

RULE 76

ARKANSAS EXTERNAL REVIEW REGULATION

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Section 1. Authority

This regulation is promulgated pursuant to Ark. Code Ann. §§23-61-108, 23-66-205, 23-66-207, 23-99-414, 25-15-203 & 204, and other applicable laws or rules.

Section 2. Purpose and Intent

The purpose of this Rule is to provide uniform standards for the establishment and maintenance of external review procedures to assure that covered persons have the opportunity for an independent review of an adverse determination or final adverse determination, as defined in this Rule.

Section 3. Definitions

For purposes of this Rule:

- A. “Adverse determination” means a determination by a health carrier or its designee utilization review organization that an admission, availability of care, continued stay or other health care service that is a covered benefit has been reviewed and, based upon the information provided, does not meet the health carrier’s requirements for medical necessity (or substantially equivalent term), appropriateness, health care setting, level of care or effectiveness, and the requested service or payment for the service is therefore denied, reduced or terminated.
- B. “Ambulatory review” means utilization review of health care services performed or provided in an outpatient setting.
- C. “Authorized representative” means:
 - (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 the covered person or the covered person’s treating health care professional only when the covered person is unable to provide consent.
- D. “Best evidence” means evidence based on:
 - (1) Randomized clinical trials;
 - (2) If randomized clinical trials are not available, cohort studies or case-control studies;
 - (3) If paragraphs (1) and (2) are not available, case-series; or
 - (4) If paragraphs (1), (2) and (3) are not available, expert opinion.
- E. “Case-control study” means a retrospective evaluation of two (2) groups of patients with different outcomes to determine which specific interventions the patients received.
- F. “Case management” means a coordinated set of activities conducted for individual patient management of serious, complicated, protracted or other health conditions.

- G. “Case-series” means an evaluation of a series of patients with a particular outcome, without the use of a control group.
- H. “Certification” means a determination by a health carrier or its designee utilization review organization that an admission, availability of care, continued stay or other health care service has been reviewed and, based on the information provided, satisfies the health carrier’s requirements for medical necessity (or substantially equivalent term), appropriateness, health care setting, level of care and effectiveness.
- I. “Clinical review criteria” means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by a health carrier to determine the necessity and appropriateness of health care services.
- J. “Cohort study” means a prospective evaluation of two (2) groups of patients with only one group of patients receiving a specific intervention(s).
- K. “Commissioner” means the Arkansas Insurance Commissioner.
- L. “Concurrent review” means utilization review conducted during a patient’s hospital stay or course of treatment.
- M. “Covered benefits” or “benefits” means those health care services to which a covered person is entitled under the terms of a health benefit plan.
- N. “Covered person” means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan.
- O. “Discharge planning” means the formal process for determining, prior to discharge from a facility, the coordination and management of the care that a patient receives following discharge from a facility.
- P. “Disclose” means to release, transfer or otherwise divulge protected health information to any person other than the individual who is the subject of the protected health information.
- Q. “Emergency medical condition” means the sudden and, at the time, unexpected onset of a health condition or illness that requires immediate medical attention, where failure to provide medical attention would result in a serious impairment to bodily functions, serious dysfunction of a bodily organ or part, or would place the person’s health in serious jeopardy.

- R. “Emergency services” means health care items and services furnished or required to evaluate and treat an emergency medical condition.
- S. “Evidence-based standard” means the conscientious, explicit and judicious use of the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients.
- T. “Expert opinion” means a belief or an interpretation by specialists with experience in a specific area about the scientific evidence pertaining to a particular service, intervention or therapy.
- U. “Facility” means an institution providing health care services or a health care setting, including but not limited to, hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.
- V. “Final adverse determination” means an adverse determination involving a covered benefit that has been upheld by a health carrier, or its designee utilization review organization, at the completion of the health carrier’s internal appeal process procedures. If the health carrier does not have, nor is it required to have, an internal appeal procedure or utilization review procedure, an adverse determination shall be considered a final adverse determination.
- W. “Health benefit plan” means a policy, contract, certificate or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.
- X. “Health care professional” means a physician or other health care practitioner licensed, accredited or certified to perform specified health care services consistent with state law
- Y. “Health care provider” or “provider” means a health care professional or a facility.
- Z. “Health care services” means services for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury or disease.
- AA. “Health carrier” means an entity subject to the insurance laws and regulations of Arkansas, or subject to the jurisdiction of the Commissioner, that contracts or offers to contract to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including an accident and health insurance company, a health maintenance organization, a nonprofit hospital and medical service corporation, or any

other entity providing a plan of health insurance, health benefits or health care services.

- BB. “Health information” means information or data, whether oral or recorded in any form or medium, and personal facts or information about events or relationships 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.
- CC. “Independent review organization” means an entity that conducts independent external reviews of adverse determinations and final adverse determinations.
- DD. “Medical or scientific evidence” means evidence found in the following sources:
- (1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;
 - (2) Peer-reviewed medical literature, including literature relating to therapies 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 Ltd. for indexing in Excerpta Medicus (EMBASE);
 - (3) Medical journals recognized by the Secretary of Health and Human Services under Section 1861(t)(2) of the federal Social Security Act;
 - (4) The following standard reference compendia:
 - (a) The American Hospital Formulary Service–Drug Information;
 - (b) Drug Facts and Comparisons;

- (c) The American Dental Association Accepted Dental Therapeutics; and
- (d) The United States Pharmacopoeia–Drug Information;
- (5) Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:
 - (a) The federal Agency for Healthcare Research and Quality;
 - (b) The National Institutes of Health;
 - (c) The National Cancer Institute;
 - (d) The National Academy of Sciences;
 - (e) The Centers for Medicare & Medicaid Services;
 - (f) The federal Food and Drug Administration; and
 - (g) Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services; or
- (6) Any other medical or scientific evidence that is comparable to the sources listed in paragraphs (1) through (5).

EE. “NAIC” means the National Association of Insurance Commissioners.

FF. “Person” means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, any similar entity or any combination of the foregoing.

GG. “Prospective review” means utilization review conducted prior to an admission or a course of treatment.

HH. “Protected health information” means health information:

- (1) That identifies an individual who is the subject of the information; or
- (2) With respect to which there is a reasonable basis to believe that the information could be used to identify an individual.

II. “Randomized clinical trial” means a controlled, prospective study of patients that have been randomized into an experimental group and a

control group at the beginning of the study with only the experimental group of patients receiving a specific intervention, which includes study of the groups for variables and anticipated outcomes over time.

- JJ. “Retrospective review” means a review of medical necessity (or substantially equivalent term) conducted after services have been provided to a patient, but does not include the review of a claim that is limited to an evaluation of reimbursement levels, veracity of documentation, accuracy of coding or adjudication for payment.
- KK. “Second opinion” means 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.
- LL. “Utilization review” means 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. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning, or retrospective review.
- MM. “Utilization review organization” means an entity that conducts utilization review, other than a health carrier performing a review for its own health benefit plans.

Section 4. Applicability and Scope

- A. Except as provided in Subsection (B) of this Section, this Rule shall apply to all health carriers.
- B. The provisions of this Rule shall not apply to a policy or certificate that provides coverage only for a specified disease, specified accident or accident-only coverage, credit, dental, disability income, hospital indemnity, short term limited duration , long-term care insurance, as defined by Ark. Code Ann. §23-97-203, vision care or any other limited supplemental benefit or to a Medicare supplement policy of insurance, as defined by the Commissioner by regulation, coverage under a plan through Medicare, Medicaid, or the federal employees health benefits program, any coverage issued under Chapter 55 of Title 10, U.S. Code and any coverage issued as supplemental to that coverage, any coverage issued as supplemental to liability insurance, workers’ compensation or similar insurance, automobile medical-payment insurance or any insurance under which benefits are payable with or without regard to fault, whether written on a group blanket or individual basis.

