TITLE 114
INSURANCE COMMISSIONER
LEGISLATIVE RULE

SERIES 97
EXTERNAL REVIEW OF ISSUERS' ADVERSE HEALTH INSURANCE DETERMINATIONS

Section.

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§114-97-1. General.

1.1. Scope. -- The purpose of this rule is to provide a process under which persons covered by health insurance have the opportunity for independent reviews of adverse coverage determinations by issuers. This rule is based on the National Association of Insurance Commissioners' "Uniform Health Carrier External Review Model Act" (Model 76), as amended in 2010. This rule should be read in conjunction with series 95 ("Utilization Review") and 96 ("Health Plan Issuers Internal Grievance Process") of this title. Although review of adverse determinations normally proceeds first through the issuer's internal grievance procedure before it is assigned to an independent review organization, the rule permits the internal review process to be circumvented when the time necessary to conduct it could adversely affect the covered person's health.

1.2. Authority. – W. Va. Code §§ 33-2-10 & 33-16H-4

1.3. Filing Date. --

1.4. Effective Date. --

§114-97-2. Definitions.

In addition to the definitions found in W. Va. Code of St. R. §§114-95-2 & 114-96-2, the following definitions apply:

2.1. "Best evidence" means evidence based on:

2.1.a. Randomized clinical trials (a "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");

2.1.b. If randomized clinical trials are not available, cohort studies (a "cohort study" means a prospective evaluation of two groups of patients with only one group of patients receiving specific interventions) or case-control studies (which means a retrospective evaluation of two groups of patients with different outcomes to determine which specific interventions the patients received);

2.1.c. If subdivisions a and b of this subsection are not available, case-series (which means an evaluation of a series of patients with a particular outcome, without the use of a control group); or

2.1.d. If subdivisions a, b and c of this subsection are not available, expert opinion (which 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).

2.2. "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.

2.3. "Independent review organization" or "IRO" means an entity, approved by the commissioner to conduct external reviews of adverse determinations and final adverse determinations.

2.4. "Medical or scientific evidence" means evidence found in the following sources:

2.4.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;

2.4.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 (Medline) and Elsevier Science Ltd. for indexing in Excerpta Medicus (EMBASE);

2.4.c. Medical journals recognized by the Secretary of Health and Human Services under Section 1861(t)(2) of the federal Social Security Act;

2.4.d. The following standard reference compendia:

2.4.d.1. The American Hospital Formulary Service-Drug Information;

2.4.d.2. Drug Facts and Comparisons;

2.4.d.3. The American Dental Association Accepted Dental Therapeutics;

and

2.4.d.4. The United States Pharmacopeia-Drug Information;

2.4.e. Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:

2.4.e.1. The federal Agency for Healthcare Research and Quality;

2.4.e.2. The National Institutes of Health;

2.4.e.3. The National Cancer Institute;

2.4.e.4. The National Academy of Sciences;

2.4.e.5. The Centers for Medicare & Medicaid Services;

2.4.e.6. The federal Food and Drug Administration; and

2.4.e.7. Any national board recognized by the National Institutes of health for the purpose of evaluating the medical value of health care services; or

2.4.f. Any other medical or scientific evidence that is comparable to the sources listed in subdivisions a through e of this subsection.

2.5. "NAIC" means the National Association of Insurance Commissioners.

§114-97-3. Notice of Right to External Review.

3.1. A written notice from an issuer of an adverse determination upon completion of the issuer's utilization review process or of a final adverse determination shall include:

3.1.a. Notice of the covered person's right to request an external review to be conducted pursuant to section 6, 7 or 8 of this rule;

3.1.b. 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, 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 to the WV Offices of the Insurance Commissioner, P.O. Box 50540, Charleston, WV 25305."

3.1.c. The description provided pursuant to subsection 15.1 of this rule of both the standard and expedited external review procedures, highlighting the provisions in the external review procedures that give the covered person the opportunity to submit additional information and including any forms used to process an external review request.

3.1.d. A form approved by the commissioner by which the covered person authorizes the issuer 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.

