

105TH CONGRESS
2D SESSION

H. R. 3469

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to require that group and individual health insurance coverage and group health plans provide for external appeals in the case of adverse determinations involving experimental treatment, significant costs, or a serious medical condition.

IN THE HOUSE OF REPRESENTATIVES

MARCH 17, 1998

Mr. CARDIN introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to require that group and individual health insurance coverage and group health plans provide for external appeals in the case of adverse determinations involving experimental treatment, significant costs, or a serious medical condition.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Patient Right to Inde-
3 pendent Appeal Act of 1998”.

4 **SEC. 2. EXTERNAL APPEALS PROCESS FOR HEALTH PLANS.**

5 (a) GROUP HEALTH PLANS.—

6 (1) PUBLIC HEALTH SERVICE ACT AMEND-
7 MENTS.—(A) Subpart 2 of part A of title XXVII of
8 the Public Health Service Act is amended by adding
9 at the end the following new section:

10 **“SEC. 2706. EXTERNAL APPEALS OF ADVERSE DETERMINA-
11 TIONS.**

12 “(a) RIGHT TO EXTERNAL APPEAL.—

13 “(1) IN GENERAL.—A group health plan, and a
14 health insurance issuer offering group health insur-
15 ance coverage, shall provide for an external appeals
16 process that meets the requirements of this section
17 in the case of an externally appealable decision de-
18 scribed in paragraph (2). The Secretary shall estab-
19 lish standards to carry out such requirements.

20 “(2) EXTERNALLY APPEALABLE DECISION DE-
21 FINED.—For purposes of this section, the term ‘ex-
22 ternally appealable decision’ means a benefit denial,
23 reduction, or termination of, or failure to provide or
24 make, payment (in whole or in part) for, a benefit
25 (including a denial of choice of provider to the ex-
26 tent such a choice is permitted under a plan), if—

1 “(A) the denial or failure involves a deter-
2 mination that a treatment is experimental or in-
3 vestigational in nature;

4 “(B) the denial or failure is based on a de-
5 termination that services are not medically nec-
6 essary or appropriate and the amount involved
7 exceeds a significant threshold; or

8 “(C) the patient’s life or health is jeopard-
9 ized as a consequence of the denial or failure.

10 Such term does not include a denial of (or failure to
11 provide) coverage for services that are specifically
12 stated in plan or coverage documents as an exclusion
13 from coverage.

14 “(3) CONDITIONING APPEAL ON INTERNAL AP-
15 PEALS PROCESS.—A plan or issuer may condition
16 the use of an external appeal process in the case of
17 an externally appealable decision upon completion of
18 an internal review process but only if the internal re-
19 view process provides for a determination on the de-
20 cision in accordance with the medical exigencies of
21 the case involved, but in no event later than 15 busi-
22 ness days (or 72 hours in the case of a decision in-
23 volving emergency or urgent care) of the time of the
24 filing of the request for the internal review.

25 “(b) GENERAL ELEMENTS OF PROCESS.—

1 “(1) CONTRACT WITH QUALIFIED EXTERNAL
2 APPEAL ENTITY.—

3 “(A) CONTRACT REQUIREMENT.—Subject
4 to subparagraph (B), the external appeal proc-
5 ess under this section of a plan or issuer shall
6 be conducted under a contract between the plan
7 or issuer and one or more qualified external ap-
8 peal entities (as defined in subsection (c)).

9 “(B) RESTRICTIONS ON QUALIFIED EX-
10 TERNAL APPEAL ENTITY.—

11 “(i) BY STATE FOR HEALTH INSUR-
12 ANCE ISSUERS.—With respect to health in-
13 surance issuers in a State, the State may
14 provide for external review activities to be
15 conducted by a qualified external appeal
16 entity that is designated by the State or
17 that is selected by the State in such a
18 manner as to assure an unbiased deter-
19 mination.

20 “(ii) BY FEDERAL GOVERNMENT FOR
21 GROUP HEALTH PLANS.—With respect to
22 group health plans, the Secretary may ex-
23 ercise the same authority as a State may
24 exercise with respect to health insurance
25 issuers under clause (i). Such authority

1 may include requiring the use of the quali-
2 fied external appeal entity designated or
3 selected under such clause.