Section 5. Notice of Right to External Review

- A. (1) A health carrier shall notify the covered person in writing of the covered person's right to request an external review to be conducted pursuant to Sections 8, 9 or 10 of this Rule and include the appropriate statements and information set forth in Subsection (B) of this Section at the same time the health carrier sends written notice of:
- (a) An adverse determination upon completion of the health carrier's utilization review process; and
 - (b) A final adverse determination.
- (2) As part of the written notice required under Subsection (A) of this Section under paragraph (1), a health carrier shall include 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 professionals who have no association with us if our decision involved making a judgment as to the medical necessity (or substantially equivalent term), appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested by submitting a request for external review in writing to the Arkansas Insurance Commissioner at 1200 West 3rd Street, Little Rock, AR 72201 or by calling 1-800-282-9134."
- (3) The Commissioner may otherwise prescribe the form and content of the notice as required under this Section by bulletin, directive or other publication to health carriers.
- B. (1) The health carrier shall include in the notice required under Subsection A of this Section:
- (a) For a notice related to an adverse determination, a statement informing the covered person that:
 - (i) If the covered person has a medical condition where the time frame for completion of an expedited review of an appeal involving an adverse determination set forth in the health carrier's internal appeal procedure or utilization review procedure would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to gain maximum

function, the covered person or the covered person's authorized representative may file a request for an expedited external review to be conducted pursuant to Section 9 of this Rule, or Section 10 of this Rule if the adverse determination involves a denial of coverage based on a determination that the recommended or requested health care service or treatment is experimental or investigational and the covered person's treating physician certifies in writing that the recommended or requested health care service or treatment that is the subject of the adverse determination would be significantly less effective if not promptly initiated, at the same time the covered person or the covered person's authorized representative files a request for an expedited review of an appeal involving an adverse determination as set forth in the health carrier's internal appeal procedure or utilization review procedure, but that the independent review organization assigned to conduct the expedited external review will determine whether the covered person shall be required to complete the expedited review of the appeal prior to conducting the expedited external review; and

(ii) The covered person or the covered person's authorized representative may file an appeal under the health carrier's internal appeal process, but if the health carrier has not issued a written decision to the covered person or the covered person's authorized representative within thirty (30) days following the date the covered person or the covered person's authorized representative files the appeal with the health carrier for a pre-service claim or sixty (60) days for a post-service claim and the covered person or the covered person's authorized representative has not requested or agreed to a delay, the covered person or the covered person's authorized representative may file a request for external review pursuant to Section 6 of this Rule and shall be considered to have exhausted the health carrier's internal appeal process for purposes of Section 7 of this Rule; and

(b) For a notice related to a final adverse determination, a statement informing the covered person that:

- (i) If the covered person has a medical condition where the timeframe for completion of a standard external review pursuant to Section (8) of this Rule 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 pursuant to section 9 of this Rule; or
 - (ii) If the final adverse determination concerns:
 - (I) 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 pursuant to section 9 of this Rule; or
 - (II) A denial of coverage based on a determination that the recommended or requested health care service or treatment is experimental or investigational, the covered person or the covered person's authorized representative may file a request for a standard external review to be conducted pursuant to Section 10 of this Rule or if the covered person's treating physician certifies in writing that the recommended or requested health care service or treatment that is 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 10 of this Rule.
- (2) In addition to the information to be provided pursuant to paragraph (1), the health carrier shall include a copy of the description of both the standard and expedited external review procedures the health carrier is required to provide pursuant to Section 17 of this Rule, highlighting the provisions in the external review procedures

that give the covered person or the covered person's authorized representative the opportunity to submit additional information and including any forms used to process an external review.

- (3) As part of any forms provided under paragraph (2), the health carrier shall include an authorization form, or other document approved by the Commissioner that complies with the requirements of 45 CFR Section 164.508, by which the covered person, for purposes of conducting an external review under this Rule, authorizes the health carrier 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.

Section 6. Request for External Review

- A.
 - (1) Except for a request for an expedited external review as set forth in Section 9 of this Rule, all requests for external review shall be made in writing to the Commissioner.
 - (2) The Commissioner may prescribe the form and content of external review requests required to be submitted under this Section by bulletin, directive or other publication to health carriers.
- B. A covered person or the covered person's authorized representative may make a request for an external review of an adverse determination or final adverse determination.

Section 7. Exhaustion of Internal Appeal Process

- A.
 - (1) Except as provided in Subsection B of this Section, a request for an external review pursuant to Section 8, 9 or 10 of this Rule shall not be made until the covered person has exhausted the health carrier's internal appeal process.
 - (2) A covered person shall be considered to have exhausted the health carrier's internal appeal process for purposes of this section, if the covered person or the covered person's authorized representative:
 - (a) Has filed an appeal involving an adverse determination pursuant to the health carrier's internal appeal procedure or utilization review procedure; and
 - (b) 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 appeal

from the health carrier within thirty (30) days for a pre-service claim or sixty (60) days for a post-service claim following the date the covered person or the covered person's authorized representative filed the appeal with the health carrier.

- (3) Notwithstanding paragraph (2) of Subsection A of this Section, a covered person or the covered person's authorized representative may not make a request for an external review of an adverse determination involving a retrospective review determination made pursuant to the health carrier's internal appeal procedure or utilization review procedure until the covered person has exhausted the health carrier's internal appeal process.
- B.
- (1) (a) At the same time a covered person or the covered person's authorized representative files a request for an expedited review of an appeal involving an adverse determination as set forth in the health carrier's internal appeal procedure or utilization review procedure, the covered person or the covered person's authorized representative may file a request for an expedited external review of the adverse determination:
 - (i) Under Section 9 of this Rule if the covered person has a medical condition where the timeframe for completion of an expedited review of the appeal involving an adverse determination set forth in the health carrier's internal appeal procedure or utilization review procedure 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 10 of this Rule if the adverse determination involves a denial of coverage based on a determination that the recommended or requested health care service or treatment is experimental or investigational and the covered person's treating physician certifies in writing that the recommended or requested health care service or treatment that is the subject of the adverse determination would be significantly less effective if not promptly initiated.
 - (b) Upon receipt of a request for an expedited external review under (B)(1)(a) of this Section, the independent review

organization conducting the external review in accordance with the provisions of Section 9 or 10 of this Rule shall determine whether the covered person shall be required to complete the expedited review process set forth in the health carrier's internal appeal procedure or utilization review procedure before it conducts the expedited external review.

(c) Upon a determination made pursuant to (B)(1) (b) of this Section that the covered person must first complete the expedited appeal review process set forth in the health carrier's internal review procedure or utilization review procedure, the independent review organization immediately shall notify the covered person and, if applicable, the covered person's authorized representative of this determination and that it will not proceed with the expedited external review set forth in Section 9 of this Rule until completion of the expedited appeal review process and the covered person's appeal at the completion of the expedited appeal review process remains unresolved.

(2) A request for an external review of an adverse determination may be made before the covered person has exhausted the health carrier's internal appeal procedures, as set forth in the carrier's internal review procedure whenever the health carrier agrees to waive the exhaustion requirement.

C. If the requirement to exhaust the health carrier's internal appeal procedures is waived under (B)(2) of this Section, the covered person or the covered person's authorized representative may file a request in writing for a standard external review as set forth in Section 8 or 10 of this Rule.

Section 8. Standard External Review

A. (1) Within four (4) months after the date of receipt of a notice of an adverse determination or final adverse determination pursuant to Section (5) of this Rule, a covered person or the covered person's authorized representative may file a request for an external review with the Commissioner.

(2) Within one (1) business day after the date of receipt of a request for external review pursuant to (A) (1) under this Section, the Commissioner shall send a copy of the request to the health carrier.

- B. Within five (5) business days following the date of receipt of the copy of the external review request from the Commissioner under (A)(2) of this Section, the health carrier shall complete a preliminary review of the request to determine whether:
- (1) The individual is or was a covered person in the health benefit plan at the time the health care service was requested or, in the case of a retrospective review, was a covered person in the health benefit plan at the time the health care service was provided;
 - (2) The health care service that is the subject of the adverse determination or the final adverse determination is a covered service under the covered person's health benefit plan, but for a determination by the health carrier that the health care service is not covered because it does not meet the health carrier's requirements for medical necessity (or substantially equivalent term), appropriateness, health care setting, level of care or effectiveness;
 - (3) The covered person has exhausted the health carrier's internal appeal process unless the covered person is not required to exhaust the health carrier's internal appeal process pursuant to Section (7) of this Rule; and
 - (4) The covered person has provided all the information and forms required to process an external review, including the release form provided under Section (5)(B) of this Rule.
- C. (1) Within one (1) business day after completion of the preliminary review, the health carrier shall notify the commissioner and covered person and, if applicable, the covered person's authorized representative in writing whether:
- (a) The request is complete; and
 - (b) The request is eligible for external review.
- (2) If the request:
- (a) Is not complete, the health carrier shall inform the covered person and, if applicable, the covered person's authorized representative and the commissioner in writing and include in the notice what information or materials are needed to make the request complete; or

- (b) Is not eligible for external review, the health carrier shall inform the covered person, if applicable, the covered person's authorized representative and the commissioner in writing and include in the notice the reasons for its ineligibility.
- (3)
 - (a) The Commissioner may specify the form for the health carrier's notice of initial determination under this subsection and any supporting information to be included in the notice by bulletin, directive or other publication to health carriers.
 - (b) The notice of initial determination shall include a statement informing the covered person and, if applicable, the covered person's authorized representative that a health carrier's initial determination that the external review request is ineligible for review may be appealed to the Commissioner.
- (4)
 - (a) The Commissioner may determine that a request is eligible for external review notwithstanding a health carrier's initial determination that the request is ineligible and require that it be referred for external review.
 - (b) In making a determination under (4)(a) of this Section, the Commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this Rule.
- D.
 - (1) Whenever the Commissioner receives a notice that a request is eligible for external review following the preliminary review conducted pursuant to subsection (C) under this Section, within one (1) business day after the date of receipt of the notice, the Commissioner shall:
 - (a) Assign an independent review organization from the list of approved independent review organizations compiled and maintained by the Commissioner pursuant to Section (12) of this Rule to conduct the external review and notify the health carrier of the name of the assigned independent review organization; and
 - (b) 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.