3.1.e. For a notice related to an adverse determination, a statement informing the covered person that:

3.1.e.1. If he or she has a medical condition where the time-frame for expedited review of a grievance under the issuer's internal grievance process, would seriously jeopardize his or her life, health or ability to regain maximum function, he or she may file with the commissioner, simultaneously with a request for expedited review under the issuer's internal grievance process, a request for expedited external review to be conducted pursuant to section 7 or, in cases involving denials based on the issuer's determination that the treatment or service is experimental or investigational where the covered person's treating physician certifies in writing that the recommended or requested service or treatment would be significantly less effective if not promptly initiated, pursuant to section 8 of this rule; and

3.2.e.2. The covered person may file a grievance under the issuer's internal grievance process, but if the issuer has not issued a written decision to the covered person within thirty (30) days, he or she shall, except to the extent he or she requested or agreed to a delay, be considered to have exhausted the issuer's internal grievance process for the purposes of filing a request for external review pursuant to section 5 of this rule.

3.1.f. For a notice related to a final adverse determination, a statement informing the covered person that:

3.1.f.1. If the covered person has a medical condition where the time-frame for completion of a standard external review pursuant to section 6 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 may file a request for an expedited external review pursuant to section 7 of this rule; or

3.1.f.2. If the final adverse determination concerns:

3.1.f.2.A. An admission, availability of care, continued stay or health care service for which the covered person received emergency services, but has not been discharged from a facility, the covered person may request an expedited external review pursuant to section 7 of this rule; or

3.1.f.2.B. 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 may file a request for a standard external review to be conducted pursuant to section 8 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 may request an expedited external review to be conducted under subsection 8.2 of this rule.

§114-97-4. Request For External Review.

4.1. Except for a request for an expedited external review as set forth in section 7 of this rule, all requests for external review shall be made in writing to the commissioner in a form and manner approved by the commissioner.

4.2. A covered person may make a request for an external review of an adverse determination or final adverse determination.

§114-97-5. Exhaustion of Internal Grievance Process.

5.1. Except as provided in subsection 5.3 of this section or if the exhaustion requirement is waived by the issuer, a request for external review pursuant to section 6, 7 or 8 of this rule shall not be made until the covered person has exhausted the issuer's internal grievance process.

5.2. Except to the extent the covered person requested or agreed to a delay, he or she shall be deemed to have exhausted the issuer's internal grievance process for purposes of this section if he or she has not received a written decision from the issuer within thirty (30) days after filing a grievance involving an adverse determination pursuant to the issuer's internal grievance process.

5.3. At the same time a covered person files a request for an expedited review of a grievance involving an adverse determination, the covered person may file a request for an expedited external review of the adverse determination pursuant to either section 7 or 8 of this rule, as appropriate.

5.3.a. Upon receipt of an assignment to conduct an expedited external review pursuant to section 7 of this rule, the IRO shall determine whether the covered person will be required to complete the expedited review process set forth in W. Va. Code St. R. §114-96.7 before it conducts the expedited external review.

5.3.b. Upon a determination made pursuant to subdivision a of this subsection that the covered person must first complete the expedited grievance review process set forth in W. Va. Code St. R. §114-96.7, the IRO shall immediately notify the covered person of this determination and that it will not proceed with the expedited external review set forth in section 7 of this rule until completion of the expedited grievance review process and the covered person's grievance at the completion of the expedited grievance review process remains unresolved.

§114-97-6. Standard External Review.

6.1. Within four months of receipt of a notice of an adverse determination or final adverse determination, a covered person may file a request for an external review with the commissioner and, within two business of receipt of such a request, the commissioner shall forward a copy to the issuer.

6.2. Within five (5) business days following receipt of a copy of a covered person's external review request from the commissioner, the issuer shall send the commissioner and the covered person its determination whether the request is complete and if it is eligible for external review; such determinations shall be based on consideration on the following:

6.2.a. The individual is or was a covered person at the time the health care service was requested or, in the case of retrospective review, was a covered person in the health benefit plan at the time the health care service was provided;

6.2.b. The health care service that is the subject of the adverse determination or the final adverse determination is a covered service under the health benefit plan, but for a determination by the issuer that the health care service is not covered because it does not meet the issuer's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness;

6.2.c. The covered person is deemed to have exhausted the issuer's internal grievance process; and

6.2.d. The covered person has provided all the information and forms required to process an external review.

6.3. If the request:

6.3.a Is not complete, the issuer shall inform the covered person and the commissioner in writing and include in the notice what information or materials are needed to make the request complete; or

6.3.b. Is not eligible for external review, the issuer shall inform the covered person and the commissioner in writing of the reasons for its ineligibility; such notice shall also include a statement that such determination may be appealed to the commissioner.

6.4. Notwithstanding a issuer's initial determination to the contrary, the commissioner may determine that a request is eligible for external review and require that it be referred for external review; such decision is not reviewable.

