RULE AND REGULATION NO. 76

ARKANSAS EXTERNAL REVIEW REGULATION

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Section 1. Title and Purpose

A. This regulation shall be known and may be cited as the Arkansas External Review Regulation. The purpose of this regulation is to provide 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 regulation.

B. Every health benefit plan shall provide covered persons an external review process by an independent review organization to examine the health benefit plan's adverse determinations that meet the criteria specified in this regulation.

C. This regulation does not require the coverage of any benefit or service not provided under the terms of a health benefit plan, nor does this regulation require reimbursement of any particular provider or class of providers for which coverage is not provided in a health benefit plan.

D. Nothing in this regulation shall be construed to create any private right or cause of action for or on behalf of any covered person.

E. The provisions of this regulation 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, long-term care insurance as defined by Ark. Code Ann. § 23-97-203(5)(A)(i), vision care or any other limited supplemental benefit, a Medicare supplement policy of insurance, as defined by the commissioner by regulation, coverage under a plan through Medicare, Medicaid, the Arkansas Comprehensive Health Insurance Plan in accordance with Ark. Code Ann. § 23-79-501, *et seq*., 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, or any coverage issued as supplemental to liability insurance, workers' compensation or similar insurance, or automobile medical-payment insurance.

F. Any provision in a health benefit plan, provider agreement, or other contract that is contrary to the provisions in this regulation shall be null and void.

G. A health carrier may elect to establish the right of external review for health benefit plan decisions not otherwise subject to this regulation ("Voluntary External Review"), in which case this regulation and regulations hereunder shall apply to any such Voluntary External Review.

Section 2. Authority

This regulation is promulgated pursuant to the authority granted by 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 3. Definitions

For purposes of this Regulation:

A. (1) "Adverse determination" means a determination by a health carrier that an admission, availability of care, continued stay or other health care service has been reviewed and, based upon the information provided, the requested payment for the service is denied, reduced or terminated, because:

(a) The requested health care service does not meet the health benefit plan's requirements for medical necessity, or

(b) The requested health care service has been found to be "experimental/investigational."

(2) In order to qualify as an "adverse determination" under this regulation:

(a) The adverse determination must be a final adverse determination, except as may be provided herein.

(b) The adverse determination must involve treatment, services, equipment, supplies, or drugs that would require the health benefit plan to expend five hundred dollars ($500) or more of expenditures.

(3) "Adverse determination" does not include a determination by a health carrier to deny a health care service based upon:

(a) An express exclusion in the health benefit plan other than a general exclusion for "medical necessity" or "experimental/investigational;"
(b) An express limitation in the health benefit plan with respect to the number of visits, treatments, supplies or services for a covered benefit in a given calendar period or over the lifetime of the covered person;
(c) An express limitation in the health benefit plan with respect to a maximum dollar limitation with respect to a covered benefit in a given calendar period or over the lifetime of the person;
(d) A determination by the health carrier that an individual is not eligible to be a covered person;
(e) A determination by the health carrier that treatment, service, or supplies were requested or obtained by a covered person through fraud or material misrepresentation.
(f) The health benefit plan's procedure for determining the covered person's access to a health care provider, including but not limited to any primary care gatekeeper, referral or network access provision;
(g) Illegality of services or the means or methods of administering them;
(h) FDA or other government agency determinations, reports or statements; or
(i) Licensure, permit or accreditation status of a health care provider.

B. "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) When the covered person is unable to provide consent, a family member of the covered person or the covered person's treating health care professional if a family member is unavailable.

C. "Commissioner" means the Arkansas Insurance Commissioner.

D. "Covered benefits" or "benefits" means those health care services to which a covered person is entitled under the terms of a health benefit plan.

E. "Covered person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan. "Covered person" shall also mean the covered person's authorized representative, as defined in this regulation.

F. "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.

G. “Emergency medical condition” means medical conditions of a recent onset and severity, including, but not limited to, severe pain that would lead a prudent lay person, possessing an average knowledge of medicine and health, to believe that his or her condition, sickness, or injury is of such a nature that failure to get immediate medical care could result in placing the patient's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

H. “Emergency services” means health care items and services furnished or required to evaluate and treat an emergency medical condition.