4 “(iii) LIMITATION ON PLAN OR
5 ISSUER SELECTION.—If a State or the Sec-
6 retary under this subparagraph permits
7 more than one entity to qualify as a quali-
8 fied external appeal entity with respect to
9 a group health plan or health insurance
10 issuer and the plan or issuer may select
11 among such qualified entities, the State or
12 Secretary shall assure that the selection
13 process will not create any incentives for
14 external appeal entities to make a decision
15 in a biased manner.

16 “(C) OTHER TERMS AND CONDITIONS.—
17 The terms and conditions of a contract under
18 this paragraph shall be consistent with the
19 standards the Secretary shall establish to as-
20 sure there is no real or apparent conflict of in-
21 terest in the conduct of external appeal activi-
22 ties. Such contract shall provide that the direct
23 costs of the process (not including costs of rep-
24 resentation of a participant, beneficiary, or en-

1 rollee) shall be paid by the plan or issuer, and
2 not by the participant, beneficiary, or enrollee.

3 “(2) ELEMENTS OF PROCESS.—An external ap-
4 peal process shall be conducted consistent with
5 standards established by the Secretary that include
6 at least the following:

7 “(A) FAIR PROCESS; DE NOVO DETER-
8 MINATION.—The process shall provide for a
9 fair, de novo determination.

10 “(B) DETERMINATION CONCERNING EX-
11 TERNALLY APPEALABLE DECISIONS.—A quali-
12 fied external appeal entity shall determine
13 whether a decision is an externally appealable
14 decision and related decisions, including—

15 “(i) whether such a decision involves
16 emergency or urgent care,

17 “(ii) the appropriate deadlines for in-
18 ternal review process required due to medi-
19 cal exigencies in a case, and

20 “(iii) whether such a process has been
21 completed.

22 “(C) OPPORTUNITY TO SUBMIT EVIDENCE,
23 HAVE REPRESENTATION, AND MAKE ORAL
24 PRESENTATION.—Each party to an externally
25 appealable decision—

1 “(i) may submit and review evidence
2 related to the issues in dispute,

3 “(ii) may use the assistance or rep-
4 resentation of one or more individuals (any
5 of whom may be an attorney), and

6 “(iii) may make an oral presentation.

7 “(D) PROVISION OF INFORMATION.—The
8 plan or issuer involved shall provide timely ac-
9 cess to all its records relating to the matter of
10 the externally appealable decision and to all
11 provisions of the plan or health insurance cov-
12 erage (including any coverage manual) relating
13 to the matter.

14 “(E) TIMELY DECISIONS.—A determina-
15 tion by the external appeal entity on the deci-
16 sion shall—

17 “(i) be made orally or in writing and,
18 if it is made orally, shall be supplied to the
19 parties in writing as soon as possible;

20 “(ii) be binding on the plan or issuer;

21 “(iii) be made in accordance with the
22 medical exigencies of the case involved, but
23 in no event later than 60 days (or 72
24 hours in the case of an externally appeal-
25 able decision involving emergency or ur-

1 gent care) from the date of completion of
2 the filing of notice of external appeal of
3 the decision;

4 “(iv) state, in layperson’s language,
5 the basis for the determination, including,
6 if relevant, any basis in the terms or condi-
7 tions of the plan or coverage; and

8 “(v) inform the enrollee of the enroll-
9 ee’s rights to seek further review by the
10 courts (or other process) of the external
11 appeal determination.

12 “(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTI-
13 TIES.—

14 “(1) IN GENERAL.—For purposes of this sec-
15 tion, the term ‘qualified external appeal entity’
16 means, in relation to a plan or issuer, an entity
17 (which may be a governmental entity) that is cer-
18 tified under paragraph (2) as meeting the following
19 requirements:

20 “(A) There is no real or apparent conflict
21 of interest that would impede the entity con-
22 ducting external appeal activities independent
23 of the plan or issuer.

24 “(B) The entity conducts external appeal
25 activities through clinical peers.

1 “(C) The entity has sufficient medical,
2 legal, and other expertise and sufficient staffing
3 to conduct external appeal activities for the
4 plan or issuer on a timely basis consistent with
5 subsection (b)(3)(E)(ii).

6 “(D) The entity meets such other require-
7 ments as the Secretary may impose.