6.5. Within two (2) business days after the commissioner receives a notice that the issuer has determined that the request is eligible for external review or after the commissioner determines pursuant to subsection 6.4 that a request is eligible for external review, he or she shall assign an IRO and notify the covered person and issuer in writing of such assignment. The assignment shall be done on a random basis among those approved IROs 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.

6.5.a. The commissioner shall include in the notice of IRO assignment a statement that the covered person may submit in writing to the assigned IRO, within five (5) business days following receipt of such notice, additional information that the IRO shall consider when conducting the external review and that, in its sole discretion, the IRO may accept and consider additional information submitted after five business days. Within two (2) business of receipt of any information submitted pursuant to this subdivision, the IRO shall forward a copy to the issuer.

6.5.b. Within five (5) business days after receipt of the notice provided pursuant to subsection 6.5, the issuer or its designee utilization review organization shall provide to the assigned IRO the documents and any information considered in making the adverse determination or final adverse determination; failure to provide the documents and information within the time specified may be grounds for the IRO to terminate the external review and make a decision to reverse the adverse determination or final adverse determination.

6.6. In addition to the documents and information provided pursuant to subsection 6.5, the assigned IRO, to the extent the information or documents are available and the IRO considers

them appropriate, shall consider the following in reaching a decision:

6.6.a. The covered person's medical records;

6.6.b. The attending health care professional's recommendation;

6.6.c. Consulting reports from appropriate health care professionals and other documents submitted by the issuer, covered person, the covered person's authorized representative, or the covered person's treating provider;

6.6.d. The terms of coverage under the covered person's health benefit plan;

6.6.e. 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;

6.6.f. Any applicable clinical review criteria developed and used by the issuer or its designee utilization review organization; and

6.6.g. The opinion of the IRO's clinical review or reviewers after considering subdivisions a through f of this subsection to the extent the clinical reviewers consider appropriate.

6.7. In reaching a decision, the assigned IRO is not bound by any decisions or conclusions reached during the issuer's utilization review process as set forth or the issuer's internal grievance process.

6.8. **IRO decision**. Within forty-five days after the date of receipt of the request for an external review, the assigned IRO shall provide written notice of its decision to uphold or reverse the adverse determination or the final adverse determination to the covered person, the issuer and the commissioner. The decision shall include a general description of the reason for the request for external review; the dates on which the IRO received the assignment from the commissioner to conduct the external review and when external review was conducted; the principal reason or reasons for its decision, including what applicable, if any, evidence-based standards were a basis for its decision; the rationale for its decision; and references to the evidence or documentation, including the evidence-based standards, considered in reaching its decision.

6.9. **Termination of external review**.

6.9.a. Upon receipt of a notice of a decision pursuant to subsection 6.8 of this rule

reversing the adverse determination or final adverse determination, the issuer shall immediately approve the coverage that was the subject of the adverse determination or final adverse determination.

6.9.b. The IRO shall terminate external review proceedings upon receipt of notice from the issuer that it has reversed its adverse determination or final adverse determination and will provide coverage or payment for the health care service that is the subject of the adverse determination or final adverse determination.

§114-97-7. Expedited External Review.

7.1. Except for retrospective adverse or final adverse determinations, a covered person may make a request for an expedited external review with the commissioner at the time the covered person receives an adverse determination that meets the conditions described in the notice required by subdivision e, subsection 1, section 3 of this rule or a notice of a final adverse determination that meets any of the conditions described in the notice required by subdivision f of such subsection..

7.2. The commissioner shall immediately send a copy of a request for an expedited external review to the issuer, who shall immediately make an initial determination whether the request meets the reviewability requirements set forth in subsection 6.2 of this rule and immediately notify the commissioner and the covered person of its initial determination.

7.2.a. If the issuer's initial determination is that an external review request is ineligible for review, the notice required under subsection 7.2 of this rule shall include a statement informing the covered person that may be appealed to the commissioner.

7.2.b. Notwithstanding an issuer's initial determination to the contrary, the commissioner may determine that a request is eligible for external review and require that it be referred for external review; such decision is not reviewable.

7.3. Within one (1) business day after the commissioner receives a notice that a request is eligible for external review (following the preliminary review conducted by the IRO pursuant to subsection 7.2 of this rule) or after the commissioner determines pursuant to subdivision 7.2.b of this subsection that a request is eligible for external review, he or she shall immediately assign an IRO in accordance with subsection 6.5 of this rule and notify the covered person and issuer of such assignment.