- (2) In reaching a decision, the assigned independent review organization is not bound by any decisions or conclusions reached during the health carrier's utilization review process or the health carrier's internal appeal process.
 - (3) The Commissioner shall include in the notice provided to the covered person and, if applicable, the covered person's authorized representative a statement that the covered person or the covered person's authorized representative may submit in writing to the assigned independent review organization within five (5) business days following the date of receipt of the notice provided pursuant to (D)(1) under this Section additional information that the independent review organization shall consider when conducting the external review. The independent review organization is not required to, but may, accept and consider additional information submitted after five (5) business days.
- E.
- (1) Within five (5) business days after the date of receipt of the notice provided pursuant to (D)(1) of this Section, the health carrier or its designee utilization review organization shall provide to the assigned independent review organization the documents and any information considered in making the adverse determination or final adverse determination.
 - (2) Except as provided in (E)(3) under this Section, failure by the health carrier or its utilization review organization to provide the documents and information within the time specified in (E)(1) of this Section shall not delay the conduct of the external review.
 - (3)
 - (a) If the health carrier or its utilization review organization fails to provide the documents and information within the time specified in (E)(1) of this Section, the assigned independent review organization may terminate the external review and make a decision to reverse the adverse determination or final adverse determination.
 - (b) Within one (1) business day after making the decision under (E)(3)(a) of this Section, the independent review organization shall notify the covered person, if applicable, the covered person's authorized representative, the health carrier, and the commissioner.
- F.
- (1) The assigned independent review organization shall review all of the information and documents received pursuant to Subsection (E) under this Section and any other information submitted in writing to the independent review organization by the covered person or

the covered person's authorized representative pursuant to (D)(3) of this Section.

(2) Upon receipt of any information submitted by the covered person or the covered person's authorized representative pursuant to subsection (D)(3) under this Section, the assigned independent review organization shall within one (1) business day forward the information to the health carrier.

G. (1) Upon receipt of the information, if any, required to be forwarded pursuant to subsection (F)(2) of this Section, the health carrier may reconsider its adverse determination or final adverse determination that is the subject of the external review.

(2) Reconsideration by the health carrier of its adverse determination or final adverse determination pursuant to (G)(1) under this Section shall not delay or terminate the external review.

(3) The external review may only be terminated if the health carrier decides, upon completion of its reconsideration, to reverse its adverse determination or final adverse determination and provide coverage or payment for the health care service that is the subject of the adverse determination or final adverse determination.

(4) (a) Within one (1) business day after making the decision to reverse its adverse determination or final adverse determination, as provided in (G)(3) of this Section, the health carrier shall notify the covered person, if applicable, the covered person's authorized representative, the assigned independent review organization, and the commissioner in writing of its decision.

(b) The assigned independent review organization shall terminate the external review upon receipt of the notice from the health carrier sent pursuant to (G)(4)(a) of this Section.

H. In addition to the documents and information provided pursuant to Subsection (E) under this Section, the assigned independent review organization, to the extent the information or documents are available and the independent review organization considers them appropriate, shall consider the following in reaching a decision:

(1) The covered person's medical records;

(2) The attending health care professional's recommendation;

- (3) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, 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 benefit plan with the health carrier to ensure that the independent review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier;
 - (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, national or professional medical societies, boards and associations;
 - (6) Any applicable clinical review criteria developed and used by the health carrier or its designee utilization review organization; and
 - (7) The opinion of the independent review organization's clinical reviewer or reviewers after considering paragraphs (H)(1) through (H)(6) of this Section to the extent the information or documents are available and the clinical reviewer or reviewers consider appropriate.
- I. (1) Within forty-five (45) days after the date of receipt of the request for an external review, the assigned independent review organization shall provide written notice of its decision to uphold or reverse the adverse determination or the final adverse determination to:
- (a) The covered person;
 - (b) If applicable, the covered person's authorized representative;
 - (c) The health carrier; and
 - (d) The commissioner.
- (2) The independent review organization shall include in the notice sent pursuant to (I)(1) of this Section:
- (a) A general description of the reason for the request for external review;

- (b) The date the independent review organization received the assignment from the commissioner to conduct the external review;
 - (c) The date the external review was conducted;
 - (d) The date of its decision;
 - (e) The principal reason or reasons for its decision, including what applicable, if any, evidence-based standards were a basis for its decision;
 - (f) The rationale for its decision; and
 - (g) References to the evidence or documentation, including the evidence-based standards, considered in reaching its decision.
- (3) Upon receipt of a notice of a decision pursuant to paragraph (I)(1) of this Section reversing the adverse determination or final adverse determination, the health carrier immediately shall approve the coverage that was the subject of the adverse determination or final adverse determination.

J. The assignment by the Commissioner of an approved independent review organization to conduct an external review in accordance with this section shall be done on a random basis among those approved independent review organizations qualified to conduct the particular external review based on the nature of the health care service that is the subject of the adverse determination or final adverse determination and other circumstances, including conflict of interest concerns pursuant to Section (13)(D) of this Rule.

Section 9. Expedited External Review

A. Except as provided in Subsection (F) under this Section, a covered person or the covered person’s authorized representative may make a request for an expedited external review with the Commissioner at the time the covered person receives:

- (1) An adverse determination if:
 - (a) The adverse determination involves a medical condition of the covered person for which the timeframe for completion of an expedited internal review of an appeal involving an

adverse determination set forth in the health carrier's internal appeal procedure or utilization review procedure would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function; and

(b) The covered person or the covered person's authorized representative has filed a request for an expedited review of an appeal involving an adverse determination as set forth in the health carrier's internal appeal procedure or utilization review procedure; or

(2) A final adverse determination:

(a) If the covered person has a medical condition where the timeframe for completion of a standard external review pursuant to Section (8) of this Rule would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function; or

(b) If the final adverse 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. (1) Upon receipt of a request for an expedited external review, the Commissioner immediately shall send a copy of the request to the health carrier.

(2) Immediately upon receipt of the request pursuant to (B)(1) of this Section, the health carrier shall determine whether the request meets the reviewability requirements set forth in Section (8)(B) of this Rule. The health carrier shall immediately notify the Commissioner and the covered person and, if applicable, the covered person's authorized representative of its eligibility determination.

(3) (a) The Commissioner may specify the form for the health carrier's notice of initial determination under this subsection and any supporting information to be included in the notice by bulletin, directive or other publication to health carriers.

(b) The notice of initial determination shall include a statement informing the covered person and, if applicable, the covered person's authorized representative that a health carrier's initial

determination that an external review request is ineligible for review may be appealed to the Commissioner.

