

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 661 Session of
2017

INTRODUCED BY GREENLEAF, YUDICHAK, TARTAGLIONE AND BREWSTER,
MAY 2, 2017

REFERRED TO BANKING AND INSURANCE, MAY 2, 2017

AN ACT

1 Amending Title 40 (Insurance) of the Pennsylvania Consolidated
2 Statutes, in regulation of insurers and related persons
3 generally, providing for external review.

4 The General Assembly of the Commonwealth of Pennsylvania
5 hereby enacts as follows:

6 Section 1. Part II of Title 40 of the Pennsylvania
7 Consolidated Statutes is amended by adding a chapter to read:

8 CHAPTER 39

9 EXTERNAL REVIEW

10 Sec.

11 3901. Definitions.

12 3902. Applicability of chapter.

13 3903. Notice of right to external review.

14 3904. Request for external review.

15 3905. Exhaustion of internal grievance process.

16 3906. Standard external review.

17 3907. Expedited external review.

18 3908. External review of experimental or investigational

1 treatment adverse benefit determinations.
2 3909. Binding nature of external review decision.
3 3910. Department approval of independent review organizations.
4 3911. Minimum qualifications for independent review
5 organizations.
6 3912. Hold harmless for independent review organizations.
7 3913. External review reporting requirements.
8 3914. Funding of external review.
9 3915. Disclosure requirements.
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11 3917. Regulations.
12 3918. Availability of forms.
13 § 3901. Definitions.

14 The following words and phrases when used in this chapter
15 shall have the meanings given to them in this section unless the
16 context clearly indicates otherwise:

17 "Adverse benefit determination." A determination by an
18 insurer or a utilization review organization designated by the
19 insurer that a health care service has been reviewed and, based
20 upon the information provided, does not meet the insurer's
21 requirements for medical necessity, appropriateness, health care
22 setting, level of care or effectiveness, and the requested
23 service or payment for the service is therefore denied, reduced
24 or terminated.

25 "Ambulatory review." Utilization review of health care
26 services performed or provided in an outpatient setting.

27 "Authorized representative." One of the following:

28 (1) a person to whom a covered person has given express
29 written consent to represent the covered person in an
30 external review;

1 (2) a person authorized by law to provide substituted
2 consent for a covered person; or

3 (3) a family member of a covered person or covered
4 person's treating health care professional only when the
5 covered person is unable to provide consent.

6 "Case management." A coordinated set of activities conducted
7 for individual patient management of serious, complicated,
8 protracted or other health conditions.

9 "Certification." A determination by an insurer or a
10 utilization review organization designated by the insurer that a
11 covered benefit has been reviewed and, based upon the
12 information provided, satisfies the insurer's requirements for
13 medical necessity, appropriateness, health care setting, level
14 of care and effectiveness.

15 "Clinical review criteria." The set of written screening
16 procedures, decision abstracts, clinical protocols and practice
17 guidelines used by an insurer to determine the necessity and
18 appropriateness of health care services.

19 "Commissioner." The Insurance Commissioner of the
20 Commonwealth.

21 "Concurrent review." A review by a utilization review
22 organization of all reasonably necessary supporting information,
23 which review occurs during a covered person's hospital stay or
24 course of treatment and results in a decision to approve or deny
25 payment for the health care service.

26 "Covered benefit." A health care service to which a covered
27 person is entitled under the terms of a health benefit plan.

28 "Covered person." A policyholder, subscriber or other
29 individual who is entitled to receive health care services under
30 a health insurance policy.

1 "Discharge planning." The formal process for determining,
2 prior to discharge from a facility, the coordination and
3 management of care that a patient will receive following the
4 discharge.

5 "Emergency service." A health care service provided to a
6 covered person after the sudden onset of a medical condition
7 that manifests itself by acute symptoms of sufficient severity
8 or severe pain that a prudent layperson who possesses an average
9 knowledge of health and medicine could reasonably expect the
10 absence of immediate medical attention to result in detrimental
11 consequences to the health of the covered person or, with
12 respect to a pregnant woman, the health of the woman or her
13 unborn child. This term includes:

14 (1) Emergency medical services, including those rendered
15 by an EMS agency as those terms are defined in 35 Pa.C.S. §
16 8103 (relating to definitions).

17 (2) A health care service that a health care provider
18 determines is necessary to evaluate and, if necessary,
19 stabilize the condition of a covered person so that the
20 covered person may be transported without suffering
21 detrimental consequences or aggravating the covered person's
22 condition.

23 (3) If a covered person is admitted to a facility, a
24 health care service rendered prior to discharge.

25 "Evidence-based standard." Interventions and treatment
26 approaches that have been proven effective through appropriate
27 empirical analysis.

28 "Facility." A health care setting or an institution
29 providing health care services, including:

30 (1) A general, special, psychiatric or rehabilitation

1 hospital.

2 (2) An ambulatory surgical facility.

3 (3) A cancer treatment center.

4 (4) A birth center.

5 (5) A skilled nursing center.

6 (6) An inpatient, outpatient or residential drug and
7 alcohol treatment facility.

8 (7) A laboratory, imaging, diagnostic or other
9 outpatient medical service or testing facility.

10 (8) A physician office or clinic.

11 "Final adverse benefit determination." An adverse benefit
12 determination that has been upheld by an insurer or a
13 utilization review organization designated by the insurer at the
14 completion of the insurer's internal grievance process
15 procedures as specified in section 2161 of the Insurance Company
16 Law or 45 CFR 147.136(b) (relating to internal claims and
17 appeals and external review processes).

18 "Health care provider." A health service doctor as defined
19 in section 6302 (relating to definitions).

20 "Health care services." A covered treatment, admission,
21 procedure, medical supply and equipment or other service,
22 including behavioral health, prescribed or otherwise provided or
23 proposed to be provided by a health care provider to a covered
24 person for the diagnosis, prevention, treatment, cure or relief
25 of a health condition, illness, injury or disease.

26 "Health insurance policy." A policy, subscriber contract,
27 certificate or plan issued by an insurer that provides medical
28 or health care coverage. The term does not include any of the
29 following:

30 (1) An accident only policy.

1 (2) A credit only policy.

2 (3) A long-term care or disability income policy.

3 (4) A specified disease policy.

4 (5) A Medicare supplement policy.

5 (6) A TRICARE policy, including a Civilian Health and
6 Medical Program of the Uniformed Services (CHAMPUS)
7 supplement policy.

8 (7) A fixed indemnity policy.

9 (8) A dental only policy.

10 (9) A vision only policy.

11 (10) A workers' compensation policy.

12 (11) An automobile medical payment policy under 75
13 Pa.C.S. (relating to vehicles).

14 (12) Any other similar policies providing for limited
15 benefits.

16 "Independent review organization" or "IRO." An entity that
17 conducts independent external review of adverse benefit
18 determinations and final adverse benefit determinations.

19 "Insurance Company Law." The act of May 17, 1921 (P.L.682,
20 No.284), known as The Insurance Company Law of 1921.

21 "Insurer." An entity licensed by the department to issue a
22 health insurance policy, subscriber contract, certificate or
23 plan that provides medical or health care coverage that is
24 offered or governed under any of the following:

25 (1) Section 630, Article XXIV or any other provision of
26 the Insurance Company Law.

27 (2) The act of December 29, 1972 (P.L.1701, No.364),
28 known as the Health Maintenance Organization Act.

29 (3) A provision of Chapter 61 (relating to hospital plan
30 corporations) or 63 (relating to professional health services

1 plan corporations).
2 "Medical or scientific evidence." Evidence found in any of
3 the following sources:

4 (1) A peer-reviewed scientific study published in or
5 accepted for publication by a medical journal that meets
6 nationally recognized requirements for scientific manuscripts
7 and which journal submits most of its published articles for
8 review by experts who are not part of the journal's editorial
9 staff.

10 (2) Peer-reviewed medical literature, including
11 literature relating to a therapy reviewed and approved by a
12 qualified institutional review board, biomedical compendia
13 and other medical literature that meet the criteria of the
14 National Institutes of Health's Library of Medicine for
15 indexing in Index Medicus (Medline) and Elsevier Science
16 Limited for indexing in Excerpta Medica (EMBASE).

17 (3) A medical journal recognized by the Secretary of
18 Health and Human Services under section 1861(t)(2) of the
19 Social Security Act (49 Stat. 620, 42 U.S.C. § 1395x(t)(2)).