7.4. Upon receipt of notice of the IRO assignment, the issuer or its designee utilization review organization shall transmit to the assigned IRO all documents and information considered

in making the adverse determination or final adverse determination; such transmission shall be made electronically, by telephone or facsimile, or by any other available expeditious method.

7.5. In addition to the documents and information provided or transmitted pursuant to subsection 7.4 of this rule, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, shall consider the information listed in subsection 6.6 of this rule.

7.6. 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 subsection 6.2 of this rule or after the date of receipt of a decision by the commissioner pursuant to subdivision 7.2.b of this rule that the request is eligible for external review, the assigned IRO shall notify the covered person, the issuer, and the commissioner of its decision to either uphold or reverse the adverse determination or final adverse determination.

7.7. Within forty-eight hours after providing notice of the IRO's decision provided pursuant to subsection 7.6 of this rule, the IRO shall provide written confirmation of the decision to the covered person, the issuer, and the commissioner and include in such notice the information set forth in subsection 6.8 of this rule.

7.8. Upon receipt of the notice a decision pursuant to subsection 7.6 of this rule to reverse the adverse determination or final adverse determination, the issuer immediately shall approve the coverage that was the subject of the adverse determination or final adverse determination.

§114-97-8. External Review of Experimental or Investigational Treatment Adverse Determinations.

8.1. Within four months after the date of receipt of a notice of an adverse determination or final adverse determination 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 may file a request for external review with the commissioner.

8.2. A covered person may make an oral request for an expedited external review of the adverse determination or final adverse determination pursuant to subsection 8.1 of this rule subsection 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. Such a request shall be handled in accordance with the procedure set forth in subsections 7.2 through and including 7.5 of this rule.

8.3. Except for a request for expedited external review made pursuant to subsection 8.2 of this rule, the commissioner shall notify the issuer of any request made pursuant subsection 8.1 of this rule within one business day after the date of receipt of such request.

8.4. Within six (6) business days following receipt of a copy of a covered person's external review request from the commissioner pursuant to subsection 8.3 of this rule, the issuer shall send the commissioner and the covered person its determination whether the request is complete and if it is eligible for external review; such determination shall be based on consideration on the following:

8.4.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;

8.4.b. The recommended or requested health care service or treatment that is the subject of the adverse determination or final adverse determination:

8.4.b.1. Is a covered benefit under the covered person's health benefit plan except for the issuer's determination that the service or treatment is experimental or investigational for a particular medical condition; and

8.4.b.2. Is not explicitly listed as an excluded benefit under the covered person's health benefit plan with the issuer;

8.4.c. The covered person's treating physician has certified that one of the following situations is applicable:

8.4.c.1. Standard health care services or treatments have not been effective in improving the condition of the covered person;

8.4.c.2. Standard health care services or treatments are not medically appropriate for the covered person; or

8.4.c.3. There is no available standard health care service or treatment covered by the issuer that is more beneficial than the recommended or requested health care service or treatment described in paragraph 4 of this subdivision;

8.4.d. The covered person's treating physician:

8.4.d.1. 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

8.4.d.2. Who is 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;

8.4.e. The covered person is deemed to have exhausted the issuer's internal grievance process as set forth in W. Va. Code of St. R. §114-95; and

8.4.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 subsection 5.2 of this rule.

8.5. After the issuer has completed its review pursuant to subsection 8.4, the request for external review shall thereafter proceed according to the provisions of subsections 6.3 through and including 6.9 of this rule.

8.5.a. Within one business day after the receipt of the notice of assignment to conduct the external review pursuant to subdivision a of this subsection, the assigned IRO shall:

8.5.a.1. Select one or more clinical reviewers, as it determines is appropriate, pursuant to subdivision b of this subsection to conduct the external review; and

8.5.a.2. Based on the opinion of the clinical review, or opinions if more than one clinical reviewer has been selected to conduct the external review, make decision to uphold or reverse the adverse determination or final adverse determination.

8.5.b.

8.5.b.1. In selecting clinical reviewers pursuant to paragraph 1, subdivision c of this subsection, the assigned IRO shall select physicians or other health care professionals who meet the minimum qualifications described in section 11 of this rule and, through clinical experience in the past three years, are experts in the treatment of the covered person's condition and knowledgeable about the recommended or requested health care service or treatment.

8.5.b.2. Neither the covered person, the covered person's authorized representative, if applicable, nor the issuer shall choose or control the choice of the physicians or other health care professionals to be selected to conduct the external review.