8 “(2) CERTIFICATION OF EXTERNAL APPEAL
9 ENTITIES.—

10 “(A) IN GENERAL.—In order to be treated
11 as a qualified external appeal entity with re-
12 spect to—

13 “(i) a group health plan, the entity
14 must be certified (and, in accordance with
15 subparagraph (B), periodically recertified)
16 as meeting the requirements of paragraph
17 (1) by the Secretary of Labor (or under a
18 process recognized or approved by the Sec-
19 retary of Labor); or

20 “(ii) a health insurance issuer operat-
21 ing in a State, the entity must be certified
22 (and, in accordance with subparagraph
23 (B), periodically recertified) as meeting
24 such requirements by the applicable State
25 authority (or, if the States has not estab-

1 lished an adequate certification and recer-
2 tification process, by the Secretary of
3 Health and Human Services, or under a
4 process recognized or approved by such
5 Secretary).

6 “(B) RECERTIFICATION PROCESS.—The
7 Secretary shall develop standards for the recer-
8 tification of external appeal entities. Such
9 standards shall include a specification of—

10 “(i) the information required to be
11 submitted as a condition of recertification
12 on the entity’s performance of external ap-
13 peal activities, which information shall in-
14 clude the number of cases reviewed, a sum-
15 mary of the disposition of those cases, the
16 length of time in making determinations
17 on those cases, and such information as
18 may be necessary to assure the independ-
19 ence of the entity from the plans or issuers
20 for which external appeal activities are
21 being conducted; and

22 “(ii) the periodicity which recertifi-
23 cation will be required.

24 “(3) CLINICAL PEER DEFINED.—For purposes
25 of this subsection, the term ‘clinical peer’ means,

1 with respect to an appeal, a physician (allopathic or
2 osteopathic) or other health care professional who
3 holds a non-restricted license in a State and who is
4 appropriately credentialed in the same or similar
5 specialty as typically manages the medical condition,
6 procedure, or treatment under appeal and includes a
7 pediatric specialist where appropriate.

8 “(d) CONTINUING LEGAL RIGHTS OF ENROLLEES.—
9 Nothing in this section shall be construed as removing any
10 legal rights of participants, beneficiaries, enrollees, and
11 others under State or Federal law, including the right to
12 file judicial actions to enforce rights.

13 “(e) NOTICE.—A group health plan under this part
14 shall comply with the notice requirement under section
15 713(e) of the Employee Retirement Income Security Act
16 of 1974 with respect to the requirements of this section
17 as if such section applied to such plan.”.

18 (B) Section 2723(c) of such Act (42 U.S.C.
19 300gg-23(c)), as amended by section 604(b)(2) of
20 Public Law 104-204, is amended by striking “sec-
21 tion 2704” and inserting “sections 2704 and 2706”.

22 (2) ERISA AMENDMENTS.—(A) Subpart B of
23 part 7 of subtitle B of title I of the Employee Re-
24 tirement Income Security Act of 1974 is amended by
25 adding at the end the following new section:

1 **“SEC. 713. EXTERNAL APPEALS OF ADVERSE DETERMINA-**
2 **TIONS.**

3 “(a) **RIGHT TO EXTERNAL APPEAL.—**

4 “(1) **IN GENERAL.—**A group health plan, and a
5 health insurance issuer offering group health insur-
6 ance coverage, shall provide for an external appeals
7 process that meets the requirements of this section
8 in the case of an externally appealable decision de-
9 scribed in paragraph (2). The Secretary shall estab-
10 lish standards to carry out such requirements.

11 “(2) **EXTERNALLY APPEALABLE DECISION DE-**
12 **FINED.—**For purposes of this section, the term ‘ex-
13 ternally appealable decision’ means a benefit denial,
14 reduction, or termination of, or failure to provide or
15 make, payment (in whole or in part) for, a benefit
16 (including a denial of choice of provider to the ex-
17 tent such a choice is permitted under a plan), if—

18 “(A) the denial or failure involves a deter-
19 mination that a treatment is experimental or in-
20 vestigational in nature;

21 “(B) the denial or failure is based on a de-
22 termination that services are not medically nec-
23 essary or appropriate and the amount involved
24 exceeds a significant threshold; or

25 “(C) the patient’s life or health is jeopard-
26 ized as a consequence of the denial or failure.

1 Such term does not include a denial of (or failure to
2 provide) coverage for services that are specifically
3 stated in plan or coverage documents as an exclusion
4 from coverage.