I. “Experimental or investigational” or “experimental/investigational” or substantially equivalent terms, means the definition of such terms as expressed by the health carrier in its health benefit plan as approved by the Arkansas Insurance Department.

J. “External Review” means a process, independent of all affected parties, to determine if a health care service is medically necessary or experimental/ investigational.

K. “Facility” means an institution providing health care services or a health care setting, including but not limited to, hospitals and other licensed inpatient centers, outpatient surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

L. “Final adverse determination” means an adverse determination involving a covered benefit that has been upheld by a health carrier at the completion of the health carrier’s internal grievance procedure or utilization review procedure. If the health carrier does not have, nor is required by law to have, an internal grievance procedure or utilization review procedure, an adverse determination shall be considered a final adverse determination.

M. “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.

N. “Health care professional” means a physician or other health care practitioner licensed, accredited or certified to perform specified health services consistent with state law.

O. “Health care provider” or “provider” means a health care professional or a facility.

P. “Health care services” means services for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury or disease.

Q. “Health carrier” means an entity subject to any of the provisions of Title 23 of the Arkansas Code Annotated 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, and a nonprofit hospital and health service corporation. "Health carrier" shall not mean the Arkansas Comprehensive Health Insurance Plan in accordance with Ark. Code Ann. § 23-79-501, *et seq*.

R. "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.

S. "Independent review organization" means an entity that conducts independent external reviews of adverse determinations and final adverse determinations.

T. "Internal grievance procedure" means the procedure by which:
   (1) Health carriers handle and resolve grievances, as required by Ark. Code Ann. § 23-99-703; or
   (2) Managed care plans provide covered persons with a prompt and meaningful review on the issue of denial, in whole or in part, of a health care treatment or service, as required by Ark. Code Ann. § 23-99-410.

U. "Medical or scientific evidence" means the following sources:
   (1) (a) 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;
   (b) 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, Excerpta Medicus (EMBASE), Medline and MEDLARS database Health Services Technology Assessment Research (HSTAR);
   (c) Medical journals recognized by the Secretary of Health and Human Services under Section 1861(t)(2) of the federal Social Security Regulation;
   (d) The following standard reference compendia:
      (i) The American Hospital Formulary Service–Drug Information;
      (ii) The American Dental Association Accepted Dental Therapeutics; and
      (iii) The United States Pharmacopoeia–Drug Information;

(e) Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized research institutes, including:
  (i) The federal Agency for Healthcare Research and Quality;
  (ii) The National Institutes of Health;
  (iii) The National Cancer Institute;
  (iv) The National Academy of Sciences;
  (v) The Centers for Medicare and Medicaid Services;
  (vi) Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services; and
  (vii) Any other medical or scientific evidence that is comparable to the sources listed in Subparagraphs (a) through (e).

(2) "Medical or scientific evidence" shall not include published peer-reviewed literature sponsored to a significant extent by a pharmaceutical manufacturing company or medical device manufacturer.

V. "Medically necessary" or "medical necessity" or substantially equivalent terms, means the definition of such term as expressed by the health carrier in its health benefit plan as approved by the Arkansas Insurance Department.

W. "Person" means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, a limited liability company, any similar entity or any combination of the foregoing.

X. "Post-service claim" means a claim for benefit that is not a pre-service claim.

Y. "Pre-service claim" means a claim for benefit in which the terms of the health plan condition receipt of such benefit on the health carrier determining in advance of the covered person obtaining a requested medical service, drug, supply, or equipment that such medical service, drug, supply or equipment is medically necessary and not experimental or investigational.

Z. "Protected health information" means health information that is not subject to disclosure under state and/or federal law.

AA. "Retrospective review" means a review of medical necessity 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.

BB. "Utilization review" and "utilization review procedure" mean the system required by Ark. Code Ann. § 20-9-901, et seq. for reviewing the appropriate and efficient allocation of hospital resources and medical services given or proposed to be given to a patient or group of patients.

Section 4. Notice of Right to External Review

A. A health carrier shall notify the covered person and the covered person's treating health care professional in writing or via electronic media of the covered person's right to request an external review to be conducted pursuant to Sections 7 or 8 of this regulation. Such notice shall include the appropriate statements and information set forth in this Section at the time the health carrier sends written notice of:
   (1) An adverse determination and
   (2) A final adverse determination.