8.5.c. In accordance with subsection 8.8 of this rule, each clinical reviewer shall provide a written opinion to the assigned IRO on whether the recommended or requested health care service or treatment should be covered.

8.5.d. In reaching an opinion, clinical reviewers are not bound by any decisions or conclusions reached during the issuer's utilization review process as set forth in W. Va. Code of St. R. §114-95 or the issuer's internal grievance process as set forth W. Va. Code of St. R. §114-96.

8.6.

8.6.a. Within five (5) business days after the date of receipt of the notice provided pursuant to subdivision a, subsection 8.4 of this rule, the issuer or its designee utilization review organization shall provide to the assigned IRO, the documents and any information considered in making the adverse determination or the final adverse determination.

8.6.b. Except as provided in subdivision c of this subsection, failure by the issuer or its designee utilization review organization to provide the documents and information within the time specified in subdivision a of this subsection shall not dely the conduct of the external review.

8.6.c. If the issuer or its designee utilization review organization has failed to provide the documents and information within the time specified in subdivision a of this subsection, the assigned IRO may terminate the external review and make a decision to reverse the adverse determination or final adverse determination. Immediately upon making the decision, the IRO shall notify the covered person, the issuer and the commissioner.

8.7. Each clinical reviewer selected pursuant to subsection 8.4 shall review all of the information and documents received pursuant to subsection 8.5 and any other information submitted in writing by the covered person. Upon receipt of any information submitted by the covered person pursuant to subdivision b, subsection 8.4 of this rule, within one (1) business day after the receipt of the information, the assigned IRO shall forward the information to the issuer.

8.8.

8.8.a. Upon receipt of the information required to be forwarded pursuant to

subsection 8.6, the issuer may reconsider its adverse determination or final adverse determination that is the subject of the external review. Reconsideration by the issuer of its adverse determination or final adverse determination of this subsection shall not delay or terminate the external review.

8.8.b. The external review may be terminated only if the issuer 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.

8.8.c. Immediately upon making the decision to reverse its adverse determination or final adverse determination, as provided in subdivision b of this subsection, the issuer shall notify the covered person, the assigned IRO, and the commissioner in writing of its decision. The assigned IRO shall terminate the external review upon receipt of the notice from the issuer.

8.9.

8.9.a. Except as provided in subdivision c of this subsection, within twenty (20) days after being selected in accordance with subsection 8.4 of this rule to conduct the external review, each clinical reviewer shall provide an opinion to the assigned IRO pursuant to subsection 8.9 of this rule on whether the recommended or requested health care service or treatment should be covered.

8.9.b. Except for an opinion provided pursuant to subdivision c of this subsection, each clinical reviewer's opinion shall be in writing and include the following information:

8.9.b.1. A description of the covered person's medical condition;

8.9.b.2. 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 that any available standard health care service or treatments and the adverse risks of the recommended or requested health care services or treatments;

8.9.b.3. A description and analysis of any medical or scientific evidence, as that term is defined in subsection 2.30 of this rule.

8.9.b.4. A description and analysis of any evidence-based statement, as

that term is defined in section 2.19 of this rule.

8.9.b.5. Information on whether the reviewer's rational for the opinion is based on paragraphs 1 or 2, subdivision e, subsection 8.9 of this rule.

8.9.c. For an expedited external review, each clinical reviewer shall provide an opinion orally or in writing to the assigned IRO as expeditiously as the covered person's medical condition or circumstances requires, but in no event more than five (5) calendar days after being selected in accordance with subsection 8.4 of this rule. If the opinion provided 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 IRO and include the information required under subdivision b of this subsection.

8.10. In addition to the documents and information provided pursuant to subdivision b, subsection 8.1 or subsection 8.5 of this rule, each clinical reviewer selected pursuant to subsection 8.4, 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 8.8 of this rule:

8.10.a. The covered person's pertinent medical records;

8.10.b. The attending physician or health care professional's recommendation;

8.10.c. Consulting reports from appropriate health care professionals and other documents submitted by the issuer, covered person, the covered person's authorized representative, or the covered person's treating physician or health care professional;

8.10.d. The terms of coverage under the covered person's health benefit plan with the issuer to ensure that, but for the issuer's determination that the recommended or requested health care service or treatment that is 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 issuer; and

8.10.e. Whether:

8.10.e.1. 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

8.10.e.2. 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 that 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.

8.11.