5 “(3) CONDITIONING APPEAL ON INTERNAL AP-
6 PEALS PROCESS.—A plan or issuer may condition
7 the use of an external appeal process in the case of
8 an externally appealable decision upon completion of
9 an internal review process but only if the internal re-
10 view process provides for a determination on the de-
11 cision in accordance with the medical exigencies of
12 the case involved, but in no event later than 15 busi-
13 ness days (or 72 hours in the case of a decision in-
14 volving emergency or urgent care)of the time of the
15 filing of the request for the internal review.

16 “(b) GENERAL ELEMENTS OF PROCESS.—

17 “(1) CONTRACT WITH QUALIFIED EXTERNAL
18 APPEAL ENTITY.—

19 “(A) CONTRACT REQUIREMENT.—Subject
20 to subparagraph (B), the external appeal proc-
21 ess under this section of a plan or issuer shall
22 be conducted under a contract between the plan
23 or issuer and one or more qualified external ap-
24 peal entities (as defined in subsection (c)).

1 “(B) RESTRICTIONS ON QUALIFIED EX-
2 TERNAL APPEAL ENTITY.—

3 “(i) BY STATE FOR HEALTH INSUR-
4 ANCE ISSUERS.—With respect to health in-
5 surance issuers in a State, the State may
6 provide for external review activities to be
7 conducted by a qualified external appeal
8 entity that is designated by the State or
9 that is selected by the State in such a
10 manner as to assure an unbiased deter-
11 mination.

12 “(ii) BY FEDERAL GOVERNMENT FOR
13 GROUP HEALTH PLANS.—With respect to
14 group health plans, the Secretary may ex-
15 ercise the same authority as a State may
16 exercise with respect to health insurance
17 issuers under clause (i). Such authority
18 may include requiring the use of the quali-
19 fied external appeal entity designated or
20 selected under such clause.

21 “(iii) LIMITATION ON PLAN OR
22 ISSUER SELECTION.—If a State or the Sec-
23 retary under this subparagraph permits
24 more than one entity to qualify as a quali-
25 fied external appeal entity with respect to

1 a group health plan or health insurance
2 issuer and the plan or issuer may select
3 among such qualified entities, the State or
4 Secretary shall assure that the selection
5 process will not create any incentives for
6 external appeal entities to make a decision
7 in a biased manner.

8 “(C) OTHER TERMS AND CONDITIONS.—

9 The terms and conditions of a contract under
10 this paragraph shall be consistent with the
11 standards the Secretary shall establish to as-
12 sure there is no real or apparent conflict of in-
13 terest in the conduct of external appeal activi-
14 ties. Such contract shall provide that the direct
15 costs of the process (not including costs of rep-
16 resentation of a participant, beneficiary, or en-
17 rollee) shall be paid by the plan or issuer, and
18 not by the participant, beneficiary, or enrollee.

19 “(2) ELEMENTS OF PROCESS.—An external ap-
20 peal process shall be conducted consistent with
21 standards established by the Secretary that include
22 at least the following:

23 “(A) FAIR PROCESS; DE NOVO DETER-
24 MINATION.—The process shall provide for a
25 fair, de novo determination.

1 “(B) DETERMINATION CONCERNING EX-
2 TERNALLY APPEALABLE DECISIONS.—A quali-
3 fied external appeal entity shall determine
4 whether a decision is an externally appealable
5 decision and related decisions, including—

6 “(i) whether such a decision involves
7 emergency or urgent care,

8 “(ii) the appropriate deadlines for in-
9 ternal review process required due to medi-
10 cal exigencies in a case, and

11 “(iii) whether such a process has been
12 completed.

13 “(C) OPPORTUNITY TO SUBMIT EVIDENCE,
14 HAVE REPRESENTATION, AND MAKE ORAL
15 PRESENTATION.—Each party to an externally
16 appealable decision—

17 “(i) may submit and review evidence
18 related to the issues in dispute,

19 “(ii) may use the assistance or rep-
20 resentation of one or more individuals (any
21 of whom may be an attorney), and

22 “(iii) may make an oral presentation.

23 “(D) PROVISION OF INFORMATION.—The
24 plan or issuer involved shall provide timely ac-
25 cess to all its records relating to the matter of

1 the externally appealable decision and to all
2 provisions of the plan or health insurance cov-
3 erage (including any coverage manual) relating
4 to the matter.