B. (1) The health carrier shall include in the notice required under Subsection A:
      (a) For a notice related to an adverse determination:
         (i) A statement informing the covered person that the covered person may file a request for an expedited external review to be conducted pursuant to Section 8 of this regulation at the same time the covered person files a request for an expedited review of an appeal as set forth in the health carrier's internal grievance procedure or utilization procedure if:
            (A). The covered person has a medical condition where the timeframe for completion of an expedited review of an appeal set forth in the health carrier's internal grievance 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
            (B). 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 and supports such certification with reasoning, rationale, or evidence that the recommended or requested health care service or treatment would be significantly less effective if not promptly initiated.
         (ii) A statement that the independent review organization conducting the external review in accordance with the provisions of Section 8 of this regulation shall determine whether the covered person shall be required to complete the health carrier's expedited internal grievance procedure or utilization review procedure before it conducts the expedited external review. Upon a determination that the covered person must first complete the expedited internal grievance review procedure or utilization review procedure, the

independent review organization immediately shall notify the covered person and the covered person's treating health care professional of this determination and that it will not proceed with the expedited external review until the expedited internal grievance procedure or utilization review procedure is completed and the adverse determination or final adverse determination is upheld.

(iii) A statement that the covered person may file a appeal under the health carrier's internal grievance procedure or utilization review procedure, but if the health carrier has not issued a written decision to the covered person within thirty (30) days following the date the covered person files the appeal with the health carrier for a pre-service claim or within sixty (60) days following the date the covered person files the appeal with the health carrier for a post-service claim, and the covered person has not requested or agreed to a delay, the covered person may file a request for external review pursuant to Section 5 of this regulation and shall be considered to have exhausted the health carrier's internal grievance procedure or utilization review procedure for purposes of Section 6 of this regulation.

(b) For a notice related to a final adverse determination, a statement informing the covered person that the covered person may file a request for an expedited external review pursuant to Section 8 of this regulation:

(i) If the covered person has a medical condition where the timeframe for completion of a standard external review pursuant to Section 7 of this regulation 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) If the final adverse determination concerns:

(A) An admission, availability of care, continued stay or health care service for which the covered person received emergency services, but has not been discharged from a facility; or

(B) 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 and supports such certification with reasoning, rationale, or evidence 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.

(2) In addition to the information to be provided pursuant to Paragraph (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.

(3) The health carrier shall state the required information in clear and simple terms. The health carrier shall highlight the provisions in the external review procedures that give the covered person the opportunity to submit additional information and shall include any forms used to process an external review. Such information shall also include the deadline for filing a request for external review.

(4). The description required under Subsection A shall include a statement of the right of the covered person to contact the commissioner for assistance at any time. The statement shall include the telephone number, e-mail address and mailing address of the commissioner.

C. (1) In addition to Subsection B, the health carrier 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.

(2) The health carrier shall include in the statement an authorization form, or other document approved by the commissioner, by which the covered person, for purposes of conducting an external review under this regulation, authorizes the health carrier to disclose protected health information, including medical records, concerning the covered person that are pertinent to the external review.

Section 5. Request for External Review

A. All requests for external review shall be made in writing or via electronic media to the health carrier.

B. Within sixty (60) days after the date of receipt of a notice of an adverse determination or final adverse determination pursuant to Section 4 of this regulation, a covered person may file a request for an external review with the health carrier, as specified herein.

C. (1) A request for an external review of an adverse determination may be made before the covered person has exhausted the health carrier's internal grievance procedure or utilization review procedure whenever the health carrier agrees to waive the exhaustion requirement.

(2) If the requirement to exhaust the health carrier's internal grievance procedures is waived, 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 7 of this Regulation.

D. A request for an expedited external review pursuant to Section 8 may be made in accordance with Section 4.

Section 6. Exhaustion of Internal Grievance Process

A. Except as provided in this regulation, a request for an external review pursuant to Section 7 or 8 of this regulation shall not be made until the covered person has exhausted the health carrier's internal grievance procedure or utilization review procedure.