8.11.a.

8.11.a.1. Except as provided in paragraph 2 of this subdivision, within twenty (20) days after the date it receives the opinion of each clinical reviewer pursuant to subsection 8.9 of this rule, the assigned IRO, in accordance with subdivision b of this subsection, shall make a decision and provide written notice of the decision to:

8.11.a.1.A. The covered person;

8.11.a.1.B. If applicable, the covered person's authorized representative;

8.11.a.1.C. The issuer; and

8.11.a.1.D. The commissioner.

8.11.a.2.

8.11.a.2.A. For an expedited external review, within forty-eight (48) hours after the date it receives the opinion of each clinical reviewer pursuant to subsection 8.9, the assigned IRO, in accordance with subdivision b of this subsection, shall make a decision and provide notice of the decision orally or in writing to the persons listed in paragraph 1 of this subdivision.

8.11.a.2.B. If the notice provided under subparagraph B of this paragraph was not in writing, within forty-eight (48) hours after the date of providing that notice, the assigned IROs hall provide written confirmation of the decision to the persons listed in paragraph 1 of this subdivision and include the information set forth in subdivision 3 of this subsection.

8.11.b.

8.11.b.1. If a majority of the clinical reviewers recommend that the recommended or requested health care service or treatment should be covered, the IRO shall make a decision to reverse the issuer's adverse determination or final adverse determination.

8.11.b.2. If a majority of the clinical reviewers recommend that the recommended or requested health care service should not be covered , the IRO shall make a decision to uphold the issuer's adverse determination or final adverse determination.

8.11.b.3.

8.11.b.3.A. If the clinical reviewers are evenly split as to whether the recommended or requested healthcare service or treatment should be covered, the IRO shall obtain the opinion of an additional clinical reviewer in order for the IRO to make a decision based on the opinions of a majority of the clinical reviewers pursuant to paragraph 1 or 2 of this subdivision.

8.11.b.2.B. The additional clinical reviewer selected under subparagraph A of this paragraph shall use the same information to reach an opinion as the clinical reviewers who have already submitted their opinions pursuant to subsection 8.9 of this rule.

8.11.b.2.C. The selection of the additional clinical reviewer under this paragraph shall not extend the time within which the assigned IRO is required to make a decision based on the opinions of the clinical reviewers selected under subsection 8.4 pursuant to subdivision a of this subsection.

8.11.c. The IRO shall include in the notice provided pursuant to subdivision a of this subsection:

8.11.c.1. A general description of the reason for the request for external review;

8.11.c.2. 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;

8.11.c.3. The date the IRO was assigned by the commissioner to conduct the external review;

8.11.c.4. The date the external review was conducted;

8.11.c.5. The date of its decision;

8.11.c.6. The principal reason or reasons for its decision; and

8.11.c.7. The rationale for its decision.

8.11.d. Upon receipt of a notice of a decision pursuant to subdivision a of this subsection reversing the adverse determination or final adverse determination, the issuer 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.

8.12. The assignment by the commissioner of an approved IRO to conduct an external review in accordance with this section shall be done on a random basis amount those approved IROs 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 subsection 11.4 of this rule.

§114-97-9. Binding Nature of External Review Decision; Judicial Review of IRO Decisions.

9.1. An issuer or covered person adversely affected by a final decision rendered by an IRO in accordance with this rule is entitled to judicial review thereof, but nothing in this rule shall be deemed to prevent other means of redress or relief provided by law. The commissioner may enforce a final decision of an IRO in the same manner and to the same extent as an order issued by him or her.

9.2.

9.2.a. Proceedings for review of a final decision of an IRO shall be instituted by filing a petition in the circuit court of the county in West Virginia:

9.2.a.1. In which covered person resides;

9.2.a.2. If the covered person is a non-resident of West Virginia, in which he or she works;

9.2.a.3. If the covered person neither lives nor works in West Virginia, in which the employer is primarily located; or

9.2.a.4. If none of the preceding paragraphs applies, Kanawha County.

9.2.b. The determination of venue shall be based on the covered person's or employer's circumstances at the time of the filing.

9.2.c A petition filed pursuant to this section must be filed within sixty (60) days after the date upon which the petitioner received notice of the final decision of the IRO, and the petitioner shall send a copy of the petition by registered or certified mail to the IRO and to all other parties of record to the IRO proceedings.

9.2.d. No appeal bond shall be required to effect any such appeal.