- (4) (a) The Commissioner may determine that a request is eligible for external review notwithstanding a health carrier's initial determination that the request is ineligible and require that it be referred for external review.
 - (b) In making a determination under (B)(4)(a) of this Section, the Commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this Rule.
 - (5) Upon receipt of the notice that the request meets the reviewability requirements, the commissioner immediately shall assign an independent review organization to conduct the expedited external review from the list of approved independent review organizations compiled and maintained by the Commissioner pursuant to Section (12) of this Rule. The Commissioner shall immediately notify the health carrier of the name of the assigned independent review organization.
 - (6) In reaching a decision in accordance with Subsection (E) of this Section, the assigned independent review organization is not bound by any decisions or conclusions reached during the health carrier's utilization review process or the health carrier's internal appeal process.
- C. Upon receipt of the notice from the Commissioner of the name of the independent review organization assigned to conduct the expedited external review pursuant to (B)(5) of this Section, the health carrier or its designee utilization review organization shall provide or transmit all necessary documents and information considered in making the adverse determination or final adverse determination to the assigned independent review organization electronically or by telephone or facsimile or any other available expeditious method.
- D. In addition to the documents and information provided or transmitted pursuant to Subsection (C) of this Section, the assigned independent review organization, to the extent the information or documents are available and the independent review organization considers them appropriate, shall consider the following in reaching a decision:
- (1) The covered person's pertinent medical records;

- (2) The attending health care professional's recommendation;
 - (3) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, 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 benefit plan with the health carrier to ensure that the independent review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier;
 - (5) The most appropriate practice guidelines, which shall include evidence-based standards, and may include any other practice guidelines developed by the federal government, national or professional medical societies, boards and associations;
 - (6) Any applicable clinical review criteria developed and used by the health carrier or its designee utilization review organization in making adverse determinations; and
 - (7) The opinion of the independent review organization's clinical reviewer or reviewers after considering (D)(1) through (D)(6) of this Section to the extent the information and documents are available and the clinical reviewer or reviewers consider appropriate.
- E. (1) As expeditiously as the covered person's medical condition or circumstances requires, but in no event more than seventy-two (72) hours after the date of receipt of the request for an expedited external review that meets the reviewability requirements set forth in Section (8)(B) of this Rule, the assigned independent review organization shall:
- (a) Make a decision to uphold or reverse the adverse determination or final adverse determination; and
 - (b) Notify the covered person, if applicable, the covered person's authorized representative, the health carrier, and the commissioner of the decision.
- (2) If the notice provided pursuant to (E)(1) of this Section was not in writing, within forty-eight (48) hours after the date of providing that notice, the assigned independent review organization shall:

- (a) Provide written confirmation of the decision to the covered person, if applicable, the covered person's authorized representative, the health carrier, and the commissioner; and
 - (b) Include the information set forth in Section (8)(I)(2) of this Rule.
 - (3) Upon receipt of the notice a decision pursuant to (E)(1) of this Section reversing the adverse determination or final adverse determination, the health carrier immediately shall approve the coverage that was the subject of the adverse determination or final adverse determination.
- F. An expedited external review may not be provided for retrospective adverse or final adverse determinations.
- G. The assignment by the Commissioner of an approved independent review organization to conduct an external review in accordance with this Section shall be done on a random basis among those approved independent review organizations qualified to conduct the particular external review based on the nature of the health care service that is the subject of the adverse determination or final adverse determination and other circumstances, including conflict of interest concerns pursuant to Section (13)(D) of this Rule.

Section 10. External Review of Experimental or Investigational Treatment Adverse Determinations

- A. (1) Within four (4) months after the date of receipt of a notice of an adverse determination or final adverse determination pursuant to Section (5) of this Rule that involves a denial of coverage based on a determination that the health care service or treatment recommended or requested is experimental or investigational, a covered person or the covered person's authorized representative may file a request for external review with the Commissioner.
- (2) (a) A covered person or the covered person's authorized representative may make an oral request for an expedited external review of the adverse determination or final adverse determination pursuant to (A)(1) under this Section if the covered person's treating physician certifies, in writing, that the recommended or requested health care service or treatment that is the subject of the request would be significantly less effective if not promptly initiated.

- (b) Upon receipt of a request for an expedited external review, the Commissioner immediately shall notify the health carrier.
- (c)
 - (i) Upon notice of the request for expedited external review, the health carrier immediately shall determine whether the request meets the reviewability requirements under (B) of this Section. The health carrier shall immediately notify the Commissioner and the covered person and, if applicable, the covered person's authorized representative of its eligibility determination.
 - (ii) The Commissioner may specify the form for the health carrier's notice of initial determination under (A)(2)(c)(i) of this Section and any supporting information to be included in the notice by bulletin, directive or other publication to health carriers.
 - (iii) The notice of initial determination under (A)(2)(c)(i) of this Section shall include a statement informing the covered person and, if applicable, the covered person's authorized representative that a health carrier's initial determination that the external review request is ineligible for review may be appealed to the Commissioner.
- (d)
 - (i) The Commissioner may determine that a request is eligible for external review under (B)(2) of this Section notwithstanding a health carrier's initial determination the request is ineligible and require that it be referred for external review.
 - (ii) In making a determination under (A)(2)(d)(i) of this Section, the Commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this Rule.
- (e) Upon receipt of the notice that the expedited external review request meets the reviewability requirements of (B)(2) under this Section, the Commissioner immediately shall assign an independent review organization to review the expedited request from the list of approved independent review organizations compiled and maintained by the Commissioner pursuant to Section (12) of this Rule and

notify the health carrier of the name of the assigned independent review organization.

- (f) At the time the health carrier receives the notice of the assigned independent review organization pursuant to (A)(2)(e) of this Section, the health carrier or its designee utilization review organization shall provide or transmit all necessary documents and information considered in making the adverse determination or final adverse determination to the assigned independent review organization electronically or by telephone or facsimile or any other available expeditious method.
- B.
- (1) Except for a request for an expedited external review made pursuant to (A)(2) of this Section, within one (1) business day after the date of receipt of the request, the Commissioner receives a request for an external review, the Commissioner shall notify the health carrier.
 - (2) Within five (5) business days following the date of receipt of the notice sent pursuant to paragraph (1), the health carrier shall conduct and complete a preliminary review of the request to determine whether:
 - (a) The individual is or was a covered person in the health benefit plan at the time the health care service or treatment was recommended or requested or, in the case of a retrospective review, was a covered person in the health benefit plan at the time the health care service or treatment was provided;
 - (b) The recommended or requested health care service or treatment that is the subject of the adverse determination or final adverse determination:
 - (i) Is a covered benefit under the covered person's health benefit plan except for the health carrier's determination that the service or treatment is experimental or investigational for a particular medical condition; and
 - (ii) Is not explicitly listed as an excluded benefit under the covered person's health benefit plan with the health carrier;

- (c) The covered person's treating physician has certified that one of the following situations is applicable:
 - (i) Standard health care services or treatments have not been effective in improving the condition of the covered person;
 - (ii) Standard health care services or treatments are not medically appropriate for the covered person; or
 - (iii) There is no available standard health care service or treatment covered by the health carrier that is more beneficial than the recommended or requested health care service or treatment described in subparagraph (d) of this paragraph;
- (d) The covered person's treating physician:
 - (i) Has recommended a health care service or treatment that the physician certifies, in writing, is likely to be more beneficial to the covered person, in the physician's opinion, than any available standard health care services or treatments; or
 - (ii) 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 service or treatment requested by the covered person that is the subject of the adverse determination or final adverse determination is likely to be more beneficial to the covered person than any available standard health care services or treatments;
- (e) The covered person has exhausted the health carrier's internal appeal process unless the covered person is not required to exhaust the health carrier's internal appeal process pursuant to Section (7) of this Rule; and
- (f) The covered person has provided all the information and forms required by the Commissioner that are necessary to process an external review, including the release form provided under Section (5)(B) of this Rule.

- C. (1) Within one (1) business day after completion of the preliminary review, the health carrier shall notify the Commissioner and the covered person and, if applicable, the covered person's authorized representative in writing whether:
 - (a) The request is complete; and
 - (b) The request is eligible for external review.
- (2) If the request:
 - (a) Is not complete, the health carrier shall inform in writing the Commissioner and the covered person and, if applicable, the covered person's authorized representative and include in the notice what information or materials are needed to make the request complete; or
 - (b) Is not eligible for external review, the health carrier shall inform the covered person, the covered person's authorized representative, if applicable, and the Commissioner in writing and include in the notice the reasons for its ineligibility.
- (3) (a) The Commissioner may specify the form for the health carrier's notice of initial determination under (C)(2) of this Section and any supporting information to be included in the notice by bulletin, directive or other publication to health carriers.
- (b) The notice of initial determination provided under (C)(2) of this Section shall include a statement informing the covered person and, if applicable, the covered person's authorized representative that a health carrier's initial determination that the external review request is ineligible for review may be appealed to the Commissioner.
- (4) (a) The Commissioner may determine that a request is eligible for external review notwithstanding a health carrier's initial determination that the request is ineligible and require that it be referred for external review.
- (b) In making a determination under (C)(4)(a), the Commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this Rule.

