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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

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

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

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

CHAPTER 39

EXTERNAL REVIEW

Sec.

§ 3901. Definitions.

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

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

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

"Authorized representative." One of the following:

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

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

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

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

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

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

"Commissioner." The Insurance Commissioner of the Commonwealth.

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

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

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

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

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

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

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

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

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

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

(1) A general, special, psychiatric or rehabilitation

hospital.

(2) An ambulatory surgical facility.

(3) A cancer treatment center.

(4) A birth center.

(5) A skilled nursing center.

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

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

(8) A physician office or clinic.

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

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

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

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

(1) An accident only policy.

(2) A credit only policy.

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

(4) A specified disease policy.

(5) A Medicare supplement policy.

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

(7) A fixed indemnity policy.

(8) A dental only policy.

(9) A vision only policy.

(10) A workers' compensation policy.

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

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

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

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

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

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

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

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

plan corporations).

"Medical or scientific evidence." Evidence found in any of the following sources:

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

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

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

(4) One of the following standard reference compendia:

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

(ii) Drug Facts and Compensation.

(iii) The American Dental Association Accepted Dental Therapeutics.

(iv) The United States Pharmacopoeia-Drug Information.

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

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

(ii) The National Institutes of Health.

(iii) The National Cancer Institute.

(iv) The National Academy of Sciences.

(v) The Centers for Medicare and Medicaid Services.

(vi) The Food and Drug Administration.

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

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

"NAIC." The National Association of Insurance Commissioners.

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

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

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

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

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

"Retrospective review." Review of medical necessity

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

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

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

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

§ 3902. Applicability of chapter.

This chapter applies as follows:

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

(2) For a health insurance policy for which neither rates nor forms are required to be filed with the Federal Government or the department, this chapter shall apply to a 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

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

(A) 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.

(B) 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.

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

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

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

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

(3) For a notice related to a final 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 a standard external review under section 3906 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, the covered person or covered person's authorized representative may file a request for an expedited external review under section 3907; or

(ii) if the final adverse benefit determination concerns:

(A) an admission, availability of care,

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

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

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

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

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

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

§ 3904. Request for external review.

(a) Form of request.--

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

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

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

§ 3905. Exhaustion of internal grievance process.

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

(1) Except as provided in subsection (b), a request for 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) or a request for retrospective review under section 2152 of the Insurance Company Law or 45 CFR 147.136 (relating to internal claims and appeals and external review processes) may not be made until the covered person has exhausted the insurer's internal grievance process under section 2161 of

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

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

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

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

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

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

(i) under section 3907, if the covered person has a medical condition for which the time frame for completion of an expedited review of the grievance involving an adverse benefit determination under section 2161(e) of the Insurance Company Law or 45 CFR 147.136(b)(2)(ii)(B) 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

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

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

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

(c) Notice of initial determination.--

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

(2) If the request:

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

(ii) is not eligible for external review, the

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

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

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

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

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

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

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

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

(2) 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 45 CFR 147.136(b)(2).

(e) Forwarding of required documents.--

(1) Within five business days of the date of receipt of the notice provided under subsection (d)(1), 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.

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

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

(f) Review of information.--

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

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

(g) Reconsideration by insurer.--

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

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

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

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

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

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

(h) Factors to be considered.--In addition to the documents and information provided under subsection (e), 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.

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

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

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

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

(i) Notice of decision.--

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

(i) The covered person.

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

(iii) The insurer.

(iv) The department.

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

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

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

(iii) The date the external review was conducted.

(iv) The date of its decision.

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

(vi) The rationale for its decision.

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

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

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

§ 3907. Expedited external review.

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

(1) An adverse benefit determination, if:

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

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

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

(2) A final adverse benefit determination if:

(i) the covered person has a medical condition for which the time frame for completion of a standard external review under section 3906 (relating to standard external review) 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) the final adverse benefit determination concerns an admission, availability of care, continued stay or health care service for which the covered person received emergency services but has not been discharged from a facility.

(b) Preliminary review of request.--

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

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

authorized representative of the insurer's eligibility determination.

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

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

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

(6) In reaching a decision in accordance with subsection (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.

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

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

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

(e) Notice of decision.--

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

(i) The covered person.

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

(iii) The insurer.

(iv) The department.

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

(i) The covered person.

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

(iii) The insurer.

(iv) The department.

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

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

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

(iii) The date the external review was conducted.

(iv) The date of its decision.

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

(vi) The rationale for its decision.

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

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

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

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

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

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

(a) Request for review.--

(1) Within four months of 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) that involves a denial of coverage based on a determination that the health care services recommended or requested are experimental or investigational, a covered person or the covered person's authorized representative may file a request for external review with the department.

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

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

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

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

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

terminate the external review.

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

(i) electronically;

(ii) by telephone;

(iii) by facsimile; or

(iv) by any other available expeditious method.

(b) Preliminary review request.--

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

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

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

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

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

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

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

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

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

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

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

(iv) The covered person's treating physician:

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

care services; or

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

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

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

(c) Notice of initial determination.--

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

(2) If the request:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) The assigned clinical reviewer is not 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 45 CFR 147.136(b)(2).

(e) Forwarding of required documents.--

(1) Within five business days of the date of receipt of the notice provided under subsection (d)(1), 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 the final adverse benefit determination.

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

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

(f) Review of information.--

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

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

(g) Reconsideration by insurer.--

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

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

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

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

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

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

(h) Clinical review process.--

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

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

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

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

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

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

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

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

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

(3) The following shall apply:

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

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

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

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

(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 and, if applicable, 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.

(5) Whether:

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

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

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

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

(j) Notice of decision.--

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

(i) The covered person.

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

(iii) The insurer.

(iv) The department.

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

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

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

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

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

clinical reviewers.

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

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

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

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

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

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

(iv) The date of the external review.

(v) The date of its decision.

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

(vii) The rationale for its decision.

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

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

§ 3909. Binding nature of external review decision.

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

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

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

§ 3910. Department approval of independent review organizations.

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

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

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

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

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

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

(d) Consideration of application.--

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

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

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

(e) Duration of approval.--

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

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

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

§ 3911. Minimum qualifications for independent review organizations.

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

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

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

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

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

(iv) The confidentiality of medical and treatment

records and clinical review criteria.

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

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

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

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

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

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

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

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

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

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

(d) Conflicts of interest.--

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

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

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

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

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

are subject of the external review.

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

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

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

(e) Accreditation.--

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

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

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

standards available to the department or the NAIC in order for the department to determine if the entity's standards exceed or are equivalent to the minimum qualifications established under this section. The department may exclude a private accrediting entity that is not reviewed by the NAIC.

§ 3912. Hold harmless for independent review organizations.

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

§ 3913. External review reporting requirements.

(a) Recordkeeping by IROs.--

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

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

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

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

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

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

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

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

(vi) Other information the department requests or requires.

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

(b) Recordkeeping by insurers.--

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

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

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

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

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

(iii) Other information the department requests or requires.

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

§ 3914. Funding of external review.

The insurer against which a request for standard external review or expedited 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) is filed shall pay the cost of the IRO to conduct the external review.

§ 3915. Disclosure requirements.

(a) Disclosure to covered persons.--

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

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

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

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

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

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

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

§ 3916. Severability.

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

§ 3917. Regulations.

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

§ 3918. Availability of forms.

The department shall make available, in an electronic format

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

Section 2. Repeals are as follows:

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

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

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

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