9.2.e. The filing of the petition by an issuer shall not stay the commissioner's enforcement of the IRO decision, but the issuer may, at any time after the filing of the petition, apply to the circuit court for a stay of such IRO decision and the court may grant a stay upon such terms as it deems proper.

9.2.f.

9.2.f.1. Within fifteen days after receipt of a copy of the petition by the IRO, the IRO shall transmit to such circuit court the original or a certified copy of the entire record of the proceeding under review, including a transcript of all testimony and all papers, motions, documents, evidence and records as were before the IRO: Provided, That the record may be shortened by stipulation of all parties,.

9.2.f.2. The expense of preparing and filing such record shall be deemed to be a cost of the underlying proceeding before the IRO, except that a party that unreasonably refuses to stipulate to limit the record may be taxed by the court for the additional costs involved.

9.2.f.3. Upon demand by any party, the IRO shall furnish, at the cost of the requesting party, a copy of such record.

9.3. The review conducted by the court shall be upon the record made before the IRO, except that in cases of alleged irregularities in procedure before the IRO, not shown in the record, testimony thereon may be taken before the court.

9.4. The court may affirm the decision of the IRO or remand the case to the IRO for further proceedings; it shall reverse, vacate or modify the order or decision of the IRO if the substantial rights of the petitioner has been prejudiced because the findings, inferences, conclusions, decision or order are:

9.4.a. In violation of constitutional or statutory provisions;

9.4.b. In excess of the statutory authority of the IRO;

9.4.c. Made upon unlawful procedures;

9.4.d. Affected by other error of law;

9.4.e. Clearly wrong in view of the reliable, probative and substantial evidence on the whole record; or

9.4.f. Arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

9.5. 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 rule.

§114-97-10. Approval of IROs.

10.1. The commissioner shall approve IROs eligible to be assigned to conduct external reviews under this rule.

10.2. In order to be eligible for approval by the commissioner under this section to conduct external reviews under this rule as an IRO:

10.2.a. Except as otherwise provided in this section, shall be accredited by a nationally recognized private accrediting entity that the commissioner has determined has IRO accreditation standards that are equivalent to or exceed the minimum qualifications for IROs established under section 11 of this rule; and

10.2.b. Shall submit an application for approval in accordance with subsection 10.4 of this rule.

10.3. The commissioner shall develop an application form for initially approving and for re-approving IROs to conduct external reviews.

10.4.

10.4.a. Any IRO wishing to be approved to conduct external reviews under this rule shall submit the application and include with the form all documentation and information necessary for the commissioner to determine if the IRO satisfies the minimum qualifications

established under section 11 of this rule.

10.4.b.

10.4.b.1. Subject to paragraph 2 of this subdivision, an IRO 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 IRO accreditation standards that are equivalent to or exceed the minimum qualifications for IROs under section 11 of this rule.

10.4.b.2. The commissioner may approve IROs that are not accredited by a nationally recognized private accrediting entity if there are no acceptable nationally recognized private accrediting entities providing IRO accreditation.

10.4.c. The commissioner may charge an application fee that IROs shall submit to the commissioner with an application for approval and re-approval.

10.5.

10.5.a. An approval is effective for two (2) years, unless the commissioner determines before its expiration that the IRO is not satisfying the minimum qualifications established under section 11 of this rule.

10.5.b. Whenever the commissioner determines that an IRO has lost its accreditation or no longer satisfies the minimum requirements established under section 11 of this rule, the commissioner shall terminate the approval of the IRO and remove it from the list maintained pursuant to subsection 10.6 of this rule.

10.6. The commissioner shall maintain and periodically update a list of approved IROs.

§114-97-11. Minimum Qualifications for IROs.

11.1. To be approved under section 10 of this rule to conduct external reviews, an IRO 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:

11.1.a. A quality assurance mechanism in place that:

11.1.a.1. Ensures that external reviews are conducted within the specified time frames and required notices are provided in a timely manner;

11.1.a.2. Ensures the selection of qualified and impartial clinical reviewers to conduct external reviews on behalf of the IRO and suitable matching of reviewers to specific cases that the IRO employs or contracts with an adequate number of clinical reviewers to meet this objective;

11.1.a.3. Ensures the confidentiality of medical and treatment records and clinical review criteria; and

11.1.a.4. Ensures that any person employed by or under contract with the IRO adheres to the requirements of this rule;

11.1.b. 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

11.1.c. Agree to maintain and provide to the commissioner the information set out in section 13 of this rule.