- (5) Whenever a request for external review is determined eligible for external review, the health carrier shall notify the Commissioner and the covered person and, if applicable, the covered person's authorized representative.
- D.
- (1) Within one (1) business day after the receipt of the notice from the health carrier that the external review request is eligible for external review pursuant to (A)(2)(d) or (C)(5) of this Section, the Commissioner shall:
 - (a) Assign an independent review organization to conduct the external review from the list of approved independent review organizations compiled and maintained by the commissioner pursuant to Section (12) of this Rule and notify the health carrier of the name of the assigned independent review organization; and
 - (b) 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.
 - (2) The Commissioner shall include in the notice provided to the covered person and, if applicable, the covered person's authorized representative a statement that the covered person or the covered person's authorized representative may submit in writing to the assigned independent review organization within five (5) business days following the date of receipt of the notice provided pursuant to (D)(1) of this Section additional information that the independent review organization shall consider when conducting the external review. The independent review organization is not required to, but may, accept and consider additional information submitted after five (5) business days.
 - (3) Within one (1) business day after the receipt of the notice of assignment to conduct the external review pursuant to (D)(1) under this Section, the assigned independent review organization shall:
 - (a) Select one or more clinical reviewers, as it determines is appropriate, pursuant to (D)(4) of this Section to conduct the external review; and
 - (b) Based on the opinion of the clinical reviewer, or opinions if more than one clinical reviewer has been selected to conduct the external review, make a decision to uphold or reverse the adverse determination or final adverse determination.

- (4)
 - (a) In selecting clinical reviewers pursuant to (D)(3)(a) of this Section, the assigned independent review organization shall select physicians or other health care professionals who meet the minimum qualifications described in Section (13) of this Rule and, through clinical experience in the past three (3) years, are experts in the treatment of the covered person's condition and knowledgeable about the recommended or requested health care service or treatment.
 - (b) Neither the covered person, the covered person's authorized representative, if applicable, nor the health carrier shall choose or control the choice of the physicians or other health care professionals to be selected to conduct the external review.
 - (5) In accordance with Subsection (H) of this Section, each clinical reviewer shall provide a written opinion to the assigned independent review organization on whether the recommended or requested health care service or treatment should be covered.
 - (6) In reaching an opinion, clinical reviewers are not bound by any decisions or conclusions reached during the health carrier's utilization review procedure or the health carrier's internal appeal procedure.
- E.
 - (1) Within five (5) business days after the date of receipt of the notice provided pursuant to (D)(1) of this Section, the health carrier or its designee utilization review organization shall provide to the assigned independent review organization, the documents and any information considered in making the adverse determination or the final adverse determination.
 - (2) Except as provided in (E)(3) under this Section, failure by the health carrier or its designee utilization review organization to provide the documents and information within the time specified in (E)(1) shall not delay the conduct of the external review.
 - (3)
 - (a) If the health carrier or its designee utilization review organization has failed to provide the documents and information within the time specified in (E)(1) in this Section, the assigned independent review organization may terminate the external review and make a decision to reverse the adverse determination or final adverse determination.

- (b) Immediately upon making the decision under (E)(3)(a) of this Section, the independent review organization shall notify the covered person, the covered person's authorized representative, if applicable, the health carrier, and the Commissioner.

- F.
 - (1) Each clinical reviewer selected pursuant to Subsection (D) under this Section shall review all of the information and documents received pursuant to Subsection (E) of this Section and any other information submitted in writing by the covered person or the covered person's authorized representative pursuant to (D)(2) of this Section.

 - (2) Upon receipt of any information submitted by the covered person or the covered person's authorized representative pursuant to subsection (D)(2) of this Section, within one (1) business day after the receipt of the information, the assigned independent review organization shall forward the information to the health carrier.

- G.
 - (1) Upon receipt of the information required to be forwarded pursuant to Subsection (F)(2) of this Section, the health carrier may reconsider its adverse determination or final adverse determination that is the subject of the external review.

 - (2) Reconsideration by the health carrier of its adverse determination or final adverse determination pursuant to (G)(1) of this Section shall not delay or terminate the external review.

 - (3) The external review may be terminated only if the health carrier decides, upon completion of its reconsideration, to reverse its adverse determination or final adverse determination and provide coverage or payment for the recommended or requested health care service or treatment that is the subject of the adverse determination or final adverse determination.

 - (4)
 - (a) Immediately upon making the decision to reverse its adverse determination or final adverse determination, as provided in (G)(3) of this Section, the health carrier shall notify the covered person, the covered person's authorized representative if applicable, the assigned independent review organization, and the commissioner in writing of its decision.

 - (b) The assigned independent review organization shall terminate the external review upon receipt of the notice

from the health carrier sent pursuant to (G)(4)(a) of this Section.

- H. (1) Except as provided in (H)(3) of this Section, within twenty (20) days after being selected in accordance with Subsection (D) of this Section to conduct the external review, each clinical reviewer shall provide an opinion to the assigned independent review organization pursuant to subsection I on whether the recommended or requested health care service or treatment should be covered.
- (2) Except for an opinion provided pursuant to (H)(3) of this Section, each clinical reviewer's opinion shall be in writing and include the following information:
- (a) A description of the covered person's medical condition;
 - (b) A description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the recommended or requested health care service or treatment is more likely than not to be beneficial to the covered person than any available standard health care services or treatments and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments;
 - (c) A description and analysis of any medical or scientific evidence, as that term is defined in Section (3)(DD) of this Rule, considered in reaching the opinion;
 - (d) A description and analysis of any evidence-based standard, as that term is defined in Section (3)(S) of this Rule; and
 - (e) Information on whether the reviewer's rationale for the opinion is based on (I)(5)(a) or (b) of this Section.
- (3) (a) For an expedited external review, each clinical reviewer shall provide an opinion orally or in writing to the assigned independent review organization as expeditiously as the covered person's medical condition or circumstance requires, but in no event more than five (5) calendar days after being selected in accordance with Subsection (D) of this Section.
- (b) If the opinion provided pursuant to (H)(3)(a) of this Section was not in writing, within forty-eight (48) hours following

the date the opinion was provided, the clinical reviewer shall provide written confirmation of the opinion to the assigned independent review organization and include the information required under (H)(2) of this Section.

- I. In addition to the documents and information provided pursuant to (A)(2) or (E) of this Section, each clinical reviewer selected pursuant to Subsection (D) of this Section, to the extent the information or documents are available and the reviewer considers appropriate, shall consider the following in reaching an opinion pursuant to Subsection (H) of this Section:
 - (1) The covered person's pertinent medical records;
 - (2) The attending physician or health care professional's recommendation;
 - (3) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person, the covered person's authorized representative, or the covered person's treating physician or health care professional;
 - (4) The terms of coverage under the covered person's health benefit plan with the health carrier to ensure that, but for the health carrier's determination that the recommended or requested health care service or treatment that is the subject of the opinion is experimental or investigational, the reviewer's opinion is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier; and
 - (5) Whether:
 - (a) The recommended or requested health care service or treatment has been approved by the federal Food and Drug Administration, if applicable, for the condition; or
 - (b) Medical or scientific evidence or evidence-based standards demonstrate that the expected benefits of the recommended or requested health care service or treatment is more likely than not to be beneficial to the covered person than any available standard health care service or treatment and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments.

- J. (1) (a) Except as provided in (J)(1)(b) of this Section, within twenty (20) days after the date it receives the opinion of each clinical reviewer pursuant to Subsection (I) of this Section, the assigned independent review organization, in accordance with (J)(2) of this Section, shall make a decision and provide written notice of the decision to:
- (i) The covered person;
 - (ii) If applicable, the covered person's authorized representative;
 - (iii) The health carrier; and
 - (iv) The Commissioner.
- (b) (i) For an expedited external review, within seventy-two (72) hours after the date it receives the opinion of each clinical reviewer pursuant to Subsection (I) under this Section, the assigned independent review organization, in accordance with (J)(2) of this Section, shall make a decision and provide notice of the decision orally or in writing to the persons listed in (J)(1)(a) under this Section.
- (ii) If the notice provided under (J)(b)(i) under this Section was not in writing, within forty-eight (48) hours after the date of providing that notice, the assigned independent review organization shall provide written confirmation of the decision to the persons listed in (J)(1)(a) of this Section and include the information set forth in (J)(3).
- (2) (a) If a majority of the clinical reviewers recommend that the recommended or requested health care service or treatment should be covered, the independent review organization shall make a decision to reverse the health carrier's adverse determination or final adverse determination.
- (b) If a majority of the clinical reviewers recommend that the recommended or requested health care service or treatment should not be covered, the independent review organization shall make a decision to uphold the health carrier's adverse determination or final adverse determination.