20 (4) One of the following standard reference compendia:

21 (i) The American Hospital Formulary Service-Drug
22 Information.

23 (ii) Drug Facts and Compensation.

24 (iii) The American Dental Association Accepted
25 Dental Therapeutics.

26 (iv) The United States Pharmacopoeia-Drug
27 Information.

28 (5) Findings, studies or research conducted by or under
29 the auspices of a Federal Government agency or nationally
30 recognized Federal research institute, including:

1 (i) The Federal Agency for Healthcare Research and
2 Quality.

3 (ii) The National Institutes of Health.

4 (iii) The National Cancer Institute.

5 (iv) The National Academy of Sciences.

6 (v) The Centers for Medicare and Medicaid Services.

7 (vi) The Food and Drug Administration.

8 (vii) Any national board recognized by the National
9 Institutes of Health for the purpose of evaluating the
10 medical value of health care services.

11 (6) Other medical or scientific evidence that is
12 comparable to the sources specified in paragraphs (1) through
13 (5).

14 "NAIC." The National Association of Insurance Commissioners.

15 "Prospective review." Utilization review conducted prior to
16 an admission or a course of treatment.

17 "Protected health information." Information or data, whether
18 oral or recorded in any form or medium, and personal facts or
19 information about events or relationships that identifies an
20 individual who is the subject of the information or for which
21 there is a reasonable basis to believe that the information
22 could be used to identify an individual, that relates to:

23 (1) the past, present or future physical, mental or
24 behavioral health or condition of an individual or a member
25 of the individual's family;

26 (2) the provision of health care services to an
27 individual; or

28 (3) payment for the provision of health care services to
29 an individual.

30 "Retrospective review." Review of medical necessity

1 conducted after health care services have been provided to a
2 covered person, not including the review of a claim that is
3 limited to an evaluation of the reimbursement levels, veracity
4 of documentation, accuracy of coding or adjustment for payment.

5 "Second opinion." An opportunity or requirement to obtain a
6 clinical evaluation by a provider other than the one originally
7 making a recommendation for a proposed health care service to
8 assess the clinical necessity and appropriateness of the initial
9 proposed health care service.

10 "Utilization review." A set of formal techniques designed to
11 monitor the use of, or evaluate the clinical necessity,
12 appropriateness, efficacy or efficiency of, health care
13 services, procedures or settings, which techniques may include
14 ambulatory review, prospective review, second opinion,
15 certification, concurrent review, case management discharge
16 planning or retrospective review.

17 "Utilization review organization." An entity that conducts
18 utilization review, other than an insurer performing utilization
19 review for the insurer's own health insurance policies.

20 § 3902. Applicability of chapter.

21 This chapter applies as follows:

22 (1) For a health insurance policy for which either rates
23 or forms are required to be filed with the Federal Government
24 or the department, this chapter shall apply to a policy for
25 which a form or rate is first filed on or after 180 days
26 after the date of enactment.

27 (2) For a health insurance policy for which neither
28 rates nor forms are required to be filed with the Federal
29 Government or the department, this chapter shall apply to a
30 policy issued or renewed on or after 60 days after the date

of enactment of this chapter.

§ 3903. Notice of right to external review.

(a) Timing of notice.--An insurer shall notify a covered person in writing of the covered person's right to request an external review under section 3906 (relating to standard external review), 3907 (relating to expedited external review) or 3908 (relating to external review of experimental or investigational treatment adverse benefit determinations) at the same time the insurer sends written notice of:

(1) an adverse benefit determination upon completion of the insurer's utilization review process specified in section 2152 of the Insurance Company Law; or

(2) a final adverse benefit determination.

(b) Content of notice.--The notice shall include:

(1) The following, or substantially equivalent, language:

We have denied your request for the provision of or payment for a health care service or course of treatment. You may have the right to have our decision reviewed by health care providers who have no association with us if our decision involved making a judgment as to the medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested. You may submit a request for external review to the Pennsylvania Insurance Department.

(2) For a notice related to an adverse benefit determination, a statement informing the covered person that:

(i) If the covered person has a medical condition for which the time frame for completion of an expedited

1 review of a grievance involving an adverse benefit
2 determination under section 2161(e) of the Insurance
3 Company Law or 45 CFR 147.136(b) (2) (ii) (B) (relating to
4 internal claims and appeals and external review
5 processes) would seriously jeopardize the life or health
6 of the covered person or would jeopardize the covered
7 person's ability to regain maximum function, the covered
8 person or the covered person's authorized representative
9 may file a request for an expedited external review at
10 the same time as a request for an expedited review of a
11 grievance involving an adverse benefit determination
12 under section 2161(e) of the Insurance Company Law or 45
13 CFR 147.136(b) (2) (ii) (B). The IRO assigned to conduct the
14 expedited external review will determine whether the
15 covered person is required to complete the expedited
16 review of the grievance prior to conducting the expedited
17 external review. The request may be filed under section
18 3907 or 3908 if:

19 (A) The adverse benefit determination involves a
20 denial of coverage based on a determination that the
21 recommended or requested health care services are
22 experimental or investigational.

23 (B) The covered person's treating physician
24 certifies in writing that the recommended or
25 requested health care services that are the subject
26 of the adverse benefit determination would be
27 significantly less effective if not promptly
28 initiated.

29 (ii) The covered person or the covered person's
30 authorized representative may file a grievance under the

1 insurer's internal grievance process under section 2161
2 of the Insurance Company Law or 45 CFR 147.136(b)(2), but
3 will be considered to have exhausted the insurer's
4 internal grievance process for purposes of section 3905
5 (relating to exhaustion of internal grievance process)
6 and may immediately file a request for external review
7 under section 3904 (relating to request for external
8 review) if:

9 (A) The insurer has not issued a written
10 decision to the covered person or the covered
11 person's authorized representative within 30 days
12 following the date the covered person or the covered
13 person's authorized representative files the
14 grievance with the insurer.

15 (B) The covered person or the covered person's
16 authorized representative has not requested or agreed
17 to a delay.

18 (3) For a notice related to a final adverse benefit
19 determination, a statement informing the covered person that:

20 (i) if the covered person has a medical condition
21 for which the time frame for completion of a standard
22 external review under section 3906 would seriously
23 jeopardize the life or health of the covered person or
24 would jeopardize the covered person's ability to regain
25 maximum function, the covered person or covered person's
26 authorized representative may file a request for an
27 expedited external review under section 3907; or

28 (ii) if the final adverse benefit determination
29 concerns:

30 (A) an admission, availability of care,

1 continued stay or health care service for which the
2 covered person received emergency services, but has
3 not been discharged from a facility, the covered
4 person or the covered person's authorized
5 representative may request an expedited external
6 review under section 3907;

7 (B) a denial of coverage based on a
8 determination that the recommended or requested
9 health care services are experimental or
10 investigational, the covered person or covered
11 person's authorized representative may file a request
12 for a standard external review to be conducted under
13 section 3908; or

14 (C) a written certification by the treating
15 physician that the recommended or requested health
16 care services that are the subject of the request
17 would be significantly less effective if not promptly
18 initiated, the covered person or the covered person's
19 authorized representative may request an expedited
20 external review to be conducted under section 3908.

21 (4) A copy of the description of both the standard and
22 expedited external review procedures required by section 3915
23 (relating to disclosure requirements), highlighting the
24 provisions in the external review procedures regarding the
25 opportunity to submit additional information and any forms
26 used to process an external review.

27 (5) An authorization form, or other document approved by
28 the department that complies with the requirements of 45 CFR
29 164.508 (relating to uses and disclosures for which an
30 authorization is required), by which the covered person, for

1 purposes of conducting an external review under this chapter,
2 authorizes the insurer and the covered person's treating
3 health care provider to disclose protected health
4 information, including medical records, concerning the
5 covered person that are pertinent to the external review.

6 § 3904. Request for external review.

7 (a) Form of request.--

8 (1) Except for a request for an expedited external
9 review under section 3907 (relating to expedited external
10 review), a request for external review shall be made in
11 writing to the department.

12 (2) The department may prescribe by regulation the form
13 and content of an external review request required to be
14 submitted under this section.

15 (b) Permitted requests.--A covered person or the covered
16 person's authorized representative may make a request for an
17 external review of an adverse benefit determination or final
18 adverse benefit determination.

