for a referral to a spe-
4 cialist that is not a participating provider, un-
5 less the issuer does not have an appropriate
6 specialist that is available and accessible to
7 treat the enrollee’s condition and that is a par-
8 ticipating provider with respect to such treat-
9 ment.

10 “(E) TREATMENT OF NONPARTICIPATING
11 PROVIDERS.—If an issuer refers an enrollee to
12 a nonparticipating specialist, services provided
13 pursuant to the approved treatment plan shall
14 be provided at no additional cost to the enrollee
15 beyond what the enrollee would otherwise pay
16 for services received by such a specialist that is
17 a participating provider.

18 “(2) SPECIALISTS AS PRIMARY CARE PROVID-
19 ERS.—

20 “(A) IN GENERAL.—A health insurance is-
21 suer, in connection with the provision of health
22 insurance coverage, shall have a procedure by
23 which a new enrollee upon enrollment, or an en-
24 rollee upon diagnosis, with an ongoing special
25 condition (as defined in subparagraph (C)) may

1 receive a referral to a specialist for such condi-
2 tion who shall be responsible for and capable of
3 providing and coordinating the enrollee's pri-
4 mary and specialty care. If such an enrollee's
5 care would most appropriately be coordinated
6 by such a specialist, the issuer shall refer the
7 enrollee to such specialist.

8 “(B) TREATMENT AS PRIMARY CARE PRO-
9 VIDER.—Such specialist shall be permitted to
10 treat the enrollee without a referral from the
11 enrollee's primary care provider and may au-
12 thorize such referrals, procedures, tests, and
13 other medical services as the enrollee's primary
14 care provider would otherwise be permitted to
15 provide or authorize, subject to the terms of the
16 treatment plan (referred to in paragraph
17 (1)(C)(i)).

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

21 “(i) is life-threatening, degenerative,
22 or disabling, and

23 “(ii) requires specialized medical care
24 over a prolonged period of time.

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

7 “(3) STANDING REFERRALS.—

8 “(A) IN GENERAL.—A health insurance is-
9 suer, in connection with the provision of health
10 insurance coverage, shall have a procedure by
11 which an enrollee who has a condition that re-
12 quires ongoing care from a specialist may re-
13 ceive a standing referral to such specialist for
14 treatment of such condition. If the issuer, or
15 the primary care provider in consultation with
16 the medical director of the issuer and the spe-
17 cialist (if any), determines that such a standing
18 referral is appropriate, the issuer shall make
19 such a referral to such a specialist.

20 “(C) TERMS OF REFERRAL.—The provi-
21 sions of subparagraphs (C) through (E) of
22 paragraph (1) shall apply with respect to refer-
23 rals under subparagraph (A) of this paragraph
24 in the same manner as they apply to referrals
25 under paragraph (1)(A).

1 **“SEC. 2773. CONTINUITY OF CARE.**

2 “(a) IN GENERAL.—If a contract between a health
3 insurance issuer, in connection with the provision of health
4 insurance coverage, and a health care provider is termi-
5 nated (other than by the issuer for failure to meet applica-
6 ble quality standards or for fraud) and an enrollee is un-
7 dergoing a course of treatment from the provider at the
8 time of such termination, the issuer shall—

9 “(1) notify the enrollee of such termination,
10 and

11 “(2) subject to subsection (c), permit the en-
12 rollee to continue the course of treatment with the
13 provider during a transitional period (provided under
14 subsection (b)).

15 “(b) TRANSITIONAL PERIOD.—

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

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

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

24 “(2) INSTITUTIONAL CARE.—The transitional
25 period under this subsection for institutional or in-
26 patient care from a provider shall extend until the

1 discharge or termination of the period of institu-
2 tionalization and shall include reasonable follow-up
3 care related to the institutionalization and shall also
4 include institutional care scheduled prior to the date
5 of termination of the provider status.

6 “(3) PREGNANCY.—If—

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

10 “(B) the provider was treating the preg-
11 nancy before date of the termination,
12 the transitional period under this subsection with re-
13 spect to provider’s treatment of the pregnancy shall
14 extend through the provision of post-partum care di-
15 rectly related to the delivery.

16 “(4) TERMINAL ILLNESS.—

17 “(A) IN GENERAL.—If—

18 “(i) an enrollee was determined to be
19 terminally ill (as defined in subparagraph
20 (B)) at the time of a provider’s termi-
21 nation of participation, and

22 “(ii) the provider was treating the ter-
23 minal illness before the date of termi-
24 nation,

1 the transitional period under this subsection
2 shall extend for the remainder of the enrollee’s
3 life for care directly related to the treatment of
4 the terminal illness.

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

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

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

17 “(2) The provider agrees to adhere to the issu-
18 er’s quality assurance standards and to provide to
19 the issuer necessary medical information related to
20 the care provided.

21 “(3) The provider agrees otherwise to adhere to
22 the issuer’s policies and procedures, including proce-
23 dures regarding referrals and obtaining prior au-
24 thorization and providing services pursuant to a
25 treatment plan approved by the issuer.

1 **“SEC. 2774. CHOICE OF PROVIDER.**

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

6 “(b) SPECIALISTS.—

7 “(1) IN GENERAL.—Subject to paragraph (2), a
8 health insurance issuer that offers health insurance
9 coverage shall permit each enrollee to receive medi-
10 cally necessary specialty care, pursuant to appro-
11 priate referral procedures, from any qualified par-
12 ticipating health care provider who is available to ac-
13 cept such enrollee for such care.

14 “(2) LIMITATION.—Paragraph (1) shall not
15 apply to speciality care if the issuer clearly informs
16 enrollees of the limitations on choice of participating
17 providers with respect to such care.

