

**AMENDMENT TO THE AMENDMENT IN THE NA-
TURE OF A SUBSTITUTE TO H.R. 4872, AS RE-
PORTED**

OFFERED BY MR. BURGESS OF TEXAS

Add at the end the following new section (and conform the table of contents accordingly):

1 **SEC. 2304. REQUIRING FAIR GRIEVANCE AND APPEALS**
2 **MECHANISMS.**

3 The Public Health Service Act (as amended by the
4 Patient Protection and Affordable Care Act) is amended—

5 (1) by redesignating section 2719A as section
6 2719C; and

7 (2) by striking section 2719 and inserting the
8 following:

9 **“SEC. 2719. UTILIZATION REVIEW ACTIVITIES.**

10 **“(a) COMPLIANCE WITH REQUIREMENTS.—**

11 **“(1) IN GENERAL.—**A group health plan and a
12 health insurance issuer offering group or individual
13 health insurance coverage shall conduct utilization
14 review activities in connection with the provision of
15 benefits under such plan or coverage only in accord-
16 ance with a utilization review program that meets
17 the requirements of this section.

1 “(2) USE OF OUTSIDE AGENTS.—Nothing in
2 this section shall be construed as preventing a group
3 health plan or health insurance issuer from arrang-
4 ing through a contract or otherwise for persons or
5 entities to conduct utilization review activities on be-
6 half of the plan or issuer, so long as such activities
7 are conducted in accordance with a utilization review
8 program that meets the requirements of this section.

9 “(3) UTILIZATION REVIEW DEFINED.—For pur-
10 poses of this section, the terms ‘utilization review’
11 and ‘utilization review activities’ mean procedures
12 used to monitor or evaluate the use or coverage,
13 clinical necessity, appropriateness, efficacy, or effi-
14 ciency of health care services, procedures or settings,
15 and includes prospective review, concurrent review,
16 second opinions, case management, discharge plan-
17 ning, or retrospective review.

18 “(b) WRITTEN POLICIES AND CRITERIA.—

19 “(1) WRITTEN POLICIES.—A utilization review
20 program shall be conducted consistent with written
21 policies and procedures that govern all aspects of the
22 program.

23 “(2) USE OF WRITTEN CRITERIA.—

24 “(A) IN GENERAL.—Such a program shall
25 utilize written clinical review criteria developed

1 with input from a range of appropriate actively
2 practicing health care professionals, as deter-
3 mined by the plan or issuer, pursuant to the
4 program. Such criteria shall include written
5 clinical review criteria that are based on valid
6 clinical evidence where available and that are
7 directed specifically at meeting the needs of at-
8 risk populations and covered individuals with
9 chronic conditions or severe illnesses, including
10 gender-specific criteria and pediatric-specific
11 criteria where available and appropriate.

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

22 “(C) REVIEW OF SAMPLE OF CLAIMS DE-
23 NIALS.—Such a program shall provide for an
24 evaluation of the clinical appropriateness of at
25 least a sample of denials of claims for benefits.

1 “(c) CONDUCT OF PROGRAM ACTIVITIES.—

2 “(1) ADMINISTRATION BY HEALTH CARE PRO-
3 FESSIONALS.—A utilization review program shall be
4 administered by qualified health care professionals
5 who shall oversee review decisions.

6 “(2) USE OF QUALIFIED, INDEPENDENT PER-
7 SONNEL.—

8 “(A) IN GENERAL.—A utilization review
9 program shall provide for the conduct of utiliza-
10 tion review activities only through personnel
11 who are qualified and have received appropriate
12 training in the conduct of such activities under
13 the program.

14 “(B) PROHIBITION OF CONTINGENT COM-
15 PENSATION ARRANGEMENTS.—Such a program
16 shall not, with respect to utilization review ac-
17 tivities, permit or provide compensation or any-
18 thing of value to its employees, agents, or con-
19 tractors in a manner that encourages denials of
20 claims for benefits.

21 “(C) PROHIBITION OF CONFLICTS.—Such
22 a program shall not permit a health care pro-
23 fessional who is providing health care services
24 to an individual to perform utilization review

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

3 “(3) ACCESSIBILITY OF REVIEW.—Such a pro-
4 gram shall provide that appropriate personnel per-
5 forming utilization review activities under the pro-
6 gram, including the utilization review administrator,
7 are reasonably accessible by tollfree telephone during
8 normal business hours to discuss patient care and
9 allow response to telephone requests, and that ap-
10 propriate provision is made to receive and respond
11 promptly to calls received during other hours.

12 “(4) LIMITS ON FREQUENCY.—Such a program
13 shall not provide for the performance of utilization
14 review activities with respect to a class of services
15 furnished to an individual more frequently than is
16 reasonably required to assess whether the services
17 under review are medically necessary or appropriate.