19 § 3905. Exhaustion of internal grievance process.

20 (a) Requirement to exhaust internal grievance process.--

21 (1) Except as provided in subsection (b), a request for
22 external review under section 3906 (relating to standard
23 external review), 3907 (relating to expedited external
24 review) or 3908 (relating to external review of experimental
25 or investigational treatment adverse benefit determinations)
26 or a request for retrospective review under section 2152 of
27 the Insurance Company Law or 45 CFR 147.136 (relating to
28 internal claims and appeals and external review processes)
29 may not be made until the covered person has exhausted the
30 insurer's internal grievance process under section 2161 of

1 the Insurance Company Law or 45 CFR 147.136(b) (2).

2 (2) A covered person is considered to have exhausted the
3 insurer's internal grievance process for purposes of this
4 section if the covered person or the covered person's
5 authorized representative:

6 (i) Has filed a grievance involving an adverse
7 benefit determination under section 2161 of the Insurance
8 Company Law or 45 CFR 147.136(b) (2).

9 (ii) Except to the extent the covered person or the
10 covered person's authorized representative requested or
11 agreed to a delay, has not received a written decision on
12 the grievance from the insurer within 30 days following
13 the date the covered person or the covered person's
14 authorized representative filed the grievance with the
15 insurer.

16 (b) Procedure for requesting expedited external review.--

17 (1) At the same time a covered person or the covered
18 person's authorized representative files a request for
19 expedited review of a grievance involving an adverse benefit
20 determination under section 2161(e) of the Insurance Company
21 Law or 45 CFR 147.136(b) (2) (ii) (B), the covered person or the
22 covered person's authorized representative may file a request
23 for an expedited external review of the adverse benefit
24 determination:

25 (i) under section 3907, if the covered person has a
26 medical condition for which the time frame for completion
27 of an expedited review of the grievance involving an
28 adverse benefit determination under section 2161(e) of
29 the Insurance Company Law or 45 CFR 147.136(b) (2) (ii) (B)
30 would seriously jeopardize the life or health of the

covered person or would jeopardize the covered person's ability to regain maximum function; or

(ii) under section 3908, if the adverse benefit determination involves a denial of coverage based on a determination that the recommended or requested health care services are experimental or investigational, and the covered person's treating physician certifies in writing that the recommended or requested health care services that are the subject of the adverse benefit determination would be significantly less effective if not promptly initiated.

(2) Upon receipt of a request for an expedited external review under paragraph (1), the IRO conducting the external review in accordance with the provisions of section 3907 or 3908 shall determine whether the covered person is required to complete the expedited review process under section 2161(e) of the Insurance Company Law or 45 CFR 147.136(b) (2) (ii) (B) before the IRO conducts the expedited external review.

(c) Denial of request for expedited external review.--If the IRO determines that the covered person is required to first complete the internal expedited grievance review process under section 2161(e) of the Insurance Company Law or 45 CFR 147.136(b) (2) (ii) (B), the IRO shall immediately notify the covered person and, if applicable, the covered person's authorized representative that the IRO will not proceed with the expedited external review under section 3907 until the insurer has completed the expedited grievance review process and the covered person's grievance remains unresolved.

(d) Waiver of exhaustion requirement.--A request for

external review of an adverse benefit determination may be made before the covered person has exhausted the insurer's internal grievance procedures under section 2161 of the Insurance Company Law or 45 CFR 147.136(b) (2), if the insurer agrees to waive the exhaustion requirement. At that time, the covered person or the covered person's authorized representative may file a request in writing for standard external review as provided in section 3906 or 3908.

§ 3906. Standard external review.

(a) Request for review.--

(1) A covered person or the covered person's authorized representative may file a request for external review with the department within four months after the date of receipt of a notice of an adverse benefit determination or final adverse benefit determination under section 3903 (relating to notice of right to external review).

(2) The department shall send a copy of the request to the insurer within one business day of the date of receipt of a request for external review under paragraph (1).

(b) Preliminary review of request.--Within five business days of the date of receipt of the copy of the external review request received under subsection (a) (2), the insurer shall complete a preliminary review of the request to determine whether:

(1) The individual is or was a covered person by the health insurance policy at the time the health care service was requested or, in the case of a retrospective review, was a covered person by the health insurance policy at the time the health care service was provided.

(2) The health care service that is the subject of the

1 adverse benefit determination or the final adverse benefit
2 determination is a covered service under the covered person's
3 health insurance policy, except for a determination by the
4 insurer that the health care service is not covered because
5 it does not meet the insurer's requirements for medical
6 necessity, appropriateness, health care setting, level of
7 care or effectiveness.

8 (3) The covered person has exhausted the insurer's
9 internal grievance process under section 2161 of the
10 Insurance Company Law or 45 CFR 147.136(b) (2) (relating to
11 internal claims and appeals and external review processes),
12 unless the covered person is not required to exhaust the
13 insurer's internal grievance process under section 3905
14 (relating to exhaustion of internal grievance process).

15 (4) The covered person has not provided all the
16 information and forms required to process an external review,
17 including the release form provided under section 3903(b).

18 (c) Notice of initial determination.--

19 (1) Within one business day of completion of the
20 preliminary review, the insurer shall notify the department
21 and the covered person and, if applicable, the covered
22 person's authorized representative in writing whether the
23 request is complete and eligible for external review.

24 (2) If the request:

25 (i) is not complete, the insurer shall inform the
26 covered person and, if applicable, the covered person's
27 authorized representative and the department in writing
28 and include in the notice what information or materials
29 are needed to make the request complete; or

30 (ii) is not eligible for external review, the

1 insurer shall inform the covered person and, if
2 applicable, the covered person's authorized
3 representative and the department in writing and include
4 in the notice the reasons for the request's
5 ineligibility.

6 (3) Notification under paragraph (2) shall be provided
7 in a form as specified by the department and include a
8 statement informing the covered person and, if applicable,
9 the covered person's authorized representative that an
10 insurer's initial determination that the external review
11 request is ineligible for review may be appealed to the
12 department.

13 (4) Notwithstanding an insurer's initial determination
14 that the request is ineligible for review, the department may
15 determine, based upon the terms of the covered person's
16 health insurance policy, that a request is eligible for
17 external review under subsection (b). The determination shall
18 be binding on the insurer and the covered person and may be
19 appealed to the commissioner. An appeal to the commissioner
20 shall be subject to 2 Pa.C.S. Ch. 5 Subch. A (relating to
21 practice and procedure of Commonwealth agencies).
22 Consideration of the appeal may not delay or terminate the
23 external review.

24 (d) Procedure for review of eligible requests.--

25 (1) Within one business day of the date of receipt of
26 notice that a request is eligible for external review
27 following the preliminary review conducted under subsection
28 (c), the department shall:

29 (i) Assign an IRO to conduct the external review
30 from the list of approved IROs compiled and maintained by

1 the department under section 3910 (relating to department
2 approval of independent review organizations) and notify
3 the insurer of the name of the assigned IRO.

4 (ii) Notify in writing the covered person and, if
5 applicable, the covered person's authorized
6 representative of the request's eligibility and
7 acceptance for external review. The notification shall
8 include a statement that the covered person or the
9 covered person's authorized representative may submit in
10 writing to the assigned IRO, within five business days of
11 the date of receipt of the notice provided under
12 subparagraph (i), additional information that the IRO
13 shall consider when conducting the external review. The
14 IRO may accept and consider additional information
15 submitted after five business days.

16 (2) The assigned IRO shall not be bound by a decision or
17 conclusion reached during the insurer's utilization review
18 process under section 2152 of the Insurance Company Law or
19 the insurer's internal grievance process under section 2161
20 of the Insurance Company Law or 45 CFR 147.136(b) (2).

21 (e) Forwarding of required documents.--

22 (1) Within five business days of the date of receipt of
23 the notice provided under subsection (d) (1), the insurer or a
24 utilization review organization designated by the insurer
25 shall provide to the assigned IRO the documents and
26 information considered in making the adverse benefit
27 determination or final adverse benefit determination.

28 (2) If the insurer or a utilization review organization
29 designated by the insurer fails to provide documents and
30 information within the time period specified in paragraph

1 (1), the IRO may proceed with the review, terminate the
2 external review and make a decision to reverse the adverse
3 benefit determination or final adverse benefit determination.
4 Within one business day of making the decision under
5 paragraph (1), the IRO shall notify the department, the
6 insurer, the covered person and, if applicable, the covered
7 person's authorized representative.