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

21 **“SEC. 2775. COVERAGE FOR INDIVIDUALS PARTICIPATING**
22 **IN APPROVED CLINICAL TRIALS.**

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

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

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

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

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

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

18 “(2) The enrollee is eligible to participate in an
19 approved clinical trial with respect to treatment of
20 such illness.

21 “(3) The enrollee and the referring physician
22 conclude that the enrollee’s participation in such
23 trial would be appropriate.

1 “(4) The enrollee’s participation in the trial of-
2 fers potential for significant clinical benefit for the
3 enrollee.

4 “(c) PAYMENT.—

5 “(1) IN GENERAL.—Under this section an is-
6 suer shall provide for payment for routine patient
7 costs described in subsection (a)(2) but is not re-
8 quired to pay for costs of items and services that are
9 reasonably expected (as determined by the Sec-
10 retary) to be paid for by the sponsors of an ap-
11 proved clinical trial.

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

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

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

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

24 “(1) The National Institutes of Health.

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

3 “(3) The Department of Veterans Affairs.

4 “(4) The Department of Defense.

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

6 “If a health insurance issuer offers health insurance
7 coverage that provides benefits with respect to prescription
8 drugs but the coverage limits such benefits to drugs in-
9 cluded in a formulary, the issuer shall—

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

12 “(2) disclose the nature of the formulary re-
13 strictions; and

14 “(3) provide for exceptions from the formulary
15 limitation when medical necessity, as determined by
16 the enrollee’s physician subject to reasonable review
17 by the issuer, dictates that a non-formulary alter-
18 native is indicated.

19 “SUBPART 2—QUALITY ASSURANCE

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

21 “(a) REQUIREMENT.—A health insurance issuer that
22 offers health insurance coverage shall establish and main-
23 tain an ongoing, internal quality assurance and continuous
24 quality improvement program that meets the requirements
25 of subsection (b).

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

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

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

10 “(A) The activities to be conducted.

11 “(B) The organizational structure.

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

13 “(D) Criteria and procedures for the as-
14 sessment of quality.

15 “(E) Systems for ongoing and focussed
16 evaluation activities.

17 “(3) SYSTEMATIC REVIEW.—The program pro-
18 vides for systematic review of the type of health
19 services provided, consistency of services provided
20 with good medical practice, and patient outcomes.

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

22 “(A) uses criteria that are based on per-
23 formance and clinical outcomes where feasible
24 and appropriate, and

1 “(B) includes criteria that are directed
2 specifically at meeting the needs of at-risk pop-
3 ulations and enrollees with chronic or severe ill-
4 nesses.

5 “(5) SYSTEM FOR REPORTING.—The program
6 has procedures for reporting of possible quality con-
7 cerns by providers and enrollees and for remedial ac-
8 tions to correct quality problems, including written
9 procedures for responding to concerns and taking
10 appropriate corrective action.

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

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

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

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

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

22 “(a) IN GENERAL.—A health insurance issuer that
23 offers health insurance coverage shall collect uniform qual-
24 ity data that include—

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

3 “(2) additional data that are consistent with
4 the requirements of a nationally recognized body
5 identified by the Secretary.

6 “(b) MINIMUM UNIFORM DATA SET.—The Secretary
7 shall specify the data required to be included in the mini-
8 mum uniform data set under subsection (a)(1) and the
9 standard format for such data. Such data shall include
10 at least—

11 “(1) aggregate utilization data;

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

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

16 “(4) data on enrollee satisfaction, including
17 data on enrollee disenrollment and grievances; and

18 “(5) data on quality indicators.

19 “(c) AVAILABILITY.—A summary of the data col-
20 lected under subsection (a) shall be disclosed under section
21 2782(b)(4).

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

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

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

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

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

15 “A health insurance issuer that provides health insur-
16 ance coverage that includes benefits for prescription drugs
17 shall establish and maintain a drug utilization program
18 which—

19 “(1) encourages appropriate use of prescription
20 drugs by enrollees and providers,

21 “(2) monitors illnesses arising from improper
22 drug use or from adverse drug reactions or inter-
23 actions, and

24 “(3) takes appropriate action to reduce the inci-
25 dence of improper drug use and adverse drug reac-
26 tions and interactions.

1 **“SEC. 2781. STANDARDS FOR UTILIZATION REVIEW ACTIVI-**
2 **TIES.**

3 “(a) COMPLIANCE WITH REQUIREMENTS.—

4 “(1) IN GENERAL.—A health insurance issuer
5 shall conduct utilization review activities in connec-
6 tion with the provision of health insurance coverage
7 only in accordance with a utilization review program
8 that meets the requirements of this section.

9 “(2) USE OF OUTSIDE AGENTS.—Nothing in
10 this section shall be construed as preventing a health
11 insurance issuer from arranging through a contract
12 or otherwise for persons or entities to conduct utili-
13 zation review activities on behalf of the issuer, so
14 long as such activities are conducted in accordance
15 with a utilization review program that meets the re-
16 quirements of this section.

17 “(3) UTILIZATION REVIEW DEFINED.—For pur-
18 poses of this section, the terms ‘utilization review’
19 and ‘utilization review activities’ mean procedures
20 used to monitor or evaluate the clinical necessity,
21 appropriateness, efficacy, or efficiency of health care
22 services, procedures or settings, and includes ambu-
23 latory review, prospective review, concurrent review,
24 second opinions, case management, discharge plan-
25 ning, or retrospective review.