5 “(E) TIMELY DECISIONS.—A determina-
6 tion by the external appeal entity on the deci-
7 sion shall—

8 “(i) be made orally or in writing and,
9 if it is made orally, shall be supplied to the
10 parties in writing as soon as possible;

11 “(ii) be binding on the plan or issuer;

12 “(iii) be made in accordance with the
13 medical exigencies of the case involved, but
14 in no event later than 60 days (or 72
15 hours in the case of an externally appeal-
16 able decision involving emergency or ur-
17 gent care) from the date of completion of
18 the filing of notice of external appeal of
19 the decision;

20 “(iv) state, in layperson’s language,
21 the basis for the determination, including,
22 if relevant, any basis in the terms or condi-
23 tions of the plan or coverage; and

24 “(v) inform the enrollee of the enroll-
25 ee’s rights to seek further review by the

1 courts (or other process) of the external
2 appeal determination.

3 “(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTI-
4 TIES.—

5 “(1) IN GENERAL.—For purposes of this sec-
6 tion, the term ‘qualified external appeal entity’
7 means, in relation to a plan or issuer, an entity
8 (which may be a governmental entity) that is cer-
9 tified under paragraph (2) as meeting the following
10 requirements:

11 “(A) There is no real or apparent conflict
12 of interest that would impede the entity con-
13 ducting external appeal activities independent
14 of the plan or issuer.

15 “(B) The entity conducts external appeal
16 activities through clinical peers.

17 “(C) The entity has sufficient medical,
18 legal, and other expertise and sufficient staffing
19 to conduct external appeal activities for the
20 plan or issuer on a timely basis consistent with
21 subsection (b)(3)(E)(ii).

22 “(D) The entity meets such other require-
23 ments as the Secretary may impose.

24 “(2) CERTIFICATION OF EXTERNAL APPEAL
25 ENTITIES.—

1 “(A) IN GENERAL.—In order to be treated
2 as a qualified external appeal entity with re-
3 spect to—

4 “(i) a group health plan, the entity
5 must be certified (and, in accordance with
6 subparagraph (B), periodically recertified)
7 as meeting the requirements of paragraph
8 (1) by the Secretary of Labor (or under a
9 process recognized or approved by the Sec-
10 retary of Labor); or

11 “(ii) a health insurance issuer operat-
12 ing in a State, the entity must be certified
13 (and, in accordance with subparagraph
14 (B), periodically recertified) as meeting
15 such requirements by the applicable State
16 authority (or, if the States has not estab-
17 lished an adequate certification and recer-
18 tification process, by the Secretary of
19 Health and Human Services, or under a
20 process recognized or approved by such
21 Secretary).

22 “(B) RECERTIFICATION PROCESS.—The
23 Secretary shall develop standards for the recer-
24 tification of external appeal entities. Such
25 standards shall include a specification of—

1 “(i) the information required to be
2 submitted as a condition of recertification
3 on the entity’s performance of external ap-
4 peal activities, which information shall in-
5 clude the number of cases reviewed, a sum-
6 mary of the disposition of those cases, the
7 length of time in making determinations
8 on those cases, and such information as
9 may be necessary to assure the independ-
10 ence of the entity from the plans or issuers
11 for which external appeal activities are
12 being conducted; and

13 “(ii) the periodicity which recertifi-
14 cation will be required.

15 “(3) CLINICAL PEER DEFINED.—For purposes
16 of this subsection, the term ‘clinical peer’ means,
17 with respect to an appeal, a physician (allopathic or
18 osteopathic) or other health care professional who
19 holds a non-restricted license in a State and who is
20 appropriately credentialed in the same or similar
21 specialty as typically manages the medical condition,
22 procedure, or treatment under appeal and includes a
23 pediatric specialist where appropriate.

24 “(d) CONTINUING LEGAL RIGHTS OF ENROLLEES.—
25 Nothing in this section shall be construed as removing any

1 legal rights of participants, beneficiaries, enrollees, and
2 others under State or Federal law, including the right to
3 file judicial actions to enforce rights.

4 “(e) NOTICE UNDER GROUP HEALTH PLAN.—The
5 imposition of the requirement of this section shall be treat-
6 ed as a material modification in the terms of the plan de-
7 scribed in section 102(a)(1), for purposes of assuring no-
8 tice of such requirements under the plan; except that the
9 summary description required to be provided under the
10 last sentence of section 104(b)(1) with respect to such
11 modification shall be provided by not later than 60 days
12 after the first day of the first plan year in which such
13 requirement apply.”.

14 (B) Section 731(e) of such Act (29 U.S.C.
15 1191(e)) is amended by striking “section 711” and
16 inserting “sections 711 and 713”.