18 “(d) DEADLINE FOR DETERMINATIONS.—

19 “(1) PRIOR AUTHORIZATION SERVICES.—

20 “(A) IN GENERAL.—Except as provided in
21 paragraph (2), in the case of a utilization re-
22 view activity involving the prior authorization of
23 health care items and services for an individual,
24 the utilization review program shall make a de-
25 termination concerning such authorization, and

1 provide notice of the determination to the indi-
2 vidual or the individual's designee and the indi-
3 vidual's health care provider by telephone and
4 in printed form, as soon as possible in accord-
5 ance with the medical exigencies of the case,
6 and in no event later than the deadline specified
7 in subparagraph (B).

8 “(B) DEADLINE.—

9 “(i) IN GENERAL.—Subject to clauses
10 (ii), (iii), and (iv), the deadline specified in
11 this subparagraph is 14 days after the
12 date of receipt of the request for prior au-
13 thorization, but in no event later than 3
14 business days after the date of receipt of
15 information that is reasonably necessary to
16 make such determination.

17 “(ii) EXTENSION PERMITTED WHERE
18 NOTICE OF ADDITIONAL INFORMATION RE-
19 QUIRED.—If a utilization review pro-
20 gram—

21 “(I) receives a request for a prior
22 authorization;

23 “(II) determines that additional
24 information is necessary to complete

1 the review and make the determina-
2 tion on the request; and

3 “(III) notifies the requester, not
4 later than 5 business days after the
5 date of receiving the request, of the
6 need for such specified additional in-
7 formation; the deadline specified in
8 this subparagraph is 14 days after the
9 date the program receives the speci-
10 fied additional information, but in no
11 case later than 28 days after the date
12 of receipt of the request for the prior
13 authorization. This clause shall not
14 apply if the deadline is specified in
15 clause (iii).

16 “(iii) EXPEDITED CASES.—In the case
17 of a situation described in section
18 2719A(c)(1)(A), the deadline specified in
19 this subparagraph is 72 hours after the
20 time of the request for prior authorization.

21 “(iv) EXCEPTION FOR EMERGENCY
22 SERVICES.—No prior approval shall be re-
23 quired in the case of emergency services
24 provided by a hospital.

25 “(2) ONGOING CARE.—

1 “(A) CONCURRENT REVIEW.—

2 “(i) IN GENERAL.—Subject to sub-
3 paragraph (B), in the case of a concurrent
4 review of ongoing care (including hos-
5 pitalization), which results in a termination
6 or reduction of such care, the plan or
7 issuer must provide by telephone and in
8 printed form notice of the concurrent re-
9 view determination to the individual or the
10 individual’s designee and the individual’s
11 health care provider as soon as possible in
12 accordance with the medical exigencies of
13 the case, and in no event later than 1 busi-
14 ness day after the date of receipt of infor-
15 mation that is reasonably necessary to
16 make such determination, with sufficient
17 time prior to the termination or reduction
18 to allow for an appeal under section
19 2719A(c)(1)(A) to be completed before the
20 termination or reduction takes effect.

21 “(ii) CONTENTS OF NOTICE.—Such
22 notice shall include, with respect to ongo-
23 ing health care items and services, the
24 number of ongoing services approved, the
25 new total of approved services, the date of

1 onset of services, and the next review date,
2 if any, as well as a statement of the indi-
3 vidual's rights to further appeal.

4 “(B) EXCEPTION.—Subparagraph (A)
5 shall not be interpreted as requiring plans or
6 issuers to provide coverage of care that would
7 exceed the coverage limitations for such care.

8 “(3) PREVIOUSLY PROVIDED SERVICES.—In the
9 case of a utilization review activity involving retro-
10 spective review of health care services previously pro-
11 vided for an individual, the utilization review pro-
12 gram shall make a determination concerning such
13 services, and provide notice of the determination to
14 the individual or the individual's designee and the
15 individual's health care provider by telephone and in
16 printed form, within 30 days of the date of receipt
17 of information that is reasonably necessary to make
18 such determination, but in no case later than 60
19 days after the date of receipt of the claim for bene-
20 fits.

21 “(4) FAILURE TO MEET DEADLINE.—In a case
22 in which a plan or issuer fails to make a determina-
23 tion on a claim for benefit under paragraph (1),
24 (2)(A), or (3) by the applicable deadline established
25 under the respective paragraph, the failure shall be

1 treated under this subtitle as a denial of the claim
2 as of the date of the deadline.