26 “(b) WRITTEN POLICIES AND CRITERIA.—

1 “(1) WRITTEN POLICIES.—A utilization review
2 program shall be conducted consistent with written
3 policies and procedures that govern all aspects of the
4 program.

5 “(2) USE OF WRITTEN CRITERIA.—

6 “(A) IN GENERAL.—Such a program shall
7 utilize written clinical review criteria developed
8 pursuant to the program with the input of ap-
9 propriate physicians.

10 “(B) CONTINUING USE OF STANDARDS IN
11 RETROSPECTIVE REVIEW.—If a health care
12 service has been specifically pre-authorized or
13 approved for an enrollee under such a program,
14 the program shall not, pursuant to retrospective
15 review, revise or modify the specific standards,
16 criteria, or procedures used for the utilization
17 review for procedures, treatment, and services
18 delivered to the enrollee during the same course
19 of treatment.

20 “(C) NO ADVERSE DETERMINATION BASED
21 ON REFUSAL TO OBSERVE SERVICE.—Such a
22 program shall not base an adverse determina-
23 tion on—

24 “(i) a refusal to consent to observing
25 any health care service, or

1 “(ii) lack of reasonable access to a
2 health care provider’s medical or treatment
3 records, unless the program has provided
4 reasonable notice to the enrollee.

5 “(c) CONDUCT OF PROGRAM ACTIVITIES.—

6 “(1) ADMINISTRATION BY HEALTH CARE PRO-
7 FESSIONALS.—A utilization review program shall be
8 administered by qualified health care professionals
9 who shall oversee review decisions. In this sub-
10 section, the term ‘health care professional’ means a
11 physician or other health care practitioner licensed,
12 accredited, or certified to perform specified health
13 services consistent with State law.

14 “(2) USE OF QUALIFIED, INDEPENDENT PER-
15 SONNEL.—

16 “(A) IN GENERAL.—A utilization review
17 program shall provide for the conduct of utiliza-
18 tion review activities only through personnel
19 who are qualified and, to the extent required,
20 who have received appropriate training in the
21 conduct of such activities under the program.

22 “(B) PEER REVIEW OF ADVERSE CLINICAL
23 DETERMINATIONS.—Such a program shall pro-
24 vide that clinical peers shall evaluate the clinical

1 appropriateness of adverse clinical determina-
2 tions. In this subsection, the term ‘clinical peer’
3 means, with respect to a review, a physician or
4 other health care professional who holds a non-
5 restricted license in a State and in the same or
6 similar specialty as typically manages the medi-
7 cal condition, procedure, or treatment under re-
8 view.

9 “(C) PROHIBITION OF CONTINGENT COM-
10 PENSATION ARRANGEMENTS.—Such a program
11 shall not, with respect to utilization review ac-
12 tivities, permit or provide compensation or any-
13 thing of value to its employees, agents, or con-
14 tractors in a manner that—

15 “(i) provides incentives, direct or indi-
16 rect, for such persons to make inappropri-
17 ate review decisions, or

18 “(ii) is based, directly or indirectly, on
19 the quantity or type of adverse determina-
20 tions rendered.

21 “(D) PROHIBITION OF CONFLICTS.—Such
22 a program shall not permit a health care pro-
23 fessional who provides health care services to an
24 enrollee to perform utilization review activities

1 in connection with the health care services
2 being provided to the enrollee.

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

5 “(A) appropriate personnel performing uti-
6 lization review activities under the program are
7 reasonably accessible by toll-free telephone not
8 less than 40 hours per week during normal
9 business hours to discuss patient care and allow
10 response to telephone requests, and

11 “(B) the program has a telephone system
12 capable of accepting, recording, or providing in-
13 struction to incoming telephone calls during
14 other than normal business hours and to ensure
15 response to accepted or recorded messages not
16 less than one business day after the date on
17 which the call was received.

18 “(4) LIMITS ON FREQUENCY.—Such a program
19 shall not provide for the performance of utilization
20 review activities with respect to a class of services
21 furnished to an enrollee more frequently than is rea-
22 sonably required to assess whether the services
23 under review are medically necessary.

24 “(5) LIMITATION ON INFORMATION RE-
25 QUESTS.—Under such a program, information shall

1 be required to be provided by health care providers
2 only to the extent it is necessary to perform the uti-
3 lization review activity involved.

4 “(d) DEADLINE FOR DETERMINATIONS.—

5 “(1) PRIOR AUTHORIZATION SERVICES.—Ex-
6 cept as provided in paragraph (2), in the case of a
7 utilization review activity involving the prior author-
8 ization of health care items and services, the utiliza-
9 tion review program shall make a determination con-
10 cerning such authorization, and provide notice of the
11 determination to the enrollee or the enrollee’s des-
12 ignee and the enrollee’s health care provider by tele-
13 phone and in writing, as soon as possible in accord-
14 ance with the medical exigencies of the cases, and in
15 no event later than 3 business days after the date
16 of receipt of the necessary information respecting
17 such determination.

18 “(2) CONTINUED CARE.—In the case of a utili-
19 zation review activity involving authorization for con-
20 tinued or extended health care services, or additional
21 services for an enrollee undergoing a course of con-
22 tinued treatment prescribed by a health care pro-
23 vider, the utilization review program shall make a
24 determination concerning such authorization, and
25 provide notice of the determination to the enrollee or

1 the enrollee’s designee and the enrollee’s health care
2 provider by telephone and in writing, within 1 busi-
3 ness day of the date of receipt of the necessary in-
4 formation respecting such determination. Such no-
5 tice shall include, with respect to continued or ex-
6 tended health care services, the number of extended
7 services approved, the new total of approved serv-
8 ices, the date of onset of services, and the next re-
9 view date.