11.2. All clinical reviewers assigned by an IRO to conduct external reviews shall be physicians or other appropriate health care providers who meet the following minimum qualifications:

11.2.a. Be an expert in the treatment of the covered person's medical condition that is the subject of the external review;

11.2.b. 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;

11.2.c. 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

11.2.d. 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.

11.3. In addition to the requirements set forth in subsection 11.1 of this rule, an IRO may

not own or control, be a subsidiary of or in anyway 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.

11.4.

11.4.a. In addition to the requirements set forth in subsection 11.1, 11.2 and 11.3 of this rule, to be approved pursuant to section 10 of this rule to conduct an external review of a specified case, neither the IRO 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 with any of the following:

11.4.a.1. The issuer that is the subject of the external review;

11.4.a.2. The covered person whose treatment is the subject of the external review or the covered person's representative;

11.4.a.3. Any officer, director or management employee of the issuer that is the subject of the external review;

11.4.a.4. 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;

11.4.a.5. The facility at which the recommended health care service or treatment would be provided; or

11.4.a.6. 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.

11.4.b. In determining whether an IRO or a clinical reviewer of the IRO has a material professional, familial or financial conflict of interest for purposes of subdivision a of this subsection, the commissioner shall take into consideration situations where the IRO to be assigned to conduct an external review of a specified case or a clinical reviewer to be assigned by the IRO 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 subdivision a of this subsection, 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 th IRO or the clinical reviewer from conducting the external review.

11.5.

11.5.a. An IRO 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 10 of this rule.

11.5.b. The commissioner shall initially review and periodically review the IRO accreditation standards of a nationally recognized private accrediting entity to determine whether the entity's standards are, and continue to be, equivalent to or 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.

11.5.c. Upon request, a nationally recognized private accrediting entity shall make its current IRO 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.

11.6. An IRO shall be unbiased. An IRO shall establish and maintain written procedures to ensure that it is unbiased in addition to any other procedures required under this section.

§114-97-12. Hold Harmless for IROs.

12.1. No IRO, clinical reviewer working on behalf of an IRO or an employee, agent or contractor of an IRO 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.

§114-97-13. External Review Reporting Requirements.

13.1.

13.1.a. An IRO assigned pursuant to section 6, 7 or 8 of this rule to conduct an external review shall maintain written records in the aggregate by State and by issuer 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 subdivision b of this subsection.

13.1.b. Each IRO required to maintain written records on all requests for external review pursuant to subdivision a of this subsection 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.

13.1.c. The report shall include in the aggregate by State, and for each issuer:

13.1.c.1. The total number of requests for external review;

13.1.c.2. 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;

13.1.c.3. The average length of time for resolution;

13.1.c.4. 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;

13.1.c.5. The number of external reviews pursuant to section 6.7 of this rule that were terminated as the result of a reconsideration by the issuer 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

13.1.c.6. Any other information the commissioner may request or require.

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

13.2.

13.2.a. Each issuer shall maintain written records in the aggregate, by State and for each type of health benefit plan offered by the issuer on all requests for external review that the issuer receives notice of from the commissioner pursuant to this rule.

13.2.b. Each issuer required to maintain written records on all requests for external review pursuant to subdivision a of this subsection shall submit to the commissioner, upon request, a report in the format specified by the commissioner.

13.2.c. The report shall include in the aggregate, by State, and by type of health

benefit plan:

13.2.c.1. The total number of requests for external review;

13.2.c.2. From the total number of requests for external review reported under paragraph 1 of this subdivision, the number of requests determined eligible for a full external review; and

13.2.c.3. Any other information the commissioner may request or write.

13.2.d. The issuer shall retain the written records required pursuant to this subsection for the lesser of the current calendar year plus five (5) calendar years or five (5) years from the closing date of the period of review for the most recent examination by the commissioner.

§114-97-14. Funding of External Review.

14.1. The issuer against which a request for a standard external review or an expedited external review is filed shall pay the cost of the IRO for conducting the external review.

§114-97-15. Disclosure Requirements.

15.1. Each issuer 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.

15.2. The description required under subsection 15.1 of this rule shall be in a format prescribed by the commissioner that informs the covered person of his or her right to file a request for an external review of an adverse determination or final adverse determination with the commissioner; explains that external review is available when the adverse determination or final adverse determination involves an issue of medical necessity, appropriateness, health care setting, level of care or effectiveness; and that includes the telephone number and address of the commissioner.

15.3. In addition to subsection 15.2 of this rule, 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.