3 “(e) NOTICE OF DENIALS OF CLAIMS FOR BENE-
4 FITS.—

5 “(1) IN GENERAL.—Notice of a denial of claims
6 for benefits under a utilization review program shall
7 be provided in printed form and written in a manner
8 calculated to be understood by the participant, bene-
9 ficiary, or enrollee and shall include—

10 “(A) the reasons for the denial (including
11 the clinical rationale);

12 “(B) instructions on how to initiate an ap-
13 peal under section 2719A; and

14 “(C) notice of the availability, upon re-
15 quest of the individual (or the individual’s des-
16 ignee) of the clinical review criteria relied upon
17 to make such denial.

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

24 “(f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM
25 FOR BENEFITS DEFINED.—For purposes of this subtitle:

1 “(1) CLAIM FOR BENEFITS.—The term ‘claim
2 for benefits’ means any request for coverage (includ-
3 ing authorization of coverage), for eligibility, or for
4 payment in whole or in part, for an item or service
5 under a qualified health plan.

6 “(2) DENIAL OF CLAIM FOR BENEFITS.—The
7 term ‘denial’ means, with respect to a claim for ben-
8 efits, means a denial, or a failure to act on a timely
9 basis upon, in whole or in part, the claim for bene-
10 fits and includes a failure to provide benefits (in-
11 cluding items and services) required to be provided
12 under this part.

13 **“SEC. 2719A. INTERNAL APPEALS PROCEDURES.**

14 “(a) RIGHT OF REVIEW.—

15 “(1) IN GENERAL.—Each group health plan
16 and each health insurance issuer offering group or
17 individual health insurance coverage—

18 “(A) shall provide adequate notice in writ-
19 ing to any participant or beneficiary under such
20 plan, or enrollee under such coverage, whose
21 claim for benefits under the plan or coverage
22 has been denied (within the meaning of section
23 2719(f)(2)), setting forth the specific reasons
24 for such denial of claim for benefits and rights
25 to any further review or appeal, written in a

1 manner calculated to be understood by the par-
2 ticipant, beneficiary, or enrollee; and

3 “(B) shall afford such a participant, bene-
4 ficiary, or enrollee (and any provider or other
5 person acting on behalf of such an individual
6 with the individual’s consent or without such
7 consent if the individual is medically unable to
8 provide such consent) who is dissatisfied with
9 such a denial of claim for benefits a reasonable
10 opportunity (of not less than 180 days) to re-
11 quest and obtain a full and fair review by a
12 named fiduciary (with respect to such plan) or
13 named appropriate individual (with respect to
14 such coverage) of the decision denying the
15 claim.

16 “(2) TREATMENT OF ORAL REQUESTS.—The
17 request for review under paragraph (1)(B) may be
18 made orally, but, in the case of an oral request, shall
19 be followed by a request in writing.

20 “(b) INTERNAL REVIEW PROCESS.—

21 “(1) CONDUCT OF REVIEW.—

22 “(A) IN GENERAL.—A review of a denial
23 of claim under this section shall be made by an
24 individual who—

1 “(i) in a case involving medical judgment, shall be a physician or, in the case
2 of limited scope coverage (as defined in
3 subparagraph (B), shall be an appropriate
4 specialist;
5

6 “(ii) has been selected by the plan or
7 issuer; and

8 “(iii) did not make the initial denial
9 in the internally appealable decision.

10 “(B) LIMITED SCOPE COVERAGE DE-
11 FINED.—For purposes of subparagraph (A), the
12 term ‘limited scope coverage’ means a plan or
13 coverage the only benefits under which are for
14 benefits described in section 2791(c)(2)(A).

15 “(2) TIME LIMITS FOR INTERNAL REVIEWS.—

16 “(A) IN GENERAL.—Having received such
17 a request for review of a denial of claim, the
18 plan administrator or issuer, in accordance with
19 the medical exigencies of the case but not later
20 than the deadline specified in subparagraph
21 (B), complete the review on the denial and
22 transmit to the participant, beneficiary, en-
23 rollee, or other person involved a decision that
24 affirms, reverses, or modifies the denial. If the
25 decision does not reverse the denial, the plan

1 administrator or issuer shall transmit, in print-
2 ed form, a notice that sets forth the grounds
3 for such decision and that includes a descrip-
4 tion of rights to any further appeal. Such deci-
5 sion shall be treated as the final decision of the
6 plan administrator or issuer. Failure to issue
7 such a decision by such deadline shall be treat-
8 ed as a final decision affirming the denial of
9 claim.

10 “(B) DEADLINE.—

11 “(i) IN GENERAL.—Subject to clauses
12 (ii) and (iii), the deadline specified in this
13 subparagraph is 14 days after the date of
14 receipt of the request for internal review.