17 (C) Section 732(a) of such Act (29 U.S.C.
18 1191a(a)) is amended by striking “section 711” and
19 inserting “sections 711 and 713”.

20 (D) The table of contents in section 1 of such
21 Act is amended by inserting after the item relating
22 to section 712 the following new item:

“Sec. 713. External appeals of adverse determinations.”.

23 (3) INTERNAL REVENUE CODE AMEND-
24 MENTS.—Subchapter B of chapter 100 of the Inter-
25 nal Revenue Code of 1986 (as amended by section

1 1531(a) of the Taxpayer Relief Act of 1997) is
 2 amended—

3 (A) in the table of sections, by inserting
 4 after the item relating to section 9812 the fol-
 5 lowing new item:

“Sec. 9813. External appeals of adverse determinations.”;

6 and

7 (B) by inserting after section 9812 the fol-
 8 lowing:

9 **“SEC. 9813. EXTERNAL APPEALS OF ADVERSE DETERMINA-**
 10 **TIONS.**

11 “(a) RIGHT TO EXTERNAL APPEAL.—

12 “(1) IN GENERAL.—A group health plan shall
 13 provide for an external appeals process that meets
 14 the requirements of this section in the case of an ex-
 15 ternally appealable decision described in paragraph
 16 (2). The Secretary shall establish standards to carry
 17 out such requirements.

18 “(2) EXTERNALLY APPEALABLE DECISION DE-
 19 FINED.—For purposes of this section, the term ‘ex-
 20 ternally appealable decision’ means a benefit denial,
 21 reduction, or termination of, or failure to provide or
 22 make, payment (in whole or in part) for, a benefit
 23 (including a denial of choice of provider to the ex-
 24 tent such a choice is permitted under a plan), if—

1 “(A) the denial or failure involves a deter-
2 mination that a treatment is experimental or in-
3 vestigational in nature;

4 “(B) the denial or failure is based on a de-
5 termination that services are not medically nec-
6 essary or appropriate and the amount involved
7 exceeds a significant threshold; or

8 “(C) the patient’s life or health is jeopard-
9 ized as a consequence of the denial or failure.

10 Such term does not include a denial of (or failure to
11 provide) coverage for services that are specifically
12 stated in plan documents as an exclusion from cov-
13 erage.

14 “(3) CONDITIONING APPEAL ON INTERNAL AP-
15 PEALS PROCESS.—A plan may condition the use of
16 an external appeal process in the case of an exter-
17 nally appealable decision upon completion of an in-
18 ternal review process but only if the internal review
19 process provides for a determination on the decision
20 in accordance with the medical exigencies of the case
21 involved, but in no event later than 15 business days
22 (or 72 hours in the case of a decision involving
23 emergency or urgent care) of the time of the filing
24 of the request for the internal review.

25 “(b) GENERAL ELEMENTS OF PROCESS.—

1 “(1) CONTRACT WITH QUALIFIED EXTERNAL
2 APPEAL ENTITY.—

3 “(A) CONTRACT REQUIREMENT.—Subject
4 to subparagraph (B), the external appeal proc-
5 ess under this section of a plan shall be con-
6 ducted under a contract between the plan and
7 one or more qualified external appeal entities
8 (as defined in subsection (c)).

9 “(B) RESTRICTIONS ON QUALIFIED EX-
10 TERNAL APPEAL ENTITY.—

11 “(i) IN GENERAL.—The Secretary
12 may provide for external review activities
13 to be conducted by a qualified external ap-
14 peal entity that is designated by the Sec-
15 retary or that is selected by the Secretary
16 in such a manner as to assure an unbiased
17 determination.

18 “(ii) LIMITATION ON PLAN SELEC-
19 TION.—If the Secretary under this sub-
20 paragraph permits more than one entity to
21 qualify as a qualified external appeal entity
22 with respect to a group health plan and
23 the plan may select among such qualified
24 entities, the Secretary shall assure that the
25 selection process will not create any incen-

1 tives for external appeal entities to make a
2 decision in a biased manner.

3 “(C) OTHER TERMS AND CONDITIONS.—

4 The terms and conditions of a contract under
5 this paragraph shall be consistent with the
6 standards the Secretary shall establish to as-
7 sure there is no real or apparent conflict of in-
8 terest in the conduct of external appeal activi-
9 ties. Such contract shall provide that the direct
10 costs of the process (not including costs of rep-
11 resentation of a participant or beneficiary) shall
12 be paid by the plan, and not by the participant
13 or beneficiary.