8 (f) Review of information.--

9 (1) The assigned IRO shall review all of the information
10 and documents received under subsection (e) and other
11 information submitted in writing to the IRO by the covered
12 person or the covered person's authorized representative
13 under subsection (d)(3).

14 (2) Within one business day of receipt of information
15 submitted by the covered person or the covered person's
16 authorized representative, the assigned IRO shall forward the
17 information to the insurer.

18 (g) Reconsideration by insurer.--

19 (1) Upon receipt of the information, if any, required to
20 be forwarded under subsection (f)(2), the insurer may
21 reconsider its adverse benefit determination or final adverse
22 benefit determination that is the subject of the external
23 review.

24 (2) Reconsideration by the insurer of its adverse
25 benefit determination or final adverse benefit determination
26 under paragraph (1) may not delay or terminate the external
27 review.

28 (3) The external review may be terminated without an IRO
29 determination only if the insurer decides, upon completion of
30 the insurer's reconsideration, to reverse the insurer's

1 adverse benefit determination or final adverse benefit
2 determination and provide coverage or payment for the
3 recommended health care service that is the subject of the
4 external review.

5 (4) Within one business day of making the decision to
6 reverse its adverse benefit determination or final adverse
7 benefit determination, as provided in paragraph (3), the
8 insurer shall notify the department, the assigned IRO, the
9 covered person and, if applicable, the covered person's
10 authorized representative in writing of its decision.

11 (5) The assigned IRO shall terminate the external review
12 upon receipt of the notice from the insurer sent under
13 paragraph (4).

14 (h) Factors to be considered.--In addition to the documents
15 and information provided under subsection (e), the assigned IRO,
16 to the extent the information or documents are available and the
17 IRO considers them appropriate, shall consider the following
18 information in reaching a decision:

19 (1) The covered person's medical records.

20 (2) The attending health care provider's recommendation.

21 (3) Consulting reports from appropriate health care
22 providers and other documents submitted by the insurer, the
23 covered person, the covered person's authorized
24 representative or the covered person's treating provider.

25 (4) The terms of coverage under the covered person's
26 health insurance policy to ensure that the IRO's decision is
27 not contrary to the terms of coverage.

28 (5) The most appropriate practice guidelines, which
29 shall include applicable evidence-based standards and may
30 include other practice guidelines developed by the Federal

1 Government or national or professional medical societies,
2 boards and associations.

3 (6) Applicable clinical review criteria developed and
4 used by the insurer or a utilization review organization
5 designated by the insurer.

6 (7) The option of the IRO's clinical reviewer or
7 reviewers after considering the information under paragraphs
8 (1) through (6).

9 (i) Notice of decision.--

10 (1) Within 45 days of the date of receipt of the request
11 for an external review, the assigned IRO shall provide
12 written notice of its decision to uphold or reverse the
13 adverse benefit determination or the final adverse benefit
14 determination to:

15 (i) The covered person.

16 (ii) If applicable, the covered person's authorized
17 representative.

18 (iii) The insurer.

19 (iv) The department.

20 (2) The IRO shall include in the notice under paragraph
21 (1):

22 (i) A general description of the reason for the
23 request for external review.

24 (ii) The date the IRO received the assignment from
25 the department to conduct the external review.

26 (iii) The date the external review was conducted.

27 (iv) The date of its decision.

28 (v) The principal reason or reasons for its
29 decision, including what applicable evidence-based
30 standards were considered in reaching its decision.

1 (vi) The rationale for its decision.

2 (vii) References to the evidence or documentation,
3 including evidence-based standards, considered in
4 reaching its decision.

5 (3) Upon receipt of a notice of a decision under
6 paragraph (1) reversing the adverse benefit determination or
7 final adverse benefit determination, the insurer shall
8 immediately approve the coverage that was the subject of the
9 adverse benefit determination or final adverse benefit
10 determination.

11 (j) Assignment of IRO.--The department shall assign on a
12 random basis an approved IRO from those qualified to conduct the
13 particular external review based on the nature of the health
14 care service that is the subject of the adverse benefit
15 determination or final adverse benefit determination, and shall
16 consider the conflict-of-interest concerns under section 3911(d)
17 (relating to minimum qualifications for independent review
18 organizations).

19 § 3907. Expedited external review.

20 (a) Request for review.--Except as provided in subsection
21 (f), a covered person or the covered person's authorized
22 representative may make a request for expedited external review
23 with the department at the time the covered person receives:

24 (1) An adverse benefit determination, if:

25 (i) The adverse benefit determination involves a
26 medical condition of the covered person for which the
27 time frame for completion of an expedited internal review
28 of a grievance involving an adverse benefit determination
29 under section 2161(e) of the Insurance Company Law or 45
30 CFR 147.136(b) (2) (ii) (B) (relating to internal claims and

1 appeals and external review processes) would seriously
2 jeopardize the life or health of the covered person or
3 would jeopardize the covered person's ability to regain
4 maximum function.

5 (ii) The covered person or the covered person's
6 authorized representative has filed a request for an
7 expedited review of a grievance involving an adverse
8 benefit determination under section 2161(e) of the
9 Insurance Company Law or 45 CFR 147.136(b) (2) (ii) (B).

10 (2) A final adverse benefit determination if:

11 (i) the covered person has a medical condition for
12 which the time frame for completion of a standard
13 external review under section 3906 (relating to standard
14 external review) would seriously jeopardize the life or
15 health of the covered person or would jeopardize the
16 covered person's ability to regain maximum function; or

17 (ii) the final adverse benefit determination
18 concerns an admission, availability of care, continued
19 stay or health care service for which the covered person
20 received emergency services but has not been discharged
21 from a facility.

22 (b) Preliminary review of request.--

23 (1) Upon receipt of a request for an expedited external
24 review, the department shall immediately send a copy of the
25 request to the insurer.

26 (2) Immediately upon receipt of a request under
27 paragraph (1), the insurer shall determine whether the
28 request meets the reviewability requirements under section
29 3906(b). The insurer shall immediately notify the department,
30 the covered person and, if applicable, the covered person's

1 authorized representative of the insurer's eligibility
2 determination.

3 (3) Notification provided under paragraph (2) shall be
4 provided in a form as specified by the department and include
5 a statement informing the covered person and, if applicable,
6 the covered person's authorized representative that an
7 insurer's initial determination that the external review
8 request is ineligible for review may be appealed to the
9 department.

10 (4) Notwithstanding an insurer's initial determination
11 that the request is ineligible for review, the department may
12 decide, based upon the terms of the covered person's health
13 insurance policy, that a request is eligible for external
14 review under section 3906(b). The department's decision shall
15 be binding on the insurer and the covered person and may be
16 appealed to the commissioner. An appeal to the commissioner
17 shall be subject to 2 Pa.C.S. Ch. 5 Subch. A (relating to
18 practice and procedure of Commonwealth agencies).
19 Consideration of an appeal may not delay or terminate the
20 external review.

21 (5) Upon receipt of the notice that the request meets
22 reviewability requirements, the department shall immediately
23 assign an IRO to conduct the expedited external review from
24 the list of approved IROs compiled and maintained by the
25 department under section 3910 (relating to department
26 approval of independent review organizations). The department
27 shall immediately notify the insurer of the name of the
28 assigned IRO.

29 (6) In reaching a decision in accordance with subsection
30 (e), the assigned IRO shall not be bound by a decision or

conclusion reached during the insurer's utilization review process under section 2152 of the Insurance Company Law or the insurer's internal grievance process under section 2161 of the Insurance Company Law or CFR 147.136(b) (2).

(c) Forwarding of required documents.--Upon receipt of departmental notice of the name of the IRO assigned to conduct the expedited external review under subsection (b) (5), the insurer or a utilization review organization designated by the insurer shall provide to the assigned IRO the documents and information considered in making the adverse benefit determination or final adverse benefit determination by one of the following methods:

(1) electronically;

(2) by telephone;

(3) by facsimile; or

(4) by any other available expeditious method.

(d) Factors to be considered.--In addition to the documents and information provided under subsection (c), the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, shall consider the following information in reaching a decision:

(1) The covered person's medical records.

(2) The attending health care provider's recommendation.

(3) Consulting reports from appropriate health care providers and other documents submitted by the insurer, the covered person, the covered person's authorized representative or the covered person's treating provider.