15 “(ii) EXTENSION PERMITTED WHERE
16 NOTICE OF ADDITIONAL INFORMATION RE-
17 QUIRED.—If the plan administrator or
18 issuer—

19 “(I) receives a request for inter-
20 nal review,

21 “(II) determines that additional
22 information is necessary to complete
23 the review and make the determina-
24 tion on the request, and

1 “(III) notifies the requester, not
2 later than 5 business days after the
3 date of receiving the request, of the
4 need for such specified additional in-
5 formation, the deadline specified in
6 this subparagraph is 14 days after the
7 date the plan administrator or issuer
8 receives the specified additional infor-
9 mation, but in no case later than 28
10 days after the date of receipt of the
11 request for the internal review. This
12 clause shall not apply if the deadline
13 is specified in clause (iii).

14 “(iii) EXPEDITED CASES.—In the case
15 of a situation described in subsection
16 (c)(1)(A), the deadline specified in this
17 subparagraph is 72 hours after the time of
18 the request for review.

19 “(c) EXPEDITED REVIEW PROCESS.—

20 “(1) IN GENERAL.—The plan administrator of
21 a group health plan and a health insurance issuer
22 offering group or individual health insurance cov-
23 erage shall establish procedures in writing for the
24 expedited consideration of requests for review under
25 subsection (b) in situations—

1 “(A) in which, as determined by the plan
2 administrator or issuer or as certified in writing
3 by a treating health care professional, the appli-
4 cation of the normal timeframe for making a
5 determination could seriously jeopardize the life
6 or health of the participant, beneficiary, or en-
7 rollee or such an individual’s ability to regain
8 maximum function; or

9 “(B) described in section 2719(d)(2) (re-
10 lating to requests for continuation of ongoing
11 care which would otherwise be reduced or ter-
12 minated).

13 “(2) PROCESS.—Under such procedures—

14 “(A) the request for expedited review may
15 be submitted orally or in writing by an indi-
16 vidual or provider who is otherwise entitled to
17 request the review;

18 “(B) all necessary information, including
19 the plan administrator’s or issuer’s decision,
20 shall be transmitted between the plan adminis-
21 trator or issuer and the requester by telephone,
22 facsimile, or other similarly expeditious avail-
23 able method; and

24 “(C) the plan administrator or issuer shall
25 expedite the review in the case of any of the sit-

1 uations described in subparagraph (A) or (B) of
2 paragraph (1).

3 “(3) DEADLINE FOR DECISION.—The decision
4 on the expedited review must be made and commu-
5 nicated to the parties as soon as possible in accord-
6 ance with the medical exigencies of the case, and in
7 no event later than 72 hours after the time of re-
8 ceipt of the request for expedited review, except that
9 in a case described in paragraph (1)(B), the decision
10 must be made before the end of the approved period
11 of care.

12 “(d) WAIVER OF PROCESS.—The plan administrator
13 or issuer may waive its rights for an internal review under
14 subsection (b). In such case the participant, beneficiary,
15 or enrollee involved (and any designee or provider in-
16 volved) shall be relieved of any obligation to complete the
17 review involved and may, at the option of such participant,
18 beneficiary, enrollee, designee, or provider, proceed di-
19 rectly to seek further appeal through any applicable exter-
20 nal appeals process.

21 **“SEC. 2719B. EXTERNAL APPEALS PROCEDURES.**

22 “(a) RIGHT TO EXTERNAL APPEAL.—

23 “(1) IN GENERAL.—A group health plan and a
24 health insurance issuer offering group or individual
25 health insurance coverage shall provide for an exter-

1 nal appeals process that meets the requirements of
2 this section in the case of an externally appealable
3 decision described in paragraph (2), for which a
4 timely appeal is made either by the plan adminis-
5 trator or issuer or by the participant, beneficiary, or
6 enrollee (and any provider or other person acting on
7 behalf of such an individual with the individual's
8 consent or without such consent if such an indi-
9 vidual is medically unable to provide such consent).
10 The appropriate Secretary shall establish standards
11 to carry out such requirements.

12 “(2) EXTERNALLY APPEALABLE DECISION DE-
13 FINED.—

14 “(A) IN GENERAL.—For purposes of this
15 section, the term ‘externally appealable decision’
16 means a denial of claim for benefits (as defined
17 in section 2719(f)(2))—

18 “(i) that is based in whole or in part
19 on a decision that the item or service is not
20 medically necessary or appropriate or is in-
21 vestigational or experimental; or

22 “(ii) in which the decision as to
23 whether a benefit is covered involves a
24 medical judgment.

1 “(B) INCLUSION.—Such term also includes
2 a failure to meet an applicable deadline for in-
3 ternal review under section 2719A.