14 “(2) ELEMENTS OF PROCESS.—An external ap-
15 peal process shall be conducted consistent with
16 standards established by the Secretary that include
17 at least the following:

18 “(A) FAIR PROCESS; DE NOVO DETER-
19 MINATION.—The process shall provide for a
20 fair, de novo determination.

21 “(B) DETERMINATION CONCERNING EX-
22 TERNALLY APPEALABLE DECISIONS.—A quali-
23 fied external appeal entity shall determine
24 whether a decision is an externally appealable
25 decision and related decisions, including—

1 “(i) whether such a decision involves
2 emergency or urgent care,

3 “(ii) the appropriate deadlines for in-
4 ternal review process required due to medi-
5 cal exigencies in a case, and

6 “(iii) whether such a process has been
7 completed.

8 “(C) OPPORTUNITY TO SUBMIT EVIDENCE,
9 HAVE REPRESENTATION, AND MAKE ORAL
10 PRESENTATION.—Each party to an externally
11 appealable decision—

12 “(i) may submit and review evidence
13 related to the issues in dispute,

14 “(ii) may use the assistance or rep-
15 resentation of one or more individuals (any
16 of whom may be an attorney), and

17 “(iii) may make an oral presentation.

18 “(D) PROVISION OF INFORMATION.—The
19 plan involved shall provide timely access to all
20 its records relating to the matter of the exter-
21 nally appealable decision and to all provisions of
22 the plan (including any coverage manual) relat-
23 ing to the matter.

1 “(E) TIMELY DECISIONS.—A determina-
2 tion by the external appeal entity on the deci-
3 sion shall—

4 “(i) be made orally or in writing and,
5 if it is made orally, shall be supplied to the
6 parties in writing as soon as possible;

7 “(ii) be binding on the plan;

8 “(iii) be made in accordance with the
9 medical exigencies of the case involved, but
10 in no event later than 60 days (or 72
11 hours in the case of an externally appeal-
12 able decision involving emergency or ur-
13 gent care) from the date of completion of
14 the filing of notice of external appeal of
15 the decision;

16 “(iv) state, in layperson’s language,
17 the basis for the determination, including,
18 if relevant, any basis in the terms or condi-
19 tions of the plan; and

20 “(v) inform the participant, bene-
21 ficiary, or enrollee of the individual’s rights
22 to seek further review by the courts (or
23 other process) of the external appeal deter-
24 mination.

1 “(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTI-
2 TIES.—

3 “(1) IN GENERAL.—For purposes of this sec-
4 tion, the term ‘qualified external appeal entity’
5 means, in relation to a group health plan, an entity
6 (which may be a governmental entity) that is cer-
7 tified under paragraph (2) as meeting the following
8 requirements:

9 “(A) There is no real or apparent conflict
10 of interest that would impede the entity con-
11 ducting external appeal activities independent
12 of the plan.

13 “(B) The entity conducts external appeal
14 activities through clinical peers.

15 “(C) The entity has sufficient medical,
16 legal, and other expertise and sufficient staffing
17 to conduct external appeal activities for the
18 plan on a timely basis consistent with sub-
19 section (b)(3)(E)(ii).

20 “(D) The entity meets such other require-
21 ments as the Secretary may impose.

22 “(2) CERTIFICATION OF EXTERNAL APPEAL
23 ENTITIES.—

24 “(A) IN GENERAL.—In order to be treated
25 as a qualified external appeal entity with re-

1 spect to a group health plan, the entity must be
2 certified (and, in accordance with subparagraph
3 (B), periodically recertified) as meeting the re-
4 quirements of paragraph (1) by the Secretary
5 of Labor (or under a process recognized or ap-
6 proved by the Secretary of Labor.

7 “(B) RECERTIFICATION PROCESS.—The
8 Secretary shall develop standards for the recer-
9 tification of external appeal entities. Such
10 standards shall include a specification of—

11 “(i) the information required to be
12 submitted as a condition of recertification
13 on the entity’s performance of external ap-
14 peal activities, which information shall in-
15 clude the number of cases reviewed, a sum-
16 mary of the disposition of those cases, the
17 length of time in making determinations
18 on those cases, and such information as
19 may be necessary to assure the independ-
20 ence of the entity from the plans for which
21 external appeal activities are being con-
22 ducted; and

23 “(ii) the periodicity which recertifi-
24 cation will be required.