(4) The terms of coverage under the covered person's health insurance policy to ensure that the IRO'S decision is not contrary to the terms of coverage.

1 (5) The most appropriate practice guidelines, which
2 shall include applicable evidence-based standards and may
3 include any other practice guidelines developed by the
4 Federal Government or national or professional medical
5 societies, boards and associations.

6 (6) Applicable clinical review criteria developed and
7 used by the insurer or a utilization review organization
8 designated by the insurer.

9 (7) The opinion of the IRO's clinical reviewer or
10 reviewers after considering the information under paragraphs
11 (1) through (6).

12 (e) Notice of decision.--

13 (1) As expeditiously as the covered person's medical
14 condition or circumstances require, but in no event more than
15 72 hours after the date of receipt of the request for an
16 expedited external review that meets the reviewability
17 requirements under section 3906(b), the assigned IRO shall
18 provide notice of its decision to uphold or reverse the
19 adverse benefit determination or the final adverse benefit
20 determination to:

21 (i) The covered person.

22 (ii) If applicable, the covered person's authorized
23 representative.

24 (iii) The insurer.

25 (iv) The department.

26 (2) If the notice provided under paragraph (1) is not in
27 writing, within 48 hours of the date of providing that
28 notice, the assigned IRO shall provide written notice of its
29 decision to uphold or reverse the adverse benefit
30 determination or the final adverse benefit determination to:

1 (i) The covered person.

2 (ii) If applicable, the covered person's authorized
3 representative.

4 (iii) The insurer.

5 (iv) The department.

6 (3) The IRO shall include in the notice under paragraph
7 (2):

8 (i) A general description of the reason for the
9 request for external review.

10 (ii) The date the IRO received the assignment from
11 the department to conduct the external review.

12 (iii) The date the external review was conducted.

13 (iv) The date of its decision.

14 (v) The principal reason or reason for the IRO's
15 decision, including applicable evidence-based standards
16 considered in reaching its decision.

17 (vi) The rationale for its decision.

18 (vii) References to the evidence or documentation,
19 including evidence-based standards, considered in
20 reaching its decision.

21 (4) Upon receipt of a notice of a decision under
22 paragraph (1) reversing the adverse benefit determination or
23 final adverse benefit determination, the insurer shall
24 immediately approve the coverage that was the subject of the
25 adverse benefit determination or final adverse benefit
26 determination.

27 (f) Prohibition of retrospective expedited external
28 review.--An expedited external review may not be provided for
29 retrospective adverse or final adverse benefit determinations.

30 (g) Assignment of IRO.--The department shall assign on a

1 random basis an approved IRO among those qualified to conduct
2 the particular external review based on the nature of the health
3 care service that is subject of the adverse benefit
4 determination or final adverse benefit determination, and shall
5 consider the conflict-of-interest concerns under section 3911(d)
6 (relating to minimum qualifications for independent review
7 organizations).

8 § 3908. External review of experimental or investigational
9 treatment adverse benefit determinations.

10 (a) Request for review.--

11 (1) Within four months of the date of receipt of a
12 notice of an adverse benefit determination or final adverse
13 benefit determination under section 3903 (relating to notice
14 of right to external review) that involves a denial of
15 coverage based on a determination that the health care
16 services recommended or requested are experimental or
17 investigational, a covered person or the covered person's
18 authorized representative may file a request for external
19 review with the department.

20 (2) A covered person or the covered person's authorized
21 representative may make an oral request for expedited
22 external review of the adverse benefit determination or final
23 adverse benefit determination under paragraph (1) if the
24 covered person's treating physician certificates, in writing,
25 that the recommended or requested health care services that
26 are the subject of the request would be significantly less
27 effective if not promptly initiated. Upon receipt of a
28 request for an expedited external review, the department
29 shall notify the insurer immediately. With respect to notice
30 of an insurer's eligibility determination:

1 (i) Upon notice of the request for expedited
2 external review, the insurer shall immediately determine
3 whether the request meets the reviewability requirements
4 of subsection (b). The insurer shall immediately notify
5 the department, the covered person and, if applicable,
6 the covered person's authorized representative of the
7 insurer's eligibility determination.

8 (ii) The department may specify the form for the
9 insurer's notice of initial determination under
10 subparagraph (i) and any supporting information to be
11 included in the notice.

12 (iii) The notice of initial determination under
13 subparagraph (i) shall include a statement informing the
14 covered person and, if applicable, the covered person's
15 authorized representative of an insurer's initial
16 determination that the external review request is
17 ineligible for review and that the external review
18 request may be appealed to the department.

19 (3) Notwithstanding an insurer's initial determination,
20 the department may decide that a request is eligible for
21 external review under paragraph (2) and require that the
22 request be referred for external review. The department's
23 decision shall be made in accordance with the terms of the
24 covered person's health insurance policy and shall be subject
25 to all applicable provisions of this chapter. The
26 department's decision shall be binding on the insurer and the
27 covered person and may be appealed to the commissioner. An
28 appeal to the commissioner shall be subject 2 Pa.C.S. Ch. 5
29 Subch. A (relating to practice and procedure of Commonwealth
30 agencies). Consideration of an appeal may not delay or

1 terminate the external review.

2 (4) Upon receipt of a notice under paragraph (2), the
3 department shall immediately assign an IRO to review the
4 expedited request from the list of approved IROs compiled and
5 maintained by the department under section 3910 (relating to
6 department approval of independent review organizations) and
7 notify the insurer of the name of the assigned IRO. The
8 insurer or a utilization review organization designated by
9 the insurer shall then provide or transmit all necessary
10 documents and information considered in making the adverse
11 benefit determination or final adverse benefit determination
12 to the assigned IRO:

13 (i) electronically;

14 (ii) by telephone;

15 (iii) by facsimile; or

16 (iv) by any other available expeditious method.

17 (b) Preliminary review request.--

18 (1) Except for a request for an expedited external
19 review made under subsection (a)(2), within one business day
20 of the date of receipt of the request for external review,
21 the department shall notify the insurer of the department's
22 receipt of the request.

23 (2) Within five business days of the date of receipt of
24 the notice sent under paragraph (1), the insurer shall
25 conduct and complete a preliminary review of the request to
26 determine whether:

27 (i) The individual is or was a covered person under
28 the health insurance policy at the time the health care
29 services were recommended or requested or, in the case of
30 a retrospective review, was a covered person by the

1 health insurance policy at the time the health care
2 services were provided.

3 (ii) The recommended or requested health care
4 services that are the subject of the adverse benefit
5 determination or final adverse benefit determination:

6 (A) Are a covered benefit under the covered
7 person's health insurance policy, except for the
8 insurer's determination that the health care services
9 are experimental or investigational for a particular
10 medical condition.

11 (B) Are not explicitly listed as an excluded
12 benefit under the covered person's health insurance
13 policy.

14 (iii) The covered person's treating physician has
15 certified that one of the following situations is
16 applicable:

17 (A) Standard health care services have not been
18 effective in improving the condition of the covered
19 person.

20 (B) Standard health care services are not
21 medically appropriate for the covered person.

22 (C) There are no available standard health care
23 services covered by the insurer that are more
24 beneficial than the recommend or requested health
25 care services described in subparagraph (iv).

26 (iv) The covered person's treating physician:

27 (A) has recommended health care services that
28 the physician certifies, in writing, are likely to be
29 more beneficial to the covered person, in the
30 physician's opinion, than available standard health

1 care services; or

2 (B) who is a licensed, board-certified or board-
3 eligible physician qualified to practice in the area
4 of medicine appropriate to treat the covered person's
5 condition, has certified in writing that
6 scientifically valid studies using accepted protocols
7 demonstrate that the health care services requested
8 by the covered person, who is the subject of the
9 adverse benefit determination or final adverse
10 benefit determination, are likely to be more
11 beneficial to the covered person than any available
12 standard health care services;

13 (v) The covered person has exhausted the insurer's
14 internal grievance process under section 2161 of the
15 Insurance Company Law or 45 CFR 147.136(b) (2) (relating
16 to internal claims and appeals and external review
17 processes), unless the covered person is not required to
18 exhaust the insurer's internal grievance process under
19 section 3905 (relating to exhaustion of internal
20 grievance process).

21 (vi) The covered person has provided all the
22 information and forms required by the department that are
23 necessary to process an external review, including the
24 release form provided under section 3903(b).