- (i) If the clinical reviewers are evenly split as to whether the recommended or requested health care service or treatment should be covered, the independent review organization shall obtain the opinion of an additional clinical reviewer in order for the independent review organization to make a decision based on the opinions of a majority of the clinical reviewers pursuant to (J)(2)(a) or (J)(2)(b) of this Section.
 - (ii) The additional clinical reviewer selected under (J)(2)(c)(i) of this Section shall use the same information to reach an opinion as the clinical reviewers who have already submitted their opinions pursuant to Subsection (I) of this Section.
 - (iii) The selection of the additional clinical reviewer under this subparagraph shall not extend the time within which the assigned independent review organization is required to make a decision based on the opinions of the clinical reviewers selected under Subsection (D) of this Section.
- (3) The independent review organization shall include in the notice provided pursuant to (J)(1) of this Section:
 - (a) A general description of the reason for the request for external review;
 - (b) The written opinion of each clinical reviewer, including the recommendation of each clinical reviewer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the reviewer's recommendation;
 - (c) The date the independent review organization was assigned by the commissioner to conduct the external review;
 - (d) The date the external review was conducted;
 - (e) The date of its decision;
 - (f) The principal reason or reasons for its decision; and
 - (g) The rationale for its decision.

- (4) Upon receipt of a notice of a decision pursuant to (J)(1) of this Section reversing the adverse determination or final adverse determination, the health carrier immediately shall approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse determination or final adverse determination.

- L. The assignment by the Commissioner of an approved independent review organization to conduct an external review in accordance with this Section shall be done on a random basis among those approved independent review organizations qualified to conduct the particular external review based on the nature of the health care service that is the subject of the adverse determination or final adverse determination and other circumstances, including conflict of interest concerns pursuant to Section (13)(D) of this Rule.

Section 11. Binding Nature of External Review Decision

- A. An external review decision is binding on the health carrier except to the extent the health carrier has other remedies available under applicable State law.

- B. An external review decision is binding on the covered person except to the extent the covered person has other remedies available under applicable federal or State law.

- C. A covered person or the covered person's authorized representative may not file a subsequent request for external review involving the same adverse determination or final adverse determination for which the covered person has already received an external review decision pursuant to this Rule.

Section 12. Approval of Independent Review Organizations

- A. The Commissioner shall approve independent review organizations eligible to be assigned to conduct external reviews under this Rule.

- B. In order to be eligible for approval by the Commissioner under this section to conduct external reviews under this Rule an independent review organization:
 - (1) Except as otherwise provided in this section, shall be accredited by a nationally recognized private accrediting entity that the Commissioner has determined has independent review organization accreditation standards that are equivalent to or

exceed the minimum qualifications for independent review organizations established under Section (13) of this Rule; and

- (2) Shall submit an application for approval in accordance with Subsection (D) of this Section.
- C. The Commissioner shall develop an application form for initially approving and for reapproving independent review organizations to conduct external reviews.
- D. (1) Any independent review organization wishing to be approved to conduct external reviews under this Act shall submit the application form and include with the form all documentation and information necessary for the Commissioner to determine if the independent review organization satisfies the minimum qualifications established under Section (13) of this Rule.
- (2) (a) Subject to (D)(2)(b) of this Section, an independent review organization is eligible for approval under this section only if it is accredited by a nationally recognized private accrediting entity that the Commissioner has determined has independent review organization accreditation standards that are equivalent to or exceed the minimum qualifications for independent review organizations under Section (13) of this Rule.
 - (b) The Commissioner may approve independent review organizations that are not accredited by a nationally recognized private accrediting entity if there are no acceptable nationally recognized private accrediting entities providing independent review organization accreditation.
- (3) The Commissioner may charge an application fee that independent review organizations shall submit to the commissioner with an application for approval and re-approval.
- E. (1) An approval is effective for two (2) years, unless the Commissioner determines before its expiration that the independent review organization is not satisfying the minimum qualifications established under Section (13) of this Rule.
- (2) Whenever the Commissioner determines that an independent review organization has lost its accreditation or no longer satisfies the minimum requirements established under Section 13 of this Rule, the commissioner shall terminate the approval of the independent review organization and remove the independent

review organization from the list of independent review organizations approved to conduct external reviews under this Rule that is maintained by the Commissioner pursuant to Subsection (F) of this Section.

- F. The Commissioner shall maintain and periodically update a list of approved independent review organizations.

Section 13. Minimum Qualifications for Independent Review Organizations

- A. To be approved under Section (12) of this Rule to conduct external reviews, an independent review organization shall have and maintain written policies and procedures that govern all aspects of both the standard external review process and the expedited external review process set forth in this Rule that include, at a minimum:
 - (1) A quality assurance mechanism in place that:
 - (a) Ensures that external reviews are conducted within the specified time frames and required notices are provided in a timely manner;
 - (b) Ensures the selection of qualified and impartial clinical reviewers to conduct external reviews on behalf of the independent review organization and suitable matching of reviewers to specific cases and that the independent review organization employs or contracts with an adequate number of clinical reviewers to meet this objective;
 - (c) Ensures the confidentiality of medical and treatment records and clinical review criteria; and
 - (d) Ensures that any person employed by or under contract with the independent review organization adheres to the requirements of this Rule;
 - (2) A toll-free telephone service to receive information on a 24-hour-day, 7-day-a-week basis related to external reviews that is capable of accepting, recording or providing appropriate instruction to incoming telephone callers during other than normal business hours; and
 - (3) Agree to maintain and provide to the Commissioner the information set out in Section (15) of this Rule.

- B. All clinical reviewers assigned by an independent review organization to conduct external reviews shall be physicians or other appropriate health care providers who meet the following minimum qualifications:
- (1) Be an expert in the treatment of the covered person's medical condition that is the subject of the external review;
 - (2) Be knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical condition of the covered person;
 - (3) Hold a non-restricted license in a State of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review; and
 - (4) Have no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by any 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. In addition to the requirements set forth in Subsection (A) of this Section, an independent review organization may not own or control, be a subsidiary of or in any way be owned or controlled by, or exercise control with a health benefit plan, a national, State or local trade association of health benefit plans, or a national, State or local trade association of health care providers.
- D. (1) In addition to the requirements set forth in Subsections (A), (B) and (C) of this Section, to be approved pursuant to Section (12) of this Rule to conduct an external review of a specified case, neither the independent review organization selected to conduct the external review nor any clinical reviewer assigned by the independent organization to conduct the external review may have a material professional, familial or financial conflict of interest with any of the following:
- (a) The health carrier that is the subject of the external review;
 - (b) The covered person whose treatment is the subject of the external review or the covered person's authorized representative;

- (c) Any officer, director or management employee of the health carrier that is the subject of the external review;
 - (d) The health care provider, the health care provider's medical group or independent practice association recommending the health care service or treatment that is the subject of the external review;
 - (e) The facility at which the recommended health care service or treatment would be provided; or
 - (f) 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 independent review organization or a clinical reviewer of the independent review organization has a material professional, familial or financial conflict of interest for purposes of paragraph (1), the Commissioner shall take into consideration situations where the independent review organization to be assigned to conduct an external review of a specified case or a clinical reviewer to be assigned by the independent review organization to conduct an external review of a specified case may have an apparent professional, familial or financial relationship or connection with a person described in (D)(1) of this Section, but that the characteristics of that relationship or connection are such that they are not a material professional, familial or financial conflict of interest that results in the disapproval of the independent review organization or the clinical reviewer from conducting the external review.
- E. (1) An independent review organization that is accredited by a nationally recognized private accrediting entity that has independent review accreditation standards that the commissioner has determined are equivalent to or exceed the minimum qualifications of this section shall be presumed in compliance with this section to be eligible for approval under Section (12) of this Rule.
- (2) The Commissioner shall initially review and periodically review the independent review organization accreditation standards of a nationally recognized private accrediting entity to determine whether the entity's standards are, and continue to be, equivalent to or exceed the minimum qualifications established under this

section. The commissioner may accept a review conducted by the NAIC for the purpose of the determination under this paragraph.

- (3) Upon request, a nationally recognized private accrediting entity shall make its current independent review organization accreditation standards available to the Commissioner or the NAIC in order for the commissioner to determine if the entity's standards are equivalent to or exceed the minimum qualifications established under this section. The commissioner may exclude any private accrediting entity that is not reviewed by the NAIC.
- F. An independent review organization shall be unbiased. An independent review organization shall establish and maintain written procedures to ensure that it is unbiased in addition to any other procedures required under this section.

Section 14. Hold Harmless for Independent Review Organizations

No independent review organization or clinical reviewer working on behalf of an independent review organization or an employee, agent or contractor of an independent review organization shall be liable in damages to any person for any opinions rendered or acts or omissions performed within the scope of the organization's or person's duties under the law during or upon completion of an external review conducted pursuant to this Rule, unless the opinion was rendered or act or omission performed in bad faith or involved gross negligence.