1 “(3) CLINICAL PEER DEFINED.—For purposes
2 of this subsection, the term ‘clinical peer’ means,
3 with respect to an appeal, a physician (allopathic or
4 osteopathic) or other health care professional who
5 holds a non-restricted license in a State and who is
6 appropriately credentialed in the same or similar
7 specialty as typically manages the medical condition,
8 procedure, or treatment under appeal and includes a
9 pediatric specialist where appropriate.”

10 (b) INDIVIDUAL HEALTH INSURANCE.—(1) Part B
11 of title XXVII of the Public Health Service Act is amend-
12 ed by inserting after section 2751 the following new sec-
13 tion:

14 **“SEC. 2752. EXTERNAL REVIEW PROCESS.**

15 “(a) IN GENERAL.—The provisions of section 2706
16 (other than subsection (e)) shall apply to health insurance
17 coverage offered by a health insurance issuer in the indi-
18 vidual market in the same manner as they apply to health
19 insurance coverage offered by a health insurance issuer
20 in connection with a group health plan in the small or
21 large group market.

22 “(b) NOTICE.—A health insurance issuer under this
23 part shall comply with the notice requirement under sec-
24 tion 713(3) of the Employee Retirement Income Security
25 Act of 1974 with respect to the requirements referred to

1 in subsection (a) as if such section applied to such issuer
2 and such issuer were a group health plan.”.

3 (2) Section 2762(b)(2) of such Act (42 U.S.C.
4 300gg-62(b)(2)) is amended by striking “section 2751”
5 and inserting “sections 2751 and 2752”.

6 (c) AUTHORITY TO APPLY STANDARDS TO MEDI-
7 CARE AND MEDICAID PROGRAMS.—The Secretary of
8 Health and Human Services may apply the requirements
9 of section 2706 of the Public Health Service Act to
10 Medicare+Choice organizations offering plans under part
11 C under title XVIII of the Social Security Act, eligible or-
12 ganizations offering coverage under section 1876 of such
13 Act, medicaid managed care organizations or managed
14 care entity offering coverage under section 1932 of such
15 Act, and similar organizations and entities offering cov-
16 erage under title XVIII or XIX of such Act, to the extent
17 that the Secretary finds that such requirements provide
18 greater protections for enrollees under such titles and do
19 not conflict directly with requirements otherwise imposed
20 by law relating to external review and appeals.

21 (d) EFFECTIVE DATES.—

22 (1) GROUP HEALTH PLANS.—

23 (A) IN GENERAL.—Subject to subpara-
24 graph (B), the amendments made by subsection

25 (a) shall apply with respect to group health

1 plans for plan years beginning on or after Jan-
2 uary 1, 1999.

3 (B) RULE FOR CERTAIN COLLECTIVE BAR-
4 GAINING AGREEMENTS.—In the case of a group
5 health plan maintained pursuant to 1 or more
6 collective bargaining agreements between em-
7 ployee representatives and 1 or more employers
8 ratified before the date of enactment of this
9 Act, the amendments made by subsection (a)
10 shall not apply to plan years beginning before
11 the later of—

12 (i) the date on which the last collec-
13 tive bargaining agreements relating to the
14 plan terminates (determined without re-
15 gard to any extension thereof agreed to
16 after the date of enactment of this Act), or
17 (ii) January 1, 1999.

18 For purposes of clause (i), any plan amendment
19 made pursuant to a collective bargaining agree-
20 ment relating to the plan which amends the
21 plan solely to conform to any requirement
22 added by subsection (a) shall not be treated as
23 a termination of such collective bargaining
24 agreement.

1 (2) INDIVIDUAL HEALTH INSURANCE COV-
2 ERAGE.—The amendment made by subsection (b)
3 shall apply with respect to health insurance coverage
4 offered, sold, issued, renewed, in effect, or operated
5 in the individual market on or after such date.

6 (e) COORDINATED REGULATIONS.—Section 104(1) of
7 Health Insurance Portability and Accountability Act of
8 1996 is amended by striking “this subtitle (and the
9 amendments made by this subtitle and section 401)” and
10 inserting “the provisions of part 7 of subtitle B of title
11 I of the Employee Retirement Income Security Act of
12 1974, the provisions of parts A and C of title XXVII of
13 the Public Health Service Act, and chapter 100 of the In-
14 ternal Revenue Code of 1986”.

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