25 (c) Notice of initial determination.--

26 (1) Within one business day of completion of the
27 preliminary review, the insurer shall notify the department
28 and covered person and, if applicable, the covered person's
29 authorized representative, in writing whether the request is
30 complete and eligible for external review.

1 (2) If the request:

2 (i) is not complete, the insurer shall inform the
3 covered person and, if applicable, the covered person's
4 authorized representative and the department in writing
5 and include in the notice what information or materials
6 are needed to make the request complete; or

7 (ii) is not eligible for external review, the
8 insurer shall inform the covered person and, if
9 applicable, the covered person's authorized
10 representative and the department in writing and include
11 in the notice the reasons for the request's
12 ineligibility.

13 (3) Notification provided under paragraph (2) shall be
14 provided in a form specified by the department and include a
15 statement informing the covered person and, if applicable,
16 the covered person's authorized representative of an
17 insurer's initial determination that the request is
18 ineligible for external review and that the external review
19 request may be appealed to the department.

20 (4) Notwithstanding an insurer's initial determination
21 that the request is ineligible for review, the department may
22 determine, based upon the terms of the covered person's
23 health insurance policy, that the request is eligible for
24 external review under section 3906(b) (relating to standard
25 external review). The determination shall be binding on the
26 insurer and the covered person and may be appealed to the
27 commissioner. An appeal to the commissioner shall be subject
28 to 2 Pa.C.S. Ch. 5 Subch. A. Consideration of the appeal may
29 not delay or terminate the external review.

30 (5) When a request is determined to be eligible for

1 external review, the insurer shall notify the department, the
2 covered person and, if applicable, the covered person's
3 authorized representative.

4 (d) Procedure for review of requests eligible for external
5 review.--

6 (1) Within one business day of the date of receipt of
7 notice that a request is eligible for external review
8 following the preliminary review conducted under subsection
9 (c), the department shall:

10 (i) Assign an IRO to conduct the external review
11 from the list of approved IROs compiled and maintained by
12 the department under section 3910 and notify the insurer
13 of the name of the assigned IRO.

14 (ii) Notify in writing the covered person and, if
15 applicable, the covered person's authorized
16 representative of the request's eligibility and
17 acceptance for external review. The notification shall
18 include a statement that the covered person or the
19 covered person's authorized representative may submit in
20 writing to the assigned IRO, within five business days of
21 the date of receipt of the notice provided under
22 subparagraph (i), additional information that the IRO
23 shall consider when conducting the external review. The
24 IRO may accept and consider additional information
25 submitted after five business days.

26 (2) Within one business day of the receipt of the notice
27 of assignment to conduct the external review under paragraph
28 (1), the assigned IRO shall:

29 (i) Select one or more clinical reviewers under
30 paragraph (3) to conduct the external review; and

1 (ii) Based on the opinion or opinions of the
2 clinical reviewer or reviewers, make a decision to uphold
3 or reverse the adverse benefit determination or final
4 adverse benefit determination.

5 (3) In selecting a clinical reviewer, the assigned IRO
6 shall select a physician or other health care provider who
7 meets the minimum qualifications described in section 3911
8 (relating to minimum qualifications for independent review
9 organizations) and, through clinical experience in the past
10 three years, is an expert in the treatment of the covered
11 person's condition and is knowledgeable about the recommended
12 or requested health care services. The covered person, the
13 covered person's authorized representative and, if
14 applicable, the insurer may not choose or control the choice
15 of the physician or other health care provider to be selected
16 to conduct the external review.

17 (4) In accordance with subsection (e), each clinical
18 reviewer shall provide a written opinion to the assigned IRO
19 regarding whether the recommended or requested health care
20 services should be covered.

21 (5) The assigned clinical reviewer is not bound by a
22 decision or conclusion reached during the insurer's
23 utilization review process under section 2152 of the
24 Insurance Company Law or the insurer's internal grievance
25 process under section 2161 of the Insurance Company Law or 45
26 CFR 147.136(b) (2).

27 (e) Forwarding of required documents.--

28 (1) Within five business days of the date of receipt of
29 the notice provided under subsection (d) (1), the insurer or a
30 utilization review organization designated by the insurer

1 shall provide to the assigned IRO the documents and
2 information considered in making the adverse benefit
3 determination or the final adverse benefit determination.

4 (2) Except as provided in paragraph (3), failure by the
5 insurer or a utilization review organization designated by
6 the insurer to provide the documents and information within
7 the time period specified in paragraph (1) may not delay the
8 conduct of the external review.

9 (3) If the insurer or a utilization review organization
10 designated by the insurer fails to provide the documents and
11 information within the time period specified in paragraph
12 (1), the assigned IRO may terminate the external review and
13 make a decision to reverse the adverse benefit determination
14 or final adverse benefit determination. Immediately upon
15 making the decision, the IRO shall notify the department, the
16 insurer, the covered person and, if applicable, the covered
17 person's authorized representative.

18 (f) Review of information.--

19 (1) Each clinical reviewer selected under subsection (d)
20 shall review all of the information and documents received
21 under subsection (e) and other information submitted in
22 writing by the covered person or covered person's authorized
23 representative under subsection (d)(1)(ii).

24 (2) Within one business day of receipt of information
25 submitted by the covered person or covered person's
26 authorized representative under subsection (d)(1)(ii), the
27 assigned IRO shall forward the information to the insurer.

28 (g) Reconsideration by insurer.--

29 (1) Upon receipt of the information, if any, required to
30 be forwarded under subsection (f)(2), the insurer may

1 reconsider its adverse benefit determination or final adverse
2 benefit determination that is the subject of the external
3 review.

4 (2) Reconsideration by the insurer of its adverse
5 benefit determination or final adverse benefit determination
6 under paragraph (1) may not delay or terminate the external
7 review.

8 (3) The external review may be terminated without an IRO
9 determination only if the insurer decides, upon completion of
10 its reconsideration, to reverse its adverse benefit
11 determination or final adverse benefit determination and
12 provide coverage or payment for the recommended health care
13 service that is the subject of the external review.

14 (4) Within one business day of making the decision to
15 reverse the insurer's adverse benefit determination or final
16 adverse benefit determination, as provided in paragraph (3),
17 the insurer shall notify the department, the assigned IRO,
18 the covered person and, if applicable, the covered person's
19 authorized representative in writing of the insurer's
20 decision.

21 (5) The assigned IRO shall terminate the external review
22 upon receipt of the notice from the insurer under paragraph
23 (4).

24 (h) Clinical review process.--

25 (1) Except as provided in paragraph (3), within 20 days
26 of being selected in accordance with subsection (d) to
27 conduct the external review, each clinical reviewer shall
28 provide an opinion to the assigned IRO regarding whether the
29 recommended or requested health care services should be
30 covered.

1 (2) Except for an opinion provided under paragraph (3),
2 a clinical reviewer's opinion shall be in writing and include
3 the following information:

4 (i) A description of the covered person's medical
5 condition.

6 (ii) A description of the indicators relevant to
7 determining whether there is sufficient evidence to
8 demonstrate that:

9 (A) The recommended or requested health care
10 services are more likely than not to be beneficial to
11 the covered person than any available standard health
12 care services.

13 (B) The adverse risks of the recommended or
14 requested health care services would not be
15 substantially increased over the adverse risks of
16 available standard health care services.

17 (iii) A description and analysis of medical or
18 scientific evidence considered in reaching the opinion.

19 (iv) A description and analysis of an evidence-based
20 standard.

21 (v) Information on whether the reviewer's rationale
22 for the opinion is based on subsection (i)(5)(i) or (ii).

23 (3) The following shall apply:

24 (i) For an expedited external review, a clinical
25 reviewer shall provide an opinion orally or in writing to
26 the assigned IRO as expeditiously as the covered person's
27 medical condition or circumstances require, but in no
28 event more than five calendar days after being selected
29 in accordance with subsection (d).

30 (ii) If the opinion provided under subparagraph (i)

1 is not in writing, within 48 hours of the date the
2 opinion was provided, the clinical reviewer shall provide
3 written confirmation of the opinion to the assigned IRO
4 and include the information required under paragraph (2).

5 (i) Factors to be considered.--In addition to the documents
6 and information provided under subsection (a)(2) or (e), a
7 clinical reviewer selected under subsection (d), to the extent
8 the information or documents are available and the reviewer
9 considers appropriate, shall consider the following in reaching
10 an opinion under subsection (h):

11 (1) The covered person's medical records.