Section 15. External Review Reporting Requirements

- A.
- (1) An independent review organization assigned pursuant to Section (8), Section (9) or Section (10) of this Rule to conduct an external review shall maintain written records in the aggregate by State and by health carrier on all requests for external review for which it conducted an external review during a calendar year and, upon request, submit a report to the Commissioner, as required under (A)(2) of this Section.
 - (2) Each independent review organization required to maintain written records on all requests for external review pursuant to (A)(1) of this Section for which it was assigned to conduct an external review shall submit to the commissioner, upon request, a report in the format specified by the commissioner.
 - (3) The report shall include in the aggregate by State, and for each health carrier:
 - (a) The total number of requests for external review;

- (b) The number of requests for external review resolved and, of those resolved, the number resolved upholding the adverse determination or final adverse determination and the number resolved reversing the adverse determination or final adverse determination;
 - (c) The average length of time for resolution;
 - (d) A summary of the types of coverages or cases for which an external review was sought, as provided in the format required by the Commissioner;
 - (e) The number of external reviews pursuant to Section (8)(G) of this Rule that were terminated as the result of a reconsideration by the health carrier of its adverse determination or final adverse determination after the receipt of additional information from the covered person or the covered person's authorized representative; and
 - (f) Any other information the Commissioner may request or require.
- (4) The independent review organization shall retain the written records required pursuant to this subsection for at least three (3) years.
- B. (1) Each health carrier shall maintain written records in the aggregate, by State and for each type of health benefit plan offered by the health carrier on all requests for external review that the health carrier receives notice of from the Commissioner pursuant to this Rule.
- (2) Each health carrier required to maintain written records on all requests for external review pursuant to paragraph (1) shall submit to the Commissioner, upon request, a report in the format specified by the Commissioner.
- (3) The report shall include in the aggregate, by State, and by type of health benefit plan:
- (a) The total number of requests for external review;
 - (b) From the total number of requests for external review reported under (B)(3)(a) of this Section, the number of requests determined eligible for a full external review; and

- (c) Any other information the Commissioner may request or require.
- (4) The health carrier shall retain the written records required pursuant to this subsection for at least six (6) years.

Section 16. Funding of External Review

The health carrier against which a request for a standard external review or an expedited external review is filed shall pay the cost of the independent review organization for conducting the external review

Section 17. Disclosure Requirements

- A. (1) Each health carrier shall include a description of the external review procedures in or attached to the policy, certificate, membership booklet, outline of coverage or other evidence of coverage it provides to covered persons.
- (2) The disclosure required by (A)(1) of this Section shall be in a format prescribed by the Commissioner.
- B. The description required under Subsection (A) shall include a statement that informs the covered person of the right of the covered person to file a request for an external review of an adverse determination or final adverse determination with the commissioner. The statement may explain that external review is available when the adverse determination or final adverse determination involves an issue of medical necessity (or substantially equivalent term), appropriateness, health care setting, level of care or effectiveness. The statement shall include the telephone number and address of the Commissioner.
- C. In addition to Subsection (B) of this Section, the statement shall inform the covered person that, when filing a request for an external review, the covered person will be required to authorize the release of any medical records of the covered person that may be required to be reviewed for the purpose of reaching a decision on the external review.

Section 18. Severability

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

Section 19. Effective Date

This Rule shall be effective January 1, 2012.

(signed by Jay Bradford)

JAY BRADFORD
INSURANCE COMMISSIONER
STATE OF ARKANSAS

12-05-2011

DATE

NOTICE OF APPEAL RIGHTS

You have a right to appeal any decision we make that denies payment on your claim or your request for coverage of a health care service or treatment.

You may request more explanation when your claim or request for coverage of a health care service or treatment is denied or the health care service or treatment you received was not fully covered. Contact us when you:

- Do not understand the reason for the denial;
- Do not understand why the health care service or treatment was not fully covered;
- Do not understand why a request for coverage of a health care service or treatment was denied;
- Cannot find the applicable provision in your Benefit Plan Document;
- Want a copy (free of charge) of the guideline, criteria or clinical rationale that we used to make our decision; or
- Disagree with the denial or the amount not covered and you want to appeal.

If your claim was denied due to missing or incomplete information, you or your health care provider may resubmit the claim to us with the necessary information to complete the claim.

Appeals: All appeals for claim denials (or any decision that does not cover expenses you believe should have been covered) must be sent to [insert address of where appeals should be sent to the health carrier] within **180 days** of the date you receive our denial. We will provide a full and fair review of your claim by individuals associated with us, but who were not involved in making the initial denial of your claim. You may provide us with additional information that relates to your claim and you may request copies of information that we have that pertains to your claims. We will notify you of our decision in writing within **60 days** of receiving your appeal. If you do not receive our decision within **60 days** of receiving your appeal, you may be entitled to file a request for external review.

External Review: We have denied your request for the provision of or payment for a health care service or course of treatment. You may have a right to have our decision reviewed by independent health care professionals 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 by submitting a request for external review in writing within **4 months** after receipt of this notice to the External Review Division, Arkansas Insurance Department at 1200 West 3rd Street, Little Rock, AR 72201. For standard external review, a decision will be made within **45 days** of receiving your request. If you have a medical condition that would seriously jeopardize your life or health or would jeopardize your ability to regain maximum function if treatment is delayed, you may be entitled to request an **expedited external review** of our denial. If our denial to provide or pay for health care service or course of treatment is based on a determination that the service or treatment is experimental or investigation, you also may be entitled to file a request for external review of our denial. For details, please review your Benefit Plan Document, contact us or contact your state insurance department.

Appendix B – Model External Review Request Form

This **EXTERNAL REVIEW REQUEST FORM** must be filed with the External Review Division, Arkansas Insurance Commissioner 1200 West Third Street, Little Rock, AR 72201; within **FOUR (4) MONTHS** after receipt from your insurer of a denial of payment on a claim or request for coverage of a health care service or treatment.

EXTERNAL REVIEW REQUEST FORM

APPLICANT NAME _____ Covered person/Patient Provider
Authorized Representative

COVERED PERSON/PATIENT INFORMATION

Covered Person Name: _____ Patient Name: _____

Address: _____

Covered Person Phone #: Home (____) _____ Work (____) _____

INSURANCE INFORMATION

Insurer/HMO Name: _____

Covered Person Insurance ID#: _____

Insurance Claim/Reference #: _____

Insurer/HMO Mailing Address: _____

Insurer Telephone #: (____) _____

EMPLOYER INFORMATION

Employer's Name: _____

Employer's Phone #: (____) _____

Is the health coverage you have through your employer a self-funded plan? _____. If you are not certain please check with your employer. Most self-funded plans are not eligible for external review. However, some self-funded plans may voluntarily provide external review, but may have different procedures. You should check with your employer.

HEALTH CARE PROVIDER INFORMATION

Treating Physician/Health Care Provider: _____

Address:

Contact Person: _____ Phone: () _____

Medical Record #: _____

REASON FOR HEALTH CARRIER DENIAL (Please check one)

- The health care service or treatment is not medically necessary.
- The health care service or treatment is experimental or investigational.

SUMMARY OF EXTERNAL REVIEW REQUEST (Enter a brief description of the claim, the request for health care service or treatment that was denied, and/or attach a copy of the denial from your health carrier)*

*You may also describe in your own words the health care service or treatment in dispute and why you are appealing this denial using the attached pages below.

EXPEDITED REVIEW

If you need a fast decision, you may request that your external appeal be handled on an expedited basis. To complete this request, your treating health care provider must fill out the attached form stating that a delay would seriously jeopardize the life or health of the patient or would jeopardize the patient’s ability to regain maximum function.

Is this a request for an expedited appeal? Yes _____ No _____

SIGNATURE AND RELEASE OF MEDICAL RECORDS

To appeal your health carrier’s denial, you must sign and date this external review request form and consent to the release of medical records.

I, _____, hereby request an external appeal. I attest that the information provided in this application is true and accurate to the best of my knowledge. I authorize by insurance company and my health care providers to release all relevant medical or treatment records to the independent review organization and the Arkansas Insurance Department. I understand that the independent review organization and the Arkansas Insurance Department will use this information to make a determination on my external appeal and that the information will be kept confidential and not be released to anyone else. This release is valid for one year.

Signature of Covered Person (or legal representative)* Date

*(Parent, Guardian, Conservator or Other – Please Specify)

APPOINTMENT OF AUTHORIZED REPRESENTATIVE

(Fill out this section only if someone else will be representing you in this appeal.)

You can represent yourself, or you may ask another person, including your treating health care provider, to act as your authorized representative. You may revoke this authorization at any time.

I hereby authorize _____ to pursue my appeal on my behalf.