10 “(3) PREVIOUSLY PROVIDED SERVICES.—In the
11 case of a utilization review activity involving retro-
12 spective review of health care services previously pro-
13 vided, the utilization review program shall make a
14 the determination concerning such services, and pro-
15 vide 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 30 days
18 of the date of receipt of the necessary information
19 respecting such determination.

20 “(4) REFERENCE TO SPECIAL RULES FOR
21 EMERGENCY SERVICES, MAINTENANCE CARE, AND
22 POST-STABILIZATION CARE.—For waiver of prior au-
23 thorization requirements in certain cases involving
24 emergency services and maintenance care and post-

1 stabilization care, see sections 2771(a)(1)(A) and
2 2771(a)(2)(A), respectively.

3 “(e) NOTICE OF ADVERSE DETERMINATIONS.—

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

8 “(A) the reasons for the determination (in-
9 cluding the clinical rationale);

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

12 “(C) notice of the availability, upon re-
13 quest of the enrollee (or the enrollee’s designee)
14 of the clinical review criteria relied upon to
15 make such determination.

16 “(2) SPECIFICATION OF ANY ADDITIONAL IN-
17 FORMATION.—Such a notice shall also specify what
18 (if any) additional necessary information must be
19 provided to, or obtained by, person making the de-
20 termination in order to make a decision on such an
21 appeal.

22 “(f) RECONSIDERATION.—

23 “(1) AT REQUEST OF PROVIDER.—In the event
24 that a utilization review program provides for an ad-
25 verse determination without attempting to discuss

1 such matter with the enrollee’s health care provider
2 who specifically recommended the health care serv-
3 ice, procedure, or treatment under review, such
4 health care provider shall have the opportunity to re-
5 quest a reconsideration of the adverse determination
6 under this subsection.

7 “(2) TIMING AND CONDUCT.—Except in cases
8 of retrospective reviews, such reconsideration shall
9 occur as soon as possible in accordance with the
10 medical exigencies of the cases, and in no event later
11 than 1 business day after the date of receipt of the
12 request and shall be conducted by the enrollee’s
13 health care provider and the health care professional
14 making the initial determination or a designated
15 qualified health care professional if the original pro-
16 fessional cannot be available.

17 “(3) NOTICE.—In the event that the adverse
18 determination is upheld after reconsideration, the
19 utilization review program shall provide notice as re-
20 quired under subsection (e).

21 “(4) CONSTRUCTION.—Nothing in this sub-
22 section shall preclude the enrollee from initiating an
23 appeal from an adverse determination under section
24 2785.

1 “SUBPART 3—PATIENT INFORMATION

2 **“SEC. 2782. PATIENT INFORMATION.**

3 “(a) DISCLOSURE REQUIREMENT.—A health insur-
4 ance issuer in connection with the provision of health in-
5 surance coverage shall submit to the applicable State au-
6 thority, provide to enrollees (and prospective enrollees),
7 and make available to the public, in writing the informa-
8 tion described in subsection (b).

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

11 “(1) DESCRIPTION OF COVERAGE.—A descrip-
12 tion of coverage provisions, including health care
13 benefits, benefit limits, coverage exclusions, coverage
14 of emergency care, and the definition of medical ne-
15 cessity used in determining whether benefits will be
16 covered.

17 “(2) ENROLLEE FINANCIAL RESPONSIBILITY.—
18 An explanation of an enrollee’s financial responsibil-
19 ity for payment of premiums, coinsurance, copay-
20 ments, deductibles, and any other charges, including
21 limits on such responsibility and responsibility for
22 health care services that are provided by nonpartici-
23 pating providers or are furnished without meeting
24 applicable utilization review requirements.

1 “(3) INFORMATION ON PROVIDERS.—A descrip-
2 tion—

3 “(A) of procedures for enrollees to select,
4 access, and change participating primary and
5 specialty providers,

6 “(B) of the rights and procedures for ob-
7 taining referrals (including standing referrals)
8 to participating and nonparticipating providers,
9 and

10 “(C) in the case of each participating pro-
11 vider, of the name, address, and telephone num-
12 ber of the provider, the credentials of the pro-
13 vider, and the provider’s availability to accept
14 new patients.

15 “(4) UTILIZATION REVIEW ACTIVITIES.—A de-
16 scription of procedures used and requirements (in-
17 cluding circumstances, time frames, and rights to re-
18 consideration and appeal) under any utilization re-
19 view program under section 2781 or any drug utili-
20 zation program under section 2780, as well as a
21 summary of the minimum uniform data collected
22 under section 2778(a)(1).

23 “(5) GRIEVANCE PROCEDURES.—Information
24 on the grievance procedures under sections 2784 and
25 2785, including information describing—

1 “(A) the grievance procedures used by the
2 issuer to process and resolve disputes between
3 the issuer and an enrollee (including method for
4 filing grievances and the time frames and cir-
5 cumstances for acting on grievances);

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

9 “(C) the disposition of such complaints
10 and appeals.

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

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

20 “(8) ASSURING COMMUNICATIONS WITH EN-
21 ROLLEES.—A description of how the issuer address-
22 es the needs of non-English-speaking enrollees and
23 others with special communications needs, including
24 the provision of information described in this sub-
25 section to such enrollees.

1 “(c) FORM OF DISCLOSURE.—

2 “(1) UNIFORMITY.—Information required to be
3 disclosed under this section shall be provided in ac-
4 cordance with uniform, national reporting standards
5 specified by the Secretary, after consultation with
6 applicable State authorities, so that prospective en-
7 rollees may compare the attributes of different issu-
8 ers and coverage offered within an area.