B. If the health carrier does not have, nor is required by law to have, an internal grievance procedure or utilization review procedure, the covered person shall be considered to have exhausted the health carrier's internal grievance procedure or utilization review procedure once an adverse determination is received.

C. A covered person shall be considered to have exhausted the health carrier's internal grievance process or utilization review procedure for purposes of this section, if the covered person:

(1) Has filed an appeal involving an adverse determination with the health carrier; and

(2) Except to the extent the covered person requested or agreed to a delay, has not received a written decision on the appeal from the health carrier within thirty (30) days following the date the covered person filed the appeal with the health carrier for a pre-service claim or within sixty (60) days following the date the covered person files the appeal with the health carrier for a post-service claim.

Section 7. Standard External Review

A.At the time the health carrier receives a request for an external review, the health carrier shall assign an independent review organization from the list of approved independent review organizations compiled and maintained by the commissioner pursuant to Section 11 of this regulation to conduct a preliminary review of the request to determine if:

(1) The request for external review meets the applicability standards set out in of this regulation;

(2) The covered person has exhausted the health carrier's internal grievance process unless the covered person is not required to pursuant to Section 6 of this regulation; and

(3) The covered person has provided all the information and forms required to process an external review, including the authorization form described in Section 4C(2) of this regulation.

B. (1) Within five (5) business days after receipt of the request for external

review, the independent review organization assigned pursuant to Subsection A shall complete the preliminary review and notify the health carrier, the covered person and the covered person's treating health care professional in writing whether:

(a) The request is complete; and

(b) The request has been accepted for external review.

(2) The assigned independent review organization shall include in the notice provided pursuant to Paragraph (1) a statement that the health carrier, the covered person and the covered person's treating health care professional may submit in writing to the independent review organization within seven (7) business days following the date of receipt of the notice additional information and supporting documentation that the independent review organization shall consider when conducting the external review.

(3) If the request:

(a) Is not complete, the assigned independent review organization shall, within five (5) business days, inform the health carrier, the covered person, and the covered person's treating health care professional what information or materials are needed to make the request complete; or

(b) Is not accepted for external review, the assigned independent review organization shall inform the covered person, the covered person's treating health care professional and the health carrier in writing within five (5) business days of the reasons for its nonacceptance.

(4) Upon receipt of any information submitted by the covered person pursuant to Subsection B(2), the assigned independent review organization immediately shall forward copies of the information to the health carrier.

C. In reaching a decision to accept or reject a matter for external review, the assigned independent review organization is not bound by any decisions or conclusions reached during the health carrier's internal grievance procedure or utilization review procedure.

D. (1) Within seven (7) business days after the date of receipt of the notice provided pursuant to Section B, the health carrier shall provide to the assigned independent review organization, the covered person, and the covered person's treating health care professional the documents and any information considered in making the adverse determination or final adverse determination, together with any additional information the health carrier submits pursuant to Subsection B(2).

(2) Except as provided in Paragraph (3), failure by the health carrier or its utilization review organization to provide the documents and information within the time specified in Paragraph (1) 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

Paragraph (1), 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 Subparagraph (a), the independent review organization shall notify the covered person, the covered person's treating health care professional, and the health carrier.

E. The assigned independent review organization shall review all of the information and documents submitted by the covered person, the covered person's treating health care professional, and the health carrier.

F. (1) Upon receipt of the information, if any, required to be forwarded pursuant to Subsection B(4), 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 Paragraph (1) 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) Immediately upon making the decision to reverse its adverse determination or final adverse determination, as provided in Paragraph (3), the health carrier shall notify the covered person, the covered person's treating health care professional, and the assigned independent review organization 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 Subparagraph (a).

G. In exercising its independent medical judgment in reviewing an adverse determination, in addition to the documents and information provided pursuant to Subsection B, the assigned independent review organization, to the extent the information or documents are available, shall consider the following in reaching a decision:

(1) The covered person's medical records;

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

(3) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person, or the covered person's treating health care professional;

(4) The applicable terms of coverage under the covered person's health benefit plan to ensure that the independent review organization's decision is not contrary to the terms of coverage.