4 “(C) EXCLUSIONS.—Such term does not
5 include—

6 “(i) specific exclusions or express limi-
7 tations on the amount, duration, or scope
8 of coverage that do not involve medical
9 judgment; or

10 “(ii) a decision regarding whether an
11 individual is a participant, beneficiary, or
12 enrollee under the plan or coverage.

13 “(3) EXHAUSTION OF INTERNAL REVIEW PROC-
14 ESS.—Except as provided under section 2719A(d), a
15 plan or issuer may condition the use of an external
16 appeal process in the case of an externally appeal-
17 able decision upon a final decision in an internal re-
18 view under section 2719A, but only if the decision
19 is made in a timely basis consistent with the dead-
20 lines provided under this part.

21 “(4) FILING FEE REQUIREMENT.—

22 “(A) IN GENERAL.—Subject to subpara-
23 graph (B), a plan or issuer may condition the
24 use of an external appeal process upon payment

1 to the plan or issuer of a filing fee that does
2 not exceed \$25.

3 “(B) EXCEPTION FOR INDIGENCY.—The
4 plan or issuer may not require payment of the
5 filing fee in the case of an individual partici-
6 pant, beneficiary, or enrollee who certifies (in a
7 form and manner specified in guidelines estab-
8 lished by the Secretary) that the individual is
9 indigent (as defined in such guidelines).

10 “(C) REFUNDING FEE IN CASE OF SUC-
11 CESSFUL APPEALS.—The plan administrator or
12 issuer shall refund payment of the filing fee
13 under this paragraph if the recommendation of
14 the external appeal entity is to reverse or mod-
15 ify the denial of a claim for benefits which is
16 the subject of the appeal.

17 “(b) GENERAL ELEMENTS OF EXTERNAL APPEALS
18 PROCESS.—

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

21 “(A) CONTRACT REQUIREMENT.—Except
22 as provided in subparagraph (D), the external
23 appeal process under this section of a plan or
24 issuer shall be conducted under a contract be-
25 tween the plan or issuer and one or more quali-

1 fied external appeal entities (as defined in sub-
2 section (c)).

3 “(B) LIMITATION ON PLAN OR ISSUER SE-
4 LECTION.—The Secretary shall implement pro-
5 cedures—

6 “(i) to assure that the selection proc-
7 ess among qualified external appeal enti-
8 ties will not create any incentives for exter-
9 nal appeal entities to make a decision in a
10 biased manner, and

11 “(ii) for auditing a sample of deci-
12 sions by such entities to assure that no
13 such decisions are made in a biased man-
14 ner.

15 “(C) OTHER TERMS AND CONDITIONS.—
16 The terms and conditions of a contract under
17 this paragraph shall be consistent with the
18 standards the Secretary shall establish to as-
19 sure there is no real or apparent conflict of in-
20 terest in the conduct of external appeal activi-
21 ties. Such contract shall provide that all costs
22 of the process (except those incurred by the
23 participant, beneficiary, enrollee, or treating
24 professional in support of the appeal) shall be
25 paid by the plan or issuer, and not by the par-

1 ticipant, beneficiary, or enrollee. The previous
2 sentence shall not be construed as applying to
3 the imposition of a filing fee under subsection
4 (a)(4).

5 “(D) STATE AUTHORITY WITH RESPECT
6 TO QUALIFIED EXTERNAL APPEAL ENTITY FOR
7 HEALTH INSURANCE ISSUERS.—With respect to
8 group or individual health insurance coverage
9 offered in a State, the State may provide for
10 external review activities to be conducted by a
11 qualified external appeal entity that is des-
12 ignated by the State or that is selected by the
13 State in a manner determined by the State to
14 assure an unbiased determination.

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

19 “(A) FAIR AND DE NOVO DETERMINA-
20 TION.—The process shall provide for a fair, de
21 novo determination. However, nothing in this
22 paragraph shall be construed as providing for
23 coverage of items and services for which bene-
24 fits are specifically excluded under the plan or
25 coverage.

1 “(B) STANDARD OF REVIEW.—An external
2 appeal entity shall determine whether the plan
3 administrator’s or issuer’s decision is in accord-
4 ance with the medical needs of the patient in-
5 volved (as determined by the entity) taking into
6 account, as of the time of the entity’s deter-
7 mination, the patient’s medical condition and
8 any relevant and reliable evidence the entity ob-
9 tains under subparagraph (D). If the entity de-
10 termines the decision is in accordance with such
11 needs, the entity shall affirm the decision and
12 to the extent that the entity determines the de-
13 cision is not in accordance with such needs, the
14 entity shall reverse or modify the decision.

15 “(C) CONSIDERATION OF PLAN OR COV-
16 ERAGE DEFINITIONS.—In making such deter-
17 mination, the external appeal entity shall con-
18 sider (but not be bound by) any language in the
19 plan or coverage document relating to the defi-
20 nitions of the terms medical necessity, medically
21 necessary or appropriate, or experimental, in-
22 vestigational, or related terms.