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

14 “(3) UPDATING.—The information on partici-
15 pating providers described in subsection (a)(3)(C)
16 shall be updated not less frequently than monthly.
17 Nothing in this section shall prevent an issuer from
18 changing or updating other information made avail-
19 able under this section.

20 “(4) CONSTRUCTION.—Nothing in subsection
21 (a)(6) shall be construed as requiring disclosure of
22 individual contracts or financial arrangements be-
23 tween an issuer and any provider. Nothing in this

1 subsection shall be construed as preventing the in-
2 formation described in subsection (a)(3)(C) from
3 being provided in a separate document.

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

5 “A health insurance issuer that offers health insur-
6 ance coverage shall establish appropriate policies and pro-
7 cedures to ensure that all applicable State and Federal
8 laws to protect the confidentiality of individually identifi-
9 able medical information are followed.

10 “SUBPART 4—GRIEVANCE PROCEDURES

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

12 **PROCESS.**

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

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

4 “(1) Written notification to all enrollees and
5 providers of the telephone numbers and business ad-
6 dresses of the issuer employees responsible for reso-
7 lution of complaints and appeals.

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

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

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

18 “(5) A process describing how complaints and
19 appeals are processed and resolved.

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

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

1 “(c) NO REPRISAL FOR EXERCISE OF RIGHTS.—A
2 health insurance issuer shall not take any action with re-
3 spect to an enrollee or a health care provider that is in-
4 tended to penalize the enrollee, a designee of the enrollee,
5 or the health care provider for discussing or exercising any
6 rights provided under this part (including the filing of a
7 complaint or appeal pursuant to this section).

8 **“SEC. 2785. PROVISIONS RELATING TO APPEALS OF UTILI-**
9 **ZATION REVIEW DETERMINATIONS AND SIMI-**
10 **LAR DETERMINATIONS.**

11 “(a) RIGHT OF APPEAL.—

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

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

1 “(A) An adverse determination under a
2 utilization review program under section 2781.

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

5 “(C) Denial of continuation of care under
6 section 2773.

7 “(D) Denial of a choice of provider under
8 section 2774.

9 “(E) Denial of coverage of routine patient
10 costs in connection with an approval clinical
11 trial under section 2775.

12 “(F) Denial of access to needed drugs
13 under section 2776(3).

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

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

17 “(b) INFORMAL INTERNAL APPEAL PROCESS (STAGE
18 1).—

19 “(1) IN GENERAL.—Each issuer shall establish
20 and maintain an informal internal appeal process
21 (an appeal under such process in this section re-
22 ferred to as a ‘stage 1 appeal’) under which any en-
23 rollee or any provider acting on behalf of an enrollee
24 with the enrollee’s consent, who is dissatisfied with

1 any appealable decision has the opportunity to dis-
2 cuss and appeal that decision with the medical direc-
3 tor of the issuer or the health care professional who
4 made the decision.

5 “(2) TIMING.—All appeals under this para-
6 graph shall be concluded as soon as possible in ac-
7 cordance with the medical exigencies of the cases,
8 and in no event later than 72 hours in the case of
9 appeals from decisions regarding urgent care and 5
10 days in the case of all other appeals.

11 “(3) FURTHER REVIEW.—If the appeal is not
12 resolved to the satisfaction of the enrollee at this
13 level by the deadline under paragraph (2), the issuer
14 shall provide the enrollee and provider (if any) with
15 a written explanation of the decision and the right
16 to proceed to a stage 2 appeal under subsection (c).

17 “(c) FORMAL INTERNAL APPEAL PROCESS (STAGE
18 2).—

19 “(1) IN GENERAL.—Each issuer shall establish
20 and maintain a formal internal appeal process (an
21 appeal under such process in this section referred to
22 as a ‘stage 2 appeal’) under which any enrollee or
23 provider acting on behalf of an enrollee with the en-
24 rollee’s consent, who is dissatisfied with the results
25 of a stage 1 appeal has the opportunity to appeal

1 the results before a panel that includes a physician
2 or other health care professional (or professionals)
3 selected by the issuer who have not been involved in
4 the appealable decision at issue in the appeal.

5 “(2) AVAILABILITY OF CLINICAL PEERS.—The
6 panel under subparagraph (A) shall have available
7 either clinical peers (as defined in section
8 2781(e)(2)(B)) who have not been involved in the
9 appealable decision at issue in the appeal or others
10 who are mutually agreed upon by the parties. If re-
11 quested by the enrollee or enrollee’s provider with
12 the enrollee’s consent, such a peer shall participate
13 in the panel’s review of the case.

14 “(3) TIMELY ACKNOWLEDGMENT.—The issuer
15 shall acknowledge the enrollee or provider involved
16 of the receipt of a stage 2 appeals upon receipt of
17 the appeal.

18 “(4) DEADLINE.—

19 “(A) IN GENERAL.—The issuer shall con-
20 clude each stage 2 appeal as soon as possible
21 after the date of the receipt of the appeal in ac-
22 cordance with medical exigencies of the case in-
23 volved, but in no event later than 72 hours in

1 the case of appeals from decisions regarding ur-
2 gent care and (except as provided in subpara-
3 graph (B)) 20 business days in the case of all
4 other appeals.

5 “(B) EXTENSION.—An issuer may extend
6 the deadline for an appeal that does not relate
7 to a decision regarding urgent or emergency
8 care up to an additional 20 business days where
9 it can demonstrate to the applicable State au-
10 thority reasonable cause for the delay beyond
11 its control and where it provides, within the
12 original deadline under subparagraph (A), a
13 written progress report and explanation for the
14 delay to such authority and to the enrollee and
15 provider involved.