(5) The most appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines or any other practice guidelines developed by the federal government, national or professional medical societies, boards and associations;

(6) Any applicable written screening procedures, decision abstracts, clinical protocols and practice guidelines used by the health carrier to determine the necessity and appropriateness of health care services;

(7) If the adverse determination involves a denial of coverage based on a determination that the recommended or requested health care services is "experimental" or "investigational," the independent review organization shall also consider whether:

(a) The recommended or requested health care service or treatment has been approved by the federal Food and Drug Administration for the condition, while realizing that treatments or services are often legitimately used for purposes other than those listed in the FDA approval; or

(b) Medical or scientific evidence demonstrates that the expected benefits of the recommended or requested health care service or treatment is more likely than not to be more 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.

H. (1) Within forty-five (45) calendar 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, reverse, or partially uphold or reverse the adverse determination or the final adverse determination to the covered person, the covered person's treating health care professional, and the health carrier.

(2) The independent review organization shall include in the notice sent pursuant to Paragraph (1):

(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 health carrier to conduct the preliminary review of the external review request;

(c) The date the external review was conducted, if appropriate;

(d) The date of its decision;

(e) The principal reason or reasons for its decision;

(f) The rationale for its decision; and

(g) References to the evidence or documentation, including the practice guidelines, considered in reaching its decision.

(h) If the adverse determination involves a denial of coverage based on a determination that the recommended or requested health care

services is "experimental" or "investigational," the independent review organization shall also consider whether:

(i) 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 more 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; and

(ii) A description and analysis of any medical or scientific evidence, as that term is defined in Section 3T of this regulation, considered in reaching the opinion.

(3) Upon receipt of a notice of a decision pursuant to Paragraph (1) 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.

I. The assignment by a health carrier of an approved independent review organization to conduct an external review in accordance with this section shall be fair and impartial. The health carrier and the independent review organization shall comply with standards approved by the commissioner to ensure fairness and impartiality in the assignment by health carriers of approved independent review organizations to conduct external reviews.

Section 8. Expedited External Review

A. Except as provided in Subsection F, a covered person may make a request for an expedited external review with the health carrier at the time the covered person receives:

(1) An adverse determination if the criteria in Section 4B(1)(a) are met.

(2) A final adverse determination if the criteria in Section 4B(1)(b) are met.

B. At the time the covered person makes a request for an expedited external review, the covered person or the covered person's treating health care professional shall submit additional information and supporting documentation that the independent review organization shall consider when conducting the expedited external review.

C. (1) At the time the health carrier receives a request for an expedited external review, the health carrier immediately shall assign an independent review organization from the list compiled and maintained pursuant to Section 11 of this regulation to determine whether the request meets the reviewability

requirements set forth in Section 7A of this regulation and conduct the external review if the request meets the reviewability requirements.

(2) In reaching a decision in accordance with Subsection F, 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 grievance process.

D. At the time the health carrier assigns an independent review organization to conduct the expedited external review pursuant to Subsection C, the health carrier shall immediately provide or transmit all documents and information considered in making the adverse determination or final adverse determination, as well as any additional information and supporting documentation, to the assigned independent review organization, the covered person, and the covered person's treating health care professional via electronically, facsimile or any other available expeditious method. The health carrier shall also submit to the independent review organization any information the covered person submits pursuant to subsection (B).

E. In addition to the documents and information provided or transmitted pursuant to Subsections B and D, 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 information described in Section 7G of this regulation.

F. (1) As expeditiously as the covered person's medical condition or circumstances require, 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 7A of this regulation, 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, the covered person's treating health care professional, and the health carrier of the decision.

(2) If the notice provided pursuant to Paragraph (1) was not in writing, within two (2) days after the date of providing that notice, the assigned independent review organization shall:

(a) Provide a written or electronic media confirmation of the decision to the covered person and the health carrier; and

(b) Include the information set forth in Section 7H(2) of this Regulation.

(3) Upon receipt of notice of a decision pursuant to Paragraph (1) 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.

G. An expedited external review may not be provided for adverse or final adverse determinations involving a retrospective review.

H. The assignment by a health carrier of an approved independent review organization to conduct an external review in accordance with this section shall be fair and impartial. The health carrier and the independent review organization shall comply with standards approved by the commissioner to ensure fairness and impartiality in the assignment by health carriers of approved independent review organizations to conduct external reviews.