23 “(D) EVIDENCE.—

1 “(i) IN GENERAL.—An external ap-
2 peal entity shall include, among the evi-
3 dence taken into consideration—

4 “(I) the decision made by the
5 plan administrator or issuer upon in-
6 ternal review under section 2719A
7 and any guidelines or standards used
8 by the plan administrator or issuer in
9 reaching such decision;

10 “(II) any personal health and
11 medical information supplied with re-
12 spect to the individual whose denial of
13 claim for benefits has been appealed;
14 and

15 “(III) the opinion of the individ-
16 ual’s treating physician or health care
17 professional.

18 “(ii) ADDITIONAL EVIDENCE.—Such
19 external appeal entity may also take into
20 consideration but not be limited to the fol-
21 lowing evidence (to the extent available):

22 “(I) The results of studies that
23 meet professionally recognized stand-
24 ards of validity and replicability or

1 that have been published in peer-re-
2 viewed journals.

3 “(II) The results of professional
4 consensus conferences conducted or fi-
5 nanced in whole or in part by one or
6 more government agencies.

7 “(III) Practice and treatment
8 guidelines prepared or financed in
9 whole or in part by government agen-
10 cies.

11 “(IV) Government-issued cov-
12 erage and treatment policies.

13 “(V) Community standard of
14 care and generally accepted principles
15 of professional medical practice.

16 “(VI) To the extent that the enti-
17 ty determines it to be free of any con-
18 flict of interest, the opinions of indi-
19 viduals who are qualified as experts in
20 one or more fields of health care
21 which are directly related to the mat-
22 ters under appeal.

23 “(VII) To the extent that the en-
24 tity determines it to be free of any
25 conflict of interest, the results of peer

1 reviews conducted by the plan in-
2 volved.

3 “(E) DETERMINATION CONCERNING EX-
4 TERNALLY APPEALABLE DECISIONS.—A quali-
5 fied external appeal entity shall determine—

6 “(i) whether a denial of claim for ben-
7 efits is an externally appealable decision
8 (within the meaning of subsection (a)(2));

9 “(ii) whether an externally appealable
10 decision involves an expedited appeal; and

11 “(iii) for purposes of initiating an ex-
12 ternal review, whether the internal review
13 process has been completed.

14 “(F) OPPORTUNITY TO SUBMIT EVI-
15 DENCE.—Each party to an externally appeal-
16 able decision may submit evidence related to the
17 issues in dispute.

18 “(G) PROVISION OF INFORMATION.—The
19 plan administrator or issuer involved shall pro-
20 vide timely access to the external appeal entity
21 to information and to provisions of the plan or
22 coverage relating to the matter of the externally
23 appealable decision, as determined by the enti-
24 ty.

1 “(H) **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 made in accordance with the
8 medical exigencies of the case involved, but
9 in no event later than 21 days after the
10 date (or, in the case of an expedited ap-
11 peal, 72 hours after the time) of requesting
12 an external appeal of the decision;

13 “(iii) state, in layperson’s language,
14 the basis for the determination, including,
15 if relevant, any basis in the terms or condi-
16 tions of the plan or coverage; and

17 “(iv) inform the participant, bene-
18 ficiary, or enrollee of the individual’s rights
19 (including any limitation on such rights) to
20 seek further review by the courts (or other
21 process) of the external appeal determina-
22 tion.

23 “(I) **COMPLIANCE WITH DETERMINA-**
24 **TION.**—If the external appeal entity reverses or

1 modifies the denial of a claim for benefits, the
2 plan administrator or issuer shall—

3 “(i) upon the receipt of the deter-
4 mination, authorize benefits in accordance
5 with such determination;

6 “(ii) take such actions as may be nec-
7 essary to provide benefits (including items
8 or services) in a timely manner consistent
9 with such determination; and

10 “(iii) submit information to the entity
11 documenting compliance with the entity’s
12 determination and this subparagraph.

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

15 “(1) IN GENERAL.—For purposes of this sec-
16 tion, the term ‘qualified external appeal entity’
17 means, in relation to a group health plan or group
18 or individual health insurance coverage, an entity
19 that is certified under paragraph (2) as meeting the
20 following requirements:

21 “(A) The entity meets the independence
22 requirements of paragraph (3).

23 “(B) The entity conducts external appeal
24 activities through a panel of not fewer than 3
25 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)(2)(G).

6 “(D) The entity meets such other require-
7 ments as the appropriate Secretary may im-
8 pose.