16 “(5) NOTICE.—If an issuer denies a stage 2 ap-
17 peal, the issuer shall provide the enrollee and pro-
18 vider involved with written notification of the denial
19 and the reasons therefore, together with a written
20 notification of rights to any further appeal

21 “(d) DIRECT USE OF FURTHER APPEALS.—In the
22 event that the issuer fails to comply with any of the dead-
23 lines for completion of appeals under this section or in
24 the event that the issuer for any reason expressly waives

1 its rights to an internal review of an appeal under sub-
2 section (b) or (c), the enrollee and provider involved shall
3 be relieved of any obligation to complete the appeal stage
4 involved and may, at the enrollee’s or provider’s option,
5 proceed directly to seek further appeal through any appli-
6 cable external appeals process.

7 “(e) EXTERNAL APPEAL PROCESS IN CASE OF USE
8 OF EXPERIMENTAL TREATMENT TO SAVE LIFE OF PA-
9 TIENT.—

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

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

19 “(A) The enrollee has a terminal condition
20 that is highly likely to cause death within 2
21 years.

22 “(B) The enrollee’s physician certifies
23 that—

1 “(i) there is no standard, medically
2 appropriate therapy for successfully treat-
3 ing such terminal condition, but

4 “(ii) based on medical and scientific
5 evidence, there is a drug, device, proce-
6 dure, or therapy (in this section referred to
7 as the ‘experimental therapy’) that is more
8 beneficial than any available standard ther-
9 apy.

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

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

1 panel that is not favorable to the enrollee may be
2 appealed by the enrollee.

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

6 “(f) OTHER INDEPENDENT OR EXTERNAL RE-
7 VIEW.—

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

11 “(A) an external review process for such
12 decisions consistent with the requirements of
13 paragraph (3), or

14 “(B) an internal independent review pro-
15 cess for such decisions consistent with the re-
16 quirements of paragraph (4).

17 “(2) APPEALABLE DECISION DESCRIBED.—An
18 appealable decision described in this paragraph is
19 decision that does not involve a decision described in
20 subsection (e)(1) but involves—

21 “(A) a claim for benefits involving costs
22 over a significant threshold, or

23 “(B) assuring access to care for a serious
24 condition.

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

4 “(A) The process is established under
5 State law and provides for review of decisions
6 on stage 2 appeals by an independent review or-
7 ganization certified by the State.

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

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

19 “(D) All decisions under the process shall
20 be in writing and shall be accompanied by an
21 explanation of the basis for the decision.

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

24 “(F) The issuer shall provide for publica-
25 tion at least annually of information on the

1 numbers of appeals and decisions considered
2 under the process.

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

6 “(A)(i) The process must provide for the
7 participation of persons who are independent of
8 the issuer in conducting reviews and (ii) the
9 Secretary must have found (through reviews
10 conducted no less often than biannually) the
11 process to be fair and impartial.

12 “(B) If the process provides that decisions
13 in such process are not binding on issuers, the
14 process must provide for public methods of dis-
15 closing frequency of noncompliance with such
16 decisions and for sanctioning issuers that con-
17 sistently refuse to take appropriate actions in
18 response to such decisions.

19 “(C) Results of all such reviews under the
20 process are disclosed to the public, along with
21 at least annual disclosure of information on is-
22 suer compliance.

23 “(D) All decisions under the process shall
24 be in writing and shall be accompanied by an
25 explanation of the basis for the decision.

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

3 “(F) The issuer shall provide for publica-
4 tion at least annually of information on the
5 numbers of appeals and decisions considered
6 under the process.

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

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

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

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

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

6 “(a) IN GENERAL.—Each State that obtains a grant
7 under subsection (c) shall establish and maintain a Health
8 Insurance Ombudsman. Such Ombudsman may be part of
9 a independent, nonprofit entity, and shall be responsible
10 for at least the following:

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

13 “(2) To provide counseling and assistance to
14 enrollees dissatisfied with their treatment by health
15 insurance issuers in regard to such coverage and in
16 the filing of complaints and appeals regarding deter-
17 minations under such coverage.

18 “(3) To investigate instances of poor quality or
19 improper treatment of enrollees by health insurance
20 issuers in regard to such coverage and to bring such
21 instances to the attention of the applicable State au-
22 thority.

23 “(b) FEDERAL ROLE.—In the case of any State that
24 does not establish and maintain such an Ombudsman
25 under subsection (a), the Secretary shall provide for the

1 establishment and maintenance of such an official as will
2 carry out with respect to that State the functions other-
3 wise provided under subsection (a) by a Health Insurance
4 Ombudsman.

5 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated to the Secretary such
7 amounts as may be necessary to provide for grants to
8 States to establish and operate Health Insurance Ombuds-
9 men under subsection (a) or for the operation of Ombuds-
10 men under subsection (b).

11 “SUBPART 5—PROTECTION OF PROVIDERS AGAINST IN-
12 TERFERENCE WITH MEDICAL COMMUNICATIONS
13 AND IMPROPER INCENTIVE ARRANGEMENTS

14 “**SEC. 2787. PROHIBITION OF INTERFERENCE WITH CER-**
15 **TAIN MEDICAL COMMUNICATIONS.**

16 “(a) PROHIBITION.—

17 “(1) GENERAL RULE.—The provisions of any
18 contract or agreement, or the operation of any con-
19 tract or agreement, between a health insurance is-
20 suer in relation to health insurance coverage (includ-
21 ing any partnership, association, or other organiza-
22 tion that enters into or administers such a contract
23 or agreement) and a health care provider (or group

1 of health care providers) shall not prohibit or re-
2 strict the provider from engaging in medical commu-
3 nications with the provider's patient.