Section 9. 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 federal or 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 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 regulation.

Section 10. Filing Fees and Funding

A. Except in the case of a request for an expedited external review, at the time of filing a request for external review, the covered person shall submit to the independent review organization a filing fee of [$25] along with the information and documentation to be used by the independent review organization in conducting the external review.

B. Upon application by the covered person, the commissioner may waive the filing fee upon a showing of undue financial hardship.

C. The filing fee shall be refunded to the person who paid the fee if the external review results in the reversal, in whole or in part, of the health carrier's adverse determination or final adverse determination that was the subject of the external review.

D. 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 and shall not charge back the cost of the external review to a health care provider.

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Section 11. Approval of Independent Review Organizations

A. To be certified as an independent review organization under this regulation, an organization shall submit to the commissioner an application on a form acceptable to the commissioner. The application shall include the following:

(1) A description of the minimum qualifications employed by the independent review organization to select health care professionals to perform external review, their areas of expertise, and the medical credentials of the health care professionals currently available to perform external reviews;
(2) The procedures to be used by the independent review organization in making review determinations; and
(3) Any other information required by the commissioner.

B. To be approved under this regulation to conduct external reviews, an independent review organization shall submit to the commissioner and shall 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 Sections 7 and 8 of this regulation 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 peer reviewers to conduct external reviews on behalf of the independent review organization and suitable matching of reviewers to specific cases;
(2) The procedures to be used by the independent review organization to ensure the confidentiality of medical and treatment records and clinical review criteria;
(3) The procedures to be used by the independent review organization to ensure that any persons employed by or under contract with the independent review organization adhere to the requirements of this regulation; and
(4) A toll-free telephone and/or electronic mail service to receive information on a 24-hour-day, 7-day-a-week basis that is capable of accepting, recording or providing appropriate instruction to persons with questions or issues related to external reviews during other than normal business hours.

C. If at any time there is a material change in the information included in the application, the independent review organization shall submit updated information to the commissioner.

D. The independent review organization shall annually submit to the commissioner the information required by subsection (A) of this section in a form acceptable to the commissioner.

E. The commissioner may charge an application fee that independent review organizations shall submit to the commissioner with an application for approval and reapproval.

F. (1) An approval is effective for two (2) years, unless the commissioner determines before expiration of the approval that the independent review organization is not satisfying the minimum qualifications established under this regulation.

(2) Whenever the commissioner determines that an independent review organization no longer satisfies the minimum requirements established under this section, 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 regulation that is maintained by the commissioner pursuant to Subsection G.

G. The commissioner shall maintain and periodically update a list of approved independent review organizations.

H. Pursuant to Ark. Code Ann. § 23-61-104(e), the commissioner may engage the services of a health care provider or other professional to review the applications submitted.

I. The commissioner may deem an independent review organization certified by URAC to conduct external reviews as certified to conduct external reviews in Arkansas pursuant to this regulation.

Section 12. Minimum Qualifications for Independent Review Organizations

A. An independent review organization shall not be a subsidiary of, or in any way affiliated with, or owned, or controlled by an insurer, or an entity owned in whole or in part by an insurer, or a trade or professional association of payors.

B. An independent review organization shall not be a subsidiary of, or in any way affiliated with, or owned, or controlled by a trade or professional association of health care providers.

C. Health care professionals who are acting as reviewers for the independent review organization shall hold in good standing a nonrestricted license in any state of the United States and shall 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 peer reviewer's physical, mental or professional competence or moral character.

D. Health care professionals who are acting as reviewers for the independent review organization shall hold a current certification by a recognized American medical specialty board or other recognized health care professional boards in the area appropriate to the subject of the review, shall be a specialist in the treatment of the covered person's medical condition under review, and shall have actual clinical experience in that medical condition.

E. The independent review organization shall have a quality assurance mechanism to ensure the timeliness and quality of the review, the qualifications and independence of the physician reviewer, and the confidentiality of medical records and review material.