12 (2) The attending health care provider's recommendation.

13 (3) Consulting reports from appropriate health care
14 providers and other documents submitted by the insurer, the
15 covered person and, if applicable, the covered person's
16 authorized representative or the covered person's treating
17 provider.

18 (4) The terms of coverage under the covered person's
19 health insurance policy to ensure that the IRO's decision is
20 not contrary to the terms.

21 (5) Whether:

22 (i) the recommended or requested health care
23 services have been approved by the United States Food and
24 Drug Administration, if applicable, for the condition; or

25 (ii) medical or scientific evidence or evidence-
26 based standards demonstrate that:

27 (A) The expected benefits of the recommended or
28 requested health care services are more likely than
29 not to be beneficial to the covered person than any
30 available standard health care services.

1 (B) The adverse risks of the recommended or
2 requested health care services would not be
3 substantially increased over the adverse risks of
4 available standard health care services.

5 (j) Notice of decision.--

6 (1) Within 20 days of the date the assigned IRO receives
7 the opinion of a clinical reviewer, the assigned IRO shall
8 provide written notice of the assigned IRO's decision to
9 uphold or reverse the adverse benefit determination to:

10 (i) The covered person.

11 (ii) If applicable, the covered person's authorized
12 representative.

13 (iii) The insurer.

14 (iv) The department.

15 (2) If a majority of the clinical reviewers recommend
16 that:

17 (i) The recommended or requested health care
18 services be covered, the IRO shall make a decision to
19 reverse the insurer's adverse benefit determination or
20 final adverse benefit determination.

21 (ii) The recommended or requested health care
22 services not be covered, the IRO shall make a decision to
23 uphold the insurer's adverse benefit determination or
24 final adverse benefit determination.

25 (3) In the event that the clinical reviewers are evenly
26 divided as to whether the recommended or requested health
27 care services should be covered:

28 (i) The IRO shall obtain the opinion of an
29 additional clinical reviewer in order for the IRO to make
30 a decision based on the opinions of a majority of the

1 clinical reviewers.

2 (ii) The additional clinical reviewer selected shall
3 use the same information to reach an opinion as the
4 clinical reviewers who have already submitted their
5 opinion.

6 (iii) The selection of the additional clinical
7 reviewer may not extend the time within which the
8 assigned IRO is required to make a decision.

9 (4) The IRO shall include the following in the notice
10 provided under paragraph (1):

11 (i) A general description of the reason for the
12 request for external review.

13 (ii) The written opinion of each clinical reviewer,
14 including the recommendation of each clinical reviewer as
15 to whether the recommended or requested health care
16 services should be covered and the rationale for the
17 reviewer's recommendation.

18 (iii) The date the IRO was assigned by the
19 department to conduct the external review.

20 (iv) The date of the external review.

21 (v) The date of its decision.

22 (vi) The principal reason or reasons for its
23 decision.

24 (vii) The rationale for its decision.

25 (5) Upon receipt of a notice of a decision under
26 paragraph (1) reversing the adverse benefit determination or
27 final adverse benefit determination, the insurer shall
28 immediately approve the coverage that was the subject of the
29 adverse benefit determination or final adverse benefit
30 determination.

1 (k) Assignment of IRO.--The department shall assign, on a
2 random basis, an approved IRO among those qualified to conduct
3 the particular external review based on the nature of the health
4 care services that are the subject of the adverse benefit
5 determination or final adverse benefit determination, and shall
6 consider the conflict-of-interest concerns under section 3911.
7 § 3909. Binding nature of external review decision.

8 (a) Binding insurer.--An external review decision shall be
9 binding on the insurer, except to the extent the insurer has
10 other remedies available under applicable State law.

11 (b) Binding on covered person.--An external review decision
12 shall be binding on a covered person, except to the extent the
13 covered person has other remedies available under applicable
14 Federal and State law.

15 (c) Finality of decision.--Neither the covered person nor
16 the covered person's authorized representative may file a
17 subsequent request for external review involving the same
18 adverse benefit determination or final adverse benefit
19 determination for which the covered person has already received
20 an external review decision under this chapter.

21 § 3910. Department approval of independent review
22 organizations.

23 (a) General rule.--The department shall approve IROs
24 eligible to be assigned to conduct external reviews under this
25 chapter.

26 (b) Eligibility requirements.--In order to be eligible for
27 approval by the department under this section to conduct
28 external reviews under this chapter, the IRO must:

29 (1) Except as otherwise provided in this section, be
30 accredited by a nationally recognized private accrediting

1 entity that the department has determined to possess IRO
2 accreditation standards that are equivalent to or exceed the
3 minimum qualifications for the IROs established under section
4 3911 (relating to minimum qualifications for independent
5 review organizations).

6 (2) Submit an application for approval in accordance
7 with subsection (d).

8 (c) Form of application.--The department shall develop an
9 application form for initially approving and for reapproving
10 IROs to conduct external reviews.

11 (d) Consideration of application.--

12 (1) An IRO seeking to be approved to conduct external
13 review under this chapter shall submit the application form
14 and include with the form all documentation and information
15 necessary for the department to determine whether the IRO
16 satisfies the minimum qualifications established under
17 section 3911.

18 (2) The department may approve the IRO that is not
19 accredited by a nationally recognized private accrediting
20 entity as required by subsection (b)(1) if there are no
21 acceptable nationally recognized private accrediting entities
22 providing IRO accreditation.

23 (3) The department may charge an application fee that
24 IROs must submit to the department with an application for
25 approval and reapproval.

26 (e) Duration of approval.--

27 (1) An approval is valid for two years unless the
28 department determines before the approval expires that the
29 IRO no longer satisfies the minimum qualifications
30 established under section 3911.

1 (2) If the department determines that an IRO is no
2 longer accredited or no longer satisfies the minimum
3 requirements established under section 3911, the department
4 shall terminate the approval of the IRO and remove the IRO
5 from the list of IROs approved to conduct external reviews
6 under this chapter that is maintained by the department under
7 subsection (f).

8 (f) List of approved IROs.--The department shall maintain
9 and periodically update a list of approved IROs.

10 § 3911. Minimum qualifications for independent review
11 organizations.

12 (a) Requirements for department approval.--To be approved
13 under section 3910 (relating to department approval of
14 independent review organizations) to conduct external reviews,
15 an IRO must establish and maintain written policies and
16 procedures that govern all aspects of both the standard external
17 review and the expedited external review required by this
18 chapter that include, at a minimum:

19 (1) A quality assurance mechanism in place that ensures:

20 (i) That an external review is conducted within the
21 specified time period and that required notices are
22 provided in a timely manner.

23 (ii) The selection of qualified and impartial
24 clinical reviewers to conduct external review on behalf
25 of the IRO, and suitable matching of reviewers to
26 specific cases.

27 (iii) That an IRO employs or contracts with an
28 adequate number of clinical reviewers to suitably match
29 reviewers to specific cases.

30 (iv) The confidentiality of medical and treatment

1 records and clinical review criteria.

2 (v) That a person employed by or under contract with
3 the IRO adheres to the requirements of this chapter.

4 (vi) That the IRO and its assigned clinical
5 reviewers are unbiased in the conduct of an external
6 review.

7 (2) A toll-free telephone service to receive information
8 24 hours per day, 7 days per week, related to external
9 reviews, which service is capable of accepting, recording or
10 providing appropriate instruction to incoming telephone
11 callers during other-than-normal business hours.

12 (3) An agreement to maintain and provide to the
13 department the information described in section 3913
14 (relating to external review reporting requirements).

15 (b) Qualifications of clinical reviewer.--A clinical
16 reviewer assigned by an IRO to conduct external review must be a
17 physician or other appropriate health care provider who meets
18 the following minimum qualifications:

19 (1) Is an expert in the treatment of the covered
20 person's medical condition that is the subject of the
21 external review.

22 (2) Is knowledgeable about the recommended health care
23 services through recent or current actual clinical experience
24 treating patients with the same or similar medical condition
25 of the covered person.

26 (3) Holds a nonrestricted license in a state or
27 commonwealth of the United States and, for physicians, a
28 current certification from a recognized American medical
29 specialty board in the area or areas of medicine appropriate
30 to the subject of the external review.