4 “(2) NULLIFICATION.—Any contract provision
5 or agreement described in paragraph (1) shall be
6 null and void.

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

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

12 “(1) to prohibit the enforcement, as part of a
13 contract or agreement to which a health care pro-
14 vider is a party, of any mutually agreed upon terms
15 and conditions, including terms and conditions re-
16 quiring a health care provider to participate in, and
17 cooperate with, all programs, policies, and proce-
18 dures developed or operated by a health insurance
19 issuer to assure, review, or improve the quality and
20 effective utilization of health care services (if such
21 utilization is according to guidelines or protocols
22 that are based on clinical or scientific evidence and
23 the professional judgment of the provider) but only
24 if the guidelines or protocols under such utilization

1 do not prohibit or restrict medical communications
2 between providers and their patients; or

3 “(2) to permit a health care provider to mis-
4 represent the scope of benefits covered under health
5 insurance coverage or to otherwise require a health
6 insurance issuer to reimburse providers for benefits
7 not covered under the coverage.

8 “(c) PROTECTION OF RELIGIOUS OR MORAL EX-
9 PRESSION.—

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

12 “(A) licensed or certified health care pro-
13 viders at the time of their employment with the
14 issuer or at any time during such employment,
15 or

16 “(B) enrollees at the time of their enroll-
17 ment for health insurance coverage with the is-
18 suer or at any time during which such enrollees
19 have such coverage,

20 of the coverage’s limitations on providing particular
21 medical services (including limitations on referrals
22 for care provided outside of the coverage) based on
23 the religious or moral convictions of the issuer.

24 “(2) HEALTH CARE PROVIDERS.—Nothing in
25 this section shall be construed to alter the rights and

1 duties of a health care provider to determine what
2 medical communications are appropriate with re-
3 spect to each patient, except as provided for in sub-
4 section (a).

5 “(d) MEDICAL COMMUNICATION DEFINED.—

6 “(1) IN GENERAL.—In this section, the term
7 ‘medical communication’ means any communication
8 made by a health care provider with a patient of the
9 health care provider (or the guardian or legal rep-
10 resentative of such patient) with respect to—

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

13 “(B) any utilization review requirements
14 that may affect treatment options for the pa-
15 tient; or

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

18 “(2) MISREPRESENTATION.—The term ‘medical
19 communication’ does not include a communication
20 by a health care provider with a patient of the
21 health care provider (or the guardian or legal rep-
22 resentative of such patient) if the communication in-
23 volves a knowing or willful misrepresentation by
24 such provider.

1 **“SEC. 2788. PROHIBITION AGAINST TRANSFER OF INDEM-**
2 **NIFICATION OR IMPROPER INCENTIVE AR-**
3 **RANGEMENTS.**

4 “(a) PROHIBITION OF TRANSFER OF INDEMNIFICA-
5 TION.—No contract or agreement between a health insur-
6 ance issuer (or any agent acting on behalf of such an is-
7 suer) and a health care provider shall contain any clause
8 purporting to transfer to the health care provider by in-
9 demnification or otherwise any liability relating to activi-
10 ties, actions, or omissions of the issuer or agent (as op-
11 posed to the provider).

12 “(b) PROHIBITION OF IMPROPER PHYSICIAN INCEN-
13 TIVE PLANS.—

14 “(1) IN GENERAL.—A health insurance issuer
15 offering health insurance coverage may not operate
16 any physician incentive plan unless the following re-
17 quirements are met:

18 “(A) No specific payment is made directly
19 or indirectly by the issuer to a physician or
20 physician group as an inducement to reduce or
21 limit medically necessary services provided with
22 respect to a specific individual enrolled with the
23 issuer.

1 “(B) If the plan places a physician or phy-
2 sician group at substantial financial risk (as de-
3 termined by the Secretary) for services not pro-
4 vided by the physician or physician group, the
5 issuer—

6 “(i) provides stop-loss protection for
7 the physician or group that is adequate
8 and appropriate, based on standards devel-
9 oped by the Secretary that take into ac-
10 count the number of physicians placed at
11 such substantial financial risk in the group
12 or under the plan and the number of indi-
13 viduals enrolled with the issuer who receive
14 services from the physician or the physi-
15 cian group, and

16 “(ii) conducts periodic surveys of both
17 individuals enrolled and individuals pre-
18 viously enrolled with the issuer to deter-
19 mine the degree of access of such individ-
20 uals to services provided by the issuer and
21 satisfaction with the quality of such serv-
22 ices.

1 “(C) The issuer provides the applicable
2 State authority (or the Secretary if such au-
3 thority is implementing this section) with de-
4 scriptive information regarding the plan, suffi-
5 cient to permit the authority (or the Secretary
6 in such case) to determine whether the plan is
7 in compliance with the requirements of this
8 paragraph.

9 “(2) PHYSICIAN INCENTIVE PLAN DEFINED.—
10 In this section, the term ‘physician incentive plan’
11 means any compensation arrangement between a
12 health insurance issuer and a physician or physician
13 group that may directly or indirectly have the effect
14 of reducing or limiting services provided with respect
15 to individuals enrolled with the issuer.

16 “(3) APPLICATION OF MEDICARE RULES.—The
17 Secretary shall provide for the application of rules
18 under this subsection that are substantially the same
19 as the rules established to carry out section
20 1876(i)(8) of the Social Security Act.