9 “(2) INITIAL CERTIFICATION OF EXTERNAL AP-
10 PEAL ENTITIES.—

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

14 “(i) a group health plan, the entity
15 must be certified (and, in accordance with
16 subparagraph (B), periodically recertified)
17 as meeting the requirements of paragraph
18 (1)—

19 “(I) by the Secretary of Labor;

20 “(II) under a process recognized
21 or approved by the Secretary of
22 Labor; or

23 “(III) to the extent provided in
24 subparagraph (C)(i), by a qualified
25 private standard-setting organization

1 (certified under such subparagraph);

2 or

3 “(ii) a health insurance issuer offering
4 group or individual health insurance cov-
5 erage in a State, the qualified external ap-
6 peal entity must be certified (and, in ac-
7 cordance with subparagraph (B), periodi-
8 cally recertified) as meeting such require-
9 ments—

10 “(I) by the applicable State au-
11 thority (or under a process recognized
12 or approved by such authority); or

13 “(II) if the State has not estab-
14 lished a certification and recertifi-
15 cation process for such entities, by the
16 Secretary, under a process recognized
17 or approved by the Secretary, or to
18 the extent provided in subparagraph
19 (C)(ii), by a qualified private stand-
20 ard-setting organization (certified
21 under such subparagraph).

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 review of—

- 1 “(i) the number of cases reviewed;
- 2 “(ii) a summary of the disposition of
- 3 those cases;
- 4 “(iii) the length of time in making de-
- 5 terminations on those cases;
- 6 “(iv) updated information of what was
- 7 required to be submitted as a condition of
- 8 certification for the entity’s performance of
- 9 external appeal activities; and
- 10 “(v) such information as may be nec-
- 11 essary to assure the independence of the
- 12 entity from the plans or issuers for which
- 13 external appeal activities are being con-
- 14 ducted.

15 “(C) CERTIFICATION OF QUALIFIED PRI-

16 VATE STANDARD-SETTING ORGANIZATIONS.—

- 17 “(i) FOR EXTERNAL REVIEWS OF
- 18 GROUP HEALTH PLANS.—For purposes of
- 19 subparagraph (A)(i)(III), the Secretary of
- 20 Labor may provide for a process for certifi-
- 21 cation (and periodic recertification) of
- 22 qualified private standard-setting organiza-
- 23 tions which provide for certification of ex-
- 24 ternal review entities. Such an organization
- 25 shall only be certified if the organization

1 does not certify an external review entity
2 unless it meets standards required for cer-
3 tification of such an entity by such Sec-
4 retary under subparagraph (A)(i)(I).

5 “(ii) FOR EXTERNAL REVIEWS OF
6 HEALTH INSURANCE ISSUERS.—For pur-
7 poses of subparagraph (A)(ii)(II), the Sec-
8 retary may provide for a process for cer-
9 tification (and periodic recertification) of
10 qualified private standard-setting organiza-
11 tions which provide for certification of ex-
12 ternal review entities. Such an organization
13 shall only be certified if the organization
14 does not certify an external review entity
15 unless it meets standards required for cer-
16 tification of such an entity by the Sec-
17 retary under subparagraph (A)(ii)(II).

18 “(3) INDEPENDENCE REQUIREMENTS.—

19 “(A) IN GENERAL.—A clinical peer or
20 other entity meets the independence require-
21 ments of this paragraph if—

22 “(i) the peer or entity does not have
23 a familial, financial, or professional rela-
24 tionship with any related party;

1 “(ii) any compensation received by
2 such peer or entity in connection with the
3 external review is reasonable and not con-
4 tingent on any decision rendered by the
5 peer or entity;

6 “(iii) except as provided in paragraph
7 (4), the plan and the issuer have no re-
8 course against the peer or entity in connec-
9 tion with the external review; and

10 “(iv) the peer or entity does not oth-
11 erwise have a conflict of interest with a re-
12 lated party as determined under any regu-
13 lations which the Secretary may prescribe.

14 “(B) RELATED PARTY.—For purposes of
15 this paragraph, the term ‘related party’
16 means—

17 “(i) with respect to—

18 “(I) a group health plan or group
19 health insurance coverage, the plan
20 sponsor or the issuer of such cov-
21 erage; or

22 “(II) individual health insurance
23 coverage, the health insurance issuer
24 offering such coverage, or any fidu-

1 ciary, officer, director, or management
2 employee of issuer;

3 “(ii) the health care professional that
4 provided the health care involved in the
5 coverage decision;

6 “(iii) the institution at which the
7 health care involved in the coverage deci-
8 sion is provided;

9 “(iv) the manufacturer of any drug or
10 other item that was included in the health
11 care involved in the coverage decision; or

12 “(v) any other party determined
13 under any regulations which the Secretary
14 may prescribe to have a substantial inter-
15 est in the coverage decision.