F. (1) Neither the independent review organization nor any reviewers of the Independent review organization shall have any material, professional, familial, or financial conflict of interest with any of the following:
   (a) The health carrier involved in the review;
   (b) Any officer, director, or management employee of the health carrier;
   (c) The treating health care provider proposing the service or treatment or any associated independent practice association;
   (d) The institution at which the service or treatment would be provided;
   (e) The development or manufacture of the principal drug, device, procedure, or other therapy proposed for the covered person whose treatment is under review; or
   (f) The covered person.

(2) As used in this section, "conflict of interest" shall not be interpreted to include:
   (a) A contract under which an academic medical center or other similar medical center provides health care services to covered persons, except for academic medical centers that may provide the service under review;
   (b) Provider affiliations which are limited to staff privileges; or
   (c) A reviewer's relationship with an insurer as a contracting health care provider, except for a reviewer proposing to provide the service under review.

(3) (a) Potential conflicts of interest shall be referred to the commissioner or his designee, who shall determine as soon as possible whether an actual conflict of interest exists.
   (b) In determining whether a conflict of interest exists, the commissioner or his designee shall consider whether a relationship or connection with persons involved in an external review is a material conflict of interest such that the objectivity of the independent review organization to be assigned to conduct the external review or any clinical peer reviewer to be assigned by the

independent review organization to conduct the external review may actually be or may perceived to be negatively impacted.

Section 13. Hold Harmless for Independent Review Organizations and Health Carriers

A. No independent review organization or clinical peer reviewer working on behalf of an independent review organization shall be liable in damages to any person for any opinions rendered during or upon completion of an external review conducted pursuant to this regulation, unless the opinion was rendered in bad faith or involved gross negligence.

B. No health carrier shall be held liable for any negligence, improper conduct, procedural errors, judgments, opinions or omissions of an independent review organization or clinical peer reviewer working on behalf of an independent review organization.

C. No health carrier may terminate a covered person or health care provider or in any other way retaliate against a covered person or health care provider for requesting an external review or utilizing the health carrier's internal grievance process or utilization review procedures, for participating in an external review, for advocating on behalf of a covered person, or engaging in any other activity pursuant to this regulation.

Section 14. External Review Reporting Requirements

A. An independent review organization assigned pursuant to Section 7 or Section 8 of this regulation to conduct an external review shall maintain written records in the aggregate and by health carrier on all requests for external review for which it conducted an external review during a calendar year and shall submit a report to the commissioner.
   (1). Each independent review organization required to maintain written records on all requests for which it was assigned to conduct an external review shall submit to the commissioner, at least annually, a report containing the information specified below.
   (2). The report shall include in the aggregate 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) The reasons for any failure to meet to deadlines specified in this regulation.

(e) 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;
(f) The number of external reviews pursuant to Section 7F of this regulation 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; and
(g) Any other information the commissioner may request or require.

(3) The independent review organization shall retain the written records required pursuant to this subsection for at least three (3) years.

B. Each health carrier shall maintain written records in the aggregate and for each type of health benefit plan offered by the health carrier on all requests for external review that are filed with the health carrier pursuant to this Regulation.

(1) Each health carrier required to maintain written records on all requests for external review pursuant to Paragraph (1) shall submit to the commissioner, at least annually, a report containing the information specified below.

(2) The report shall include in the aggregate and by type of health benefit plan:
(a) The total number of requests for external review;
(b) From the number of requests for external review that are filed directly with the health carrier, the number of requests accepted for a full external review;
(c) 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;
(d) The average length of time for resolution;
(e) The reasons for any failure to meet any of the deadlines specified in this regulation.
(f) 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;
(g) The number of external reviews pursuant to Section 7F of this Regulation 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; and
(h) Any other information the commissioner may request or require.

(3) The health carrier shall retain the written records required pursuant to this subsection for at least three (3) years.

Section 15. Penalties

A violation of this Regulation may be considered a violation of the Trade Practices Act, Ark. Code Ann. § 23-66-201, et seq.

Section 16. Severability

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

Section 17. Effective Date

The Effective Date of this regulation is September 20, 2002.

Section 18. Compliance Date

The compliance date for this regulation shall be January 1, 2003.

__(Signed by Mike Pickens)_____
MIKE PICKENS
COMMISSIONER

____(Signed 9/6/2002_____
DATE