21 “SUBPART 6—PROMOTING GOOD MEDICAL PRACTICE
22 AND PROTECTING THE DOCTOR-PATIENT RELATIONSHIP
23 “**SEC. 2789. PROMOTING GOOD MEDICAL PRACTICE.**

24 “(a) PROHIBITING ARBITRARY LIMITATIONS OR
25 CONDITIONS FOR THE PROVISION OF SERVICES.—A

1 health insurance issuer, in connection with the provision
2 of health insurance coverage, may not impose limits on
3 the manner in which particular services are delivered if
4 the services are medically necessary and appropriate for
5 the treatment or diagnosis of an illness or injury to the
6 extent that such treatment or diagnosis is otherwise a cov-
7 ered benefit.

8 “(b) MEDICAL NECESSITY AND APPROPRIATENESS
9 DEFINED.—In subsection (a), the term ‘medically nec-
10 essary and appropriate’ means, with respect to a service
11 or benefit, a service or benefit determined by the treating
12 physician participating in the health insurance coverage
13 after consultation with the enrollee, to be required, accord-
14 ingly to generally accepted principles of good medical prac-
15 tice, for the diagnosis or direct care and treatment of an
16 illness or injury of the enrollee.

17 “(c) CONSTRUCTION.—Subsection (a) shall not be
18 construed as requiring coverage of particular services the
19 coverage of which is otherwise not covered under the terms
20 of the coverage.”.

21 (b) APPLICATION TO GROUP HEALTH INSURANCE
22 COVERAGE.—Subpart 2 of part A of title XXVII of the
23 Public Health Service Act is amended by adding at the
24 end the following new section:

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

2 “Each health insurance issuer shall comply with pa-
3 tient protection requirements under part C with respect
4 to group health insurance coverage it offers.”.

5 (c) APPLICATION TO INDIVIDUAL HEALTH INSUR-
6 ANCE COVERAGE.—Part B of title XXVII of the Public
7 Health Service Act is amended by inserting after section
8 2751 the following new section:

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

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

13 (d) MODIFICATION OF PREEMPTION STANDARDS.—

14 (1) GROUP HEALTH INSURANCE COVERAGE.—
15 Section 2723 of such Act (42 U.S.C. 300gg–23) is
16 amended—

17 (A) in subsection (a)(1), by striking “sub-
18 section (b)” and inserting “subsections (b) and
19 (c)”;

20 (B) by redesignating subsections (c) and
21 (d) as subsections (d) and (e), respectively; and

22 (C) by inserting after subsection (b) the
23 following new subsection:

24 “(c) SPECIAL RULES IN CASE OF PATIENT PROTEC-
25 TION REQUIREMENTS.—Subject to subsection (a)(2), the
26 provisions of section 2706 and part C (other than section

1 2771), and part D insofar as it applies to section 2706
2 or part C, shall not prevent a State from establishing re-
3 quirements relating to the subject matter of such provi-
4 sions (other than section 2771) so long as such require-
5 ments are at least as stringent on health insurance issuers
6 as the requirements imposed under such provisions. Sub-
7 section (a) shall apply to the provisions of section 2771
8 (and section 2706 insofar as it relates to such section).”.

9 (2) INDIVIDUAL HEALTH INSURANCE COV-
10 ERAGE.—Section 2762 of such Act (42 U.S.C.
11 300gg-62), as added by section 605(b)(3)(B) of
12 Public Law 104-204, is amended—

13 (A) in subsection (a), by striking “sub-
14 section (b), nothing in this part” and inserting
15 “subsections (b) and (c)”, and

16 (B) by adding at the end the following new
17 subsection:

18 “(c) SPECIAL RULES IN CASE OF MANAGED CARE
19 REQUIREMENTS.—Subject to subsection (b), the provi-
20 sions of section 2752 and part C (other than section
21 2771), and part D insofar as it applies to section 2752

1 or part C, shall not prevent a State from establishing re-
2 quirements relating to the subject matter of such provi-
3 sions so long as such requirements are at least as strin-
4 gent on health insurance issuers as the requirements im-
5 posed under such section. Subsection (a) shall apply to
6 the provisions of section 2771 (and section 2752 insofar
7 as it relates to such section).”.

8 (e) ADDITIONAL CONFORMING AMENDMENTS.—

9 (1) Section 2723(a)(1) of such Act (42 U.S.C.
10 300gg-23(a)(1)) is amended by striking “part C”
11 and inserting “parts C and D”.

12 (2) Section 2762(b)(1) of such Act (42 U.S.C.
13 300gg-62(b)(1)) is amended by striking “part C”
14 and inserting “part D”.

15 (f) EFFECTIVE DATES.—(1)(A) Subject to subpara-
16 graph (B), the amendments made by subsections (a), (b),
17 (d)(1), and (e) shall apply with respect to group health
18 insurance coverage for group health plan years beginning
19 on or after July 1, 1998 (in this subsection referred to
20 as the “general effective date”) and also shall apply to
21 portions of plan years occurring on and after January 1,
22 1999.

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

9 (i) the date on which the last collective bargain-
10 ing agreements relating to the plan terminates (de-
11 termined without regard to any extension thereof
12 agreed to after the date of enactment of this Act),
13 or

14 (ii) the general effective date.

15 For purposes of clause (i), any plan amendment made pur-
16 suant to a collective bargaining agreement relating to the
17 plan which amends the plan solely to conform to any re-
18 quirement added by subsection (a) or (b) shall not be
19 treated as a termination of such collective bargaining
20 agreement.

21 (2) The amendments made by subsections (a), (c),
22 (d)(2), and (e) shall apply with respect to individual health
23 insurance coverage offered, sold, issued, renewed, in effect,

- 1 or operated in the individual market on or after the gen-
- 2 eral effective date.