1 (4) Has no history of disciplinary actions or sanctions,
2 including loss of staff privileges or participation
3 restrictions, that have been taken or are pending by a
4 hospital, governmental agency or unit or regulatory body that
5 raise a substantial question as to the clinical reviewer's
6 physical, mental or professional competence or moral
7 character.

8 (c) Prohibited relationships.--In addition to the
9 requirements under subsection (a), an IRO may not own or
10 control, be a subsidiary of or in any way be owned or controlled
11 by or exercise control with an insurer, a national, State or
12 local trade association of insurers or health care providers.

13 (d) Conflicts of interest.--

14 (1) In addition to the requirements under this section,
15 to be approved under section 3910 to conduct an external
16 review of a specified case, neither the IRO selected to
17 conduct the external review nor a clinical reviewer assigned
18 by the IRO to conduct the external review may have a material
19 professional, familial or financial conflict of interest with
20 any of the following:

21 (i) The insurer that is the subject of the external
22 review.

23 (ii) The covered person whose treatment is the
24 subject of the external review or the covered person's
25 authorized representative.

26 (iii) An officer, director or management employee of
27 the insurer that is the subject of the external review.

28 (iv) The health care provider, the health care
29 provider's medical group or independent practice
30 association recommending the health care services that

1 are subject of the external review.

2 (v) The facility at which the recommended health
3 care services would be provided.

4 (vi) The developer or manufacturer of the principal
5 drug, device, procedure or other therapy being
6 recommended for the covered person whose treatment is the
7 subject of the external review.

8 (2) In determining whether an IRO or a clinical reviewer
9 of the IRO has a material professional, familial or financial
10 conflict of interest for purposes of paragraph (1), the
11 department shall take into consideration situations where an
12 apparent conflict of interest under paragraph (1) is not
13 material.

14 (e) Accreditation.--

15 (1) An IRO that is accredited by a nationally recognized
16 private accrediting entity that possesses independent review
17 accreditation standards that the department has determined
18 are equivalent to or exceed the minimum qualifications of
19 this section shall be presumed to be in compliance with this
20 section to be eligible for approval under section 3910.

21 (2) The department shall initially and periodically
22 review the IRO accreditation standards of a nationally
23 recognized private accrediting entity to determine whether
24 the entity's standards are, and continue to be, equivalent to
25 or exceeding the minimum qualifications established under
26 this section. The department may accept a review conducted by
27 the NAIC for the purposes of the determination under this
28 paragraph.

29 (3) Upon request, a nationally recognized private
30 accrediting entity shall make its current IRO accreditation

1 standards available to the department or the NAIC in order
2 for the department to determine if the entity's standards
3 exceed or are equivalent to the minimum qualifications
4 established under this section. The department may exclude a
5 private accrediting entity that is not reviewed by the NAIC.
6 § 3912. Hold harmless for independent review organizations.

7 No IRO, clinical reviewer working on behalf of an IRO or an
8 employee, agent or contractor of an IRO may be held liable for
9 damages to a person for an opinion rendered, or act or omission
10 performed, within the scope of the organization's or person's
11 duties under the law during or upon completion of an external
12 review conducted under this chapter, unless the opinion was
13 rendered, or act or omission performed, in bad faith or involved
14 gross negligence.

15 § 3913. External review reporting requirements.

16 (a) Recordkeeping by IROs.--

17 (1) An IRO assigned under this chapter to conduct an
18 external review shall maintain written records in the
19 aggregate for both the entire Commonwealth and for the
20 insurer, on all requests for which the IRO conducted an
21 external review during a calendar year.

22 (2) An IRO required to maintain written records under
23 paragraph (1) on all requests for external review for which
24 the IRO was assigned to conduct an external review shall
25 submit to the department, upon request, a report in the
26 format specified by the department.

27 (3) The report shall include in the aggregate, both for
28 the entire Commonwealth and for the insurer:

29 (i) The total number of requests for external
30 review.

1 (ii) The number of requests for external review
2 resolve and, of those involved, the number resolved
3 upholding the adverse benefit determination or final
4 adverse benefit determination and the number of resolved
5 reversing the adverse benefit determination or final
6 adverse benefit determination.

7 (iii) The average length of time for external review
8 request resolution.

9 (iv) A summary of the types of coverages or cases
10 for which an external review was sought as provided in
11 the format required by the department.

12 (v) The number of external reviews under section
13 3906(g) (relating to standard external review) and
14 3908(g) (relating to external review of experimental or
15 investigational treatment adverse benefit determinations)
16 that was terminated as the result of a reconsideration by
17 the insurer of the adverse benefit determination or final
18 adverse benefit determination after the receipt of
19 additional information from the covered person or covered
20 person's authorized representative.

21 (vi) Other information the department requests or
22 requires.

23 (4) The IRO shall retain the written records required
24 under this subsection for at least three years.

25 (b) Recordkeeping by insurers.--

26 (1) An insurer shall maintain written records in the
27 aggregate, both for the entire Commonwealth and for each type
28 of health insurance policy offered by the insurer, on all
29 requests for external review as to which the insurer receives
30 notice from the department under this chapter.

1 (2) An insurer required to maintain written records
2 under paragraph (1) shall submit to the department, upon
3 request, a report in the format specified by the department.

4 (3) The report shall include in the aggregate, both for
5 the entire Commonwealth and for each type of health insurance
6 policy offered by the insurer:

7 (i) The total number of requests for external
8 review.

9 (ii) Of the total number of requests for external
10 review reported under subparagraph (i), the number of
11 requests determined eligible for external review.

12 (iii) Other information the department requests or
13 requires.

14 (4) The insurer shall retain the written records
15 required under this subsection for at least three years.

16 § 3914. Funding of external review.

17 The insurer against which a request for standard external
18 review or expedited external review under section 3906 (relating
19 to standard external review), 3907 (relating to expedited
20 external review) or 3908 (relating to external review of
21 experimental or investigational treatment adverse benefit
22 determinations) is filed shall pay the cost of the IRO to
23 conduct the external review.

24 § 3915. Disclosure requirements.

25 (a) Disclosure to covered persons.--

26 (1) An insurer shall include a description of the
27 insurer's external review procedures in or attached to the
28 policy, certificate, membership booklet, outline of coverage
29 or other evidence of coverage the insurer provides to covered
30 persons.

1 (2) The disclosure required by paragraph (1) shall be in
2 a format as prescribed by the department.

3 (b) Required contents of disclosure.--The description of
4 procedures required under subsection (a) shall include:

5 (1) A statement that informs the covered person of the
6 right to file a request for external review of an adverse
7 benefit determination or final adverse benefit determination
8 with the department.

9 (2) The telephone number and address of the department.

10 (3) A statement that, when filing a request for an
11 external review, the covered person is required to authorize
12 the release of medical records of the covered person that may
13 be required to be reviewed for the purpose of reaching a
14 decision on the external review.

15 (4) An explanation that external review is available
16 when the adverse benefit determination or final adverse
17 benefit determination involves an issue of medical necessity,
18 appropriateness, health care setting, level of care or
19 effectiveness.

20 § 3916. Severability.

21 If any provision of this chapter or the application of the
22 provision to a person or circumstance is held invalid, the
23 remainder of the chapter and the application of the provision to
24 persons or circumstances other than those to which the provision
25 is held invalid is not affected.

26 § 3917. Regulations.

27 The department may promulgate regulations as may be necessary
28 and appropriate to carry out the provisions of this chapter.

29 § 3918. Availability of forms.

30 The department shall make available, in an electronic format

1 and, upon request, a print format, the applicable forms adopted
2 by the department related to an external review request, notice
3 of initial determination by insurer, physician certification for
4 expedited review, insurer annual report, IRO internal report or
5 other forms required by this chapter. Forms may be posted on the
6 department's publicly accessible Internet website. Notice shall
7 be published in the Pennsylvania Bulletin of the availability of
8 amended forms if revisions are made.

9 Section 2. Repeals are as follows:

10 (1) The General Assembly declares that the repeal under
11 paragraph (2) is necessary to effectuate the addition of 40
12 Pa.C.S. Ch. 39.

13 (2) Section 2162 of the act of May 17, 1921 (P.L.682,
14 No.284), known as The Insurance Company Law of 1921.

15 (3) All other acts and parts of acts are repealed
16 insofar as they are inconsistent with the addition of 40
17 Pa.C.S. Ch. 39.

18 Section 3. This act shall take effect in 180 days.