16 “(4) LIMITATION ON LIABILITY OF REVIEW-
17 ERS.—No qualified external appeal entity having a
18 contract with a group health plan or a health insur-
19 ance issuer offering group or individual health insur-
20 ance coverage under this part and no person who is
21 employed by any such entity or who furnishes pro-
22 fessional services to such entity, shall be held by rea-
23 son of the performance of any duty, function, or ac-
24 tivity required or authorized pursuant to this sec-
25 tion, to have violated any criminal law, or to be civ-

1 illy liable under any law of the United States or of
2 any State (or political subdivision thereof) if due
3 care was exercised in the performance of such duty,
4 function, or activity and there was no actual malice
5 or gross misconduct in the performance of such
6 duty, function, or activity.

7 “(d) EXTERNAL APPEAL DETERMINATION BINDING
8 ON PLAN AND ISSUER.—The determination by an external
9 appeal entity under this section is binding on the plan or
10 issuer involved in the determination.

11 “(e) PENALTIES AGAINST AUTHORIZED OFFICIALS
12 FOR REFUSING TO AUTHORIZE THE DETERMINATION OF
13 AN EXTERNAL REVIEW ENTITY.—

14 “(1) MONETARY PENALTIES.—In any case in
15 which the determination of an external review entity
16 is not followed by a plan or issuer, any person who,
17 acting in the capacity of authorizing the benefit,
18 causes such refusal may, in the discretion in a court
19 of competent jurisdiction, be liable to an aggrieved
20 participant, beneficiary, or enrollee for a civil pen-
21 alty in an amount of up to \$1,000 a day from the
22 date on which the determination was transmitted to
23 the plan or issuer by the external review entity until
24 the date the refusal to provide the benefit is cor-
25 rected.

1 “(2) CEASE AND DESIST ORDER AND ORDER OF
2 ATTORNEY’S FEES.—In any action described in
3 paragraph (1) brought by a participant, beneficiary,
4 or enrollee with respect to a plan or issuer, in which
5 a plaintiff alleges that a person referred to in such
6 paragraph has taken an action resulting in a refusal
7 of a benefit determined by an external appeal entity
8 in violation of such terms of the plan, coverage, or
9 this part, or has failed to take an action for which
10 such person is responsible under the plan, coverage,
11 or this part and which is necessary under the plan
12 or coverage for authorizing a benefit, the court shall
13 cause to be served on the defendant an order requir-
14 ing the defendant—

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

17 “(B) to pay to the plaintiff a reasonable
18 attorney’s fee and other reasonable costs relat-
19 ing to the prosecution of the action on the
20 charges on which the plaintiff prevails.

21 “(3) ADDITIONAL CIVIL PENALTIES.—

22 “(A) IN GENERAL.—In addition to any
23 penalty imposed under paragraph (1) or (2),
24 the Secretary may assess a civil penalty against
25 a person acting in the capacity of authorizing

1 a benefit determined by an external review enti-
2 ty for one or more plans or issuers, for—

3 “(i) any pattern or practice of re-
4 peated refusal to authorize a benefit deter-
5 mined by an external appeal entity in vio-
6 lation of the terms of the plan, coverage,
7 or this part; or

8 “(ii) any pattern or practice of re-
9 peated violations of the requirements of
10 this section with respect to such plan or
11 plans or issuer or issuers.

12 “(B) STANDARD OF PROOF AND AMOUNT
13 OF PENALTY.—Such penalty shall be payable
14 only upon proof by clear and convincing evi-
15 dence of such pattern or practice and shall be
16 in an amount not to exceed the lesser of—

17 “(i) 25 percent of the aggregate value
18 of benefits shown by the appropriate Sec-
19 retary to have not been provided, or unlaw-
20 fully delayed, in violation of this section
21 under such pattern or practice, or

22 “(ii) \$500,000.

23 “(4) REMOVAL AND DISQUALIFICATION.—Any
24 person acting in the capacity of authorizing benefits
25 who has engaged in any such pattern or practice de-

1 scribed in paragraph (3)(A) with respect to a plan
2 or coverage, upon the petition of the appropriate
3 Secretary, may be removed by the court from such
4 position, and from any other involvement, with re-
5 spect to such a plan or coverage, and may be pre-
6 cluded from returning to any such position or in-
7 volvement for a period determined by the court.

8 “(f) PROTECTION OF LEGAL RIGHTS.—Nothing in
9 this part shall be construed as altering or eliminating any
10 cause of action or legal rights or remedies of participants,
11 beneficiaries, enrollees, and others under State or Federal
12 law (including sections 502 and 503 of the Employee Re-
13 tirement Income Security Act of 1974), including the right
14 to file judicial actions to enforce actions.”