Signature of Covered Person (or legal representative)* Date
*(Parent, Guardian, Conservator or Other—Please Specify)
Address of Authorized Representative:

Phone #: Daytime () _____ Evening
() _____

HEALTH CARE SERVICE OR TREATMENT DECISION IN DISPUTE

DESCRIBE IN YOUR OWN WORDS THE DISAGREEMENT WITH YOUR HEALTH CARRIER. INDICATE CLEARLY THE SERVICE(S) BEING DENIED AND THE SPECIFIC DATE(S) BEING DENIED. EXPLAIN WHY YOU DISAGREE. ATTACH ADDITIONAL PAGES IF NECESSARY AND INCLUDE AVAILABLE PERTINENT MEDICAL RECORDS, ANY INFORMATION YOU RECEIVED FROM YOUR HEALTH CARRIER CONCERNING THE DENIAL, ANY PERTINENT PEER LITERATURE OR CLINICAL STUDIES, AND ANY ADDITIONAL INFORMATION FROM YOUR PHYSICIAN/HEALTH CARE PROVIDER THAT YOU WANT THE INDEPENDENT REVIEW ORGANIZATION REVIEWER TO CONSIDER.

WHAT TO SEND AND WHERE TO SEND IT

PLEASE CHECK BELOW (NOTE: YOUR REQUEST WILL NOT BE ACCEPTED FOR FULL REVIEW UNLESS ALL FOUR (4) ITEMS BELOW ARE INCLUDED*)

1. **YES**, I have included this completed application form signed and dated.
2. **YES**, I have included a photocopy of my insurance identification card or other evidence showing that I am insured by the health insurance company named in this application;
3. **YES****, I have enclosed the letter from my health carrier or utilization review company that states:
 - (a) Their decision is final and that I have exhausted all internal review procedures; or
 - (b) They have waived the requirement to exhaust all of the health carrier's internal review procedures.

******You may make a request for external review without exhausting all internal review procedures under certain circumstances. You should contact the External Review Division, Arkansas Insurance Department, 1200 West Third Street, Little Rock, Arkansas 72201, phone: 1-800-282-9134.

4. **YES**, I have included a copy of my certificate of coverage or my insurance policy benefit booklet, which lists the benefits under my health benefit plan.

*Call the Insurance Department at 1-800-282-9134 if you need help in completing this application or if you do not have one or more of the above items and would like information on alternative ways to complete your request for external review.

If you are requesting a standard external review, send all paperwork to: External Review Division, Arkansas Insurance Department 1200 West Third Street, Little Rock, AR 72201.

If you are requesting an expedited external review, call the Arkansas Insurance Department before sending your paperwork, and you will receive instructions on the quickest way to submit the application and supporting information.

**CERTIFICATION OF TREATING HEALTH CARE PROVIDER
FOR EXPEDITED CONSIDERATION OF A PATIENT'S EXTERNAL REVIEW APPEAL**

NOTE TO THE TREATING HEALTH CARE PROVIDER

Patients can request an external review when a health carrier has denied a health care service or course of treatment on the basis of a utilization review determination that the requested health care service or course of treatment does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested. The External Review Division of the Arkansas Insurance Department oversees external appeals. The standard external review process can take up to 45 days from the date the patient's request for external review is received by our department. Expedited external review is available only if the patient's treating health care provider certifies that adherence to the time frame for the 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. An expedited external review must be completed at most within 72 hours. This form is for the purpose of providing the certification necessary to trigger expedited review.

GENERAL INFORMATION

Name of Treating Health Care Provider: _____

Mailing Address:

Phone Number: (____) _____ Fax Number: (____) _____

Licensure and Area of Clinical Specialty: _____

Name of Patient: _____

Patient's Insurer Member ID#: _____

CERTIFICATION

I hereby certify that: I am a treating health care provider for _____
(hereafter referred to as “the patient”); that adherence to the time frame for conducting a standard external review of the patient’s appeal would, in my professional judgment, seriously jeopardize the life or health of the patient or would jeopardize the patient’s ability to regain maximum function; and that, for this reason, the patient’s appeal of the denial by the patient’s health carrier of the requested health care service or course of treatment should be processed on an expedited basis.

Treating Health Care Provider’s Name (Please Print)

Signature

Date

**PHYSICIAN CERTIFICATION
EXPERIMENTAL/INVESTIGATIONAL DENIALS
(To Be Completed by Treating Physician)**

I hereby certify that I am the treating physician for _____ (covered person's name) and that I have requested the authorization for a drug, device, procedure or therapy denied for coverage due to the insurance company's determination that the proposed therapy is experimental and/or investigational. I understand that in order for the covered person to obtain the right to an external review of this denial, as treating physician I must certify that the covered person's medical condition meets certain requirements:

In my medical opinion as the Insured's treating physician, I hereby certify to the following:

(Please check all that apply) (NOTE: Requirements #1 - #3 below must all apply for the covered person to qualify for an external review).

- 1) The covered person has a terminal medical condition, life threatening condition, or a seriously debilitating condition.

- 2) The covered person has a condition that qualifies under one or more of the following:
[please indicate which description(s) apply]:
 - Standard health care services or treatments have not been effective in improving the covered person's condition;
 - Standard health care services or treatments are not medically appropriate for the covered person; or
 - There is no available standard health care service or treatment covered by the health carrier that is more beneficial than the requested or recommended health care service or treatment.

- 3) The health care service or treatment I have recommended and which has been denied, in my medical opinion, is likely to be more beneficial to the covered person than any available standard health care services or treatments.

- 4) The health care service or treatment recommended would be significantly less effective if not promptly initiated.

Explain: _____

- 5) It is my medical opinion based on scientifically valid studies using accepted protocols that the health care service or treatment requested by the covered person and which has been denied is likely to be more beneficial to the covered person than any available standard health care services or treatments.

Explain: _____

Please provide a description of the recommended or requested health care service or treatment that is the subject of the denial. (Attach additional sheets as necessary)

Physician's Signature

Date

Appendix C – Independent Review Organization External Review Annual Report Form
Arkansas Insurance Department

Independent Review Organization External Review Annual Report Form

External Review Annual Summary for 20		_____.	
Due on [insert date] for previous calendar year.			
Each independent review organization (IRO) shall submit an annual report with information for each health carrier in the aggregate on external reviews performed in Arkansas only.			
1. IRO name:	_____	Filing date:	_____
2. IRO license/certification no:	_____		
3. IRO address:	_____		
City, State, ZIP:	_____		
4. IRO Web site:	_____		
5. Name, email address, phone and fax number of the person completing this form:			

6. Name and title of the person responsible for regulatory compliance and quality of external reviews:			
Name:	_____	Title:	_____
7. Total number of requests for external review received from [insert state insurance department name] during the reporting period:			

8. Number of standard external reviews:		_____	
9. Average number of days IRO required to reach a final decision in standard reviews:		_____	
10. Number of expedited reviews completed to a final decision:		_____	
11. Average number of days IRO required to reach a final decision in expedited reviews:		_____	

12. Number of medical necessity reviews decided in favor of the health carrier:		_____	
Briefly list procedures denied:		_____	
13. Number of medical necessity reviews decided in favor of the covered person:		_____	
Briefly list procedures approved:		_____ _____ _____ _____	
14. Number of experimental/investigational reviews decided in favor of the health carrier:		_____	
Briefly list procedures denied:		_____ _____ _____ _____	
15. Number of experimental/investigational reviews decided in favor of the covered person:		_____	
Briefly list procedures approved:		_____ _____ _____ _____	
16. Number of reviews terminated as the result of a reconsideration by the health carrier:		_____	
17. Number of reviews terminated by the covered person:		_____	
18. Number of reviews declined due to possible conflict with:			
Health carrier	_____	Covered person	_____
		Health care provider	_____
Describe possible conflicts(s) of interest:		_____	
19. Number of reviews declined due to other reasons not reflected in #18 above:		_____	

Appendix D – Model Health Carrier External Review Annual Report Form

Arkansas Insurance Department
Health Carrier External Review Annual Report Form

External Review Annual Summary for 20	_____.		
Due on [insert date] for previous calendar year.			
Each health carrier shall submit an annual report with information in the aggregate by State and by type of health benefit plan.			
1. Health carrier name:	_____	Filing Date:	_____
2. Health carrier address:	_____		
City, State, ZIP:	_____		
3. Health carrier Web site:	_____		
4. Name, email address, phone and fax number of the person completing this form:	_____		

5. Total number of external review requests received from [insert state insurance department name] during the reporting period:			_____
6. From the total number of external review requests provided in Question 5, the number of requests determined eligible for a full external review:			_____