WEST VIRGINIA
SECRETARY OF STATE
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ADMINISTRATIVE LAW DIVISION

Form #6

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OFFICE WEST VIRGINIA
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NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AGENCY: Insurance Commissioner TITLE NUMBER: 114

AMENDMENT TO AN EXISTING RULE: YES____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: ____

TITLE OF RULE BEING AMENDED: ____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 97

TITLE OF RULE BEING PROPOSED: External Review of Issuers' Adverse Health Insurance Determinations

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THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) Senate Bill No. 167

SECTION 64-7-2, PASSED ON March 8, 2014

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: ~~June~~ July 6, 2014.

Authorized Signature

TITLE 114
INSURANCE COMMISSIONER
LEGISLATIVE RULE

SERIES 97
EXTERNAL REVIEW OF ISSUERS' ADVERSE HEALTH INSURANCE DETERMINATIONS

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TITLE 114
INSURANCE COMMISSIONER
LEGISLATIVE RULE

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

SERIES 97
EXTERNAL REVIEW OF ISSUERS' ADVERSE HEALTH INSURANCE DETERMINATIONS

§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. -- June 6, 2014.

1.4. Effective Date. -- July 6, 2014.

§114-97-2. Definitions.

2.1. "Adverse determination" means a determination by an issuer or its designee utilization review organization that an admission, availability of care, continued stay or other healthcare service that is a covered benefit has been reviewed and, based upon the information provided, does not meet the issuer's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness and the requested service or payment for the service is therefore denied, reduced or terminated.

2.2. "Ambulatory review" means utilization review of health care services performed or provided in an outpatient setting.

2.3. "Authorized representative" means:

2.3.a. A person to whom a covered person has given express written consent to represent the covered person in an external review;

2.3.b. A person authorized by law to provide substituted consent for a covered

person;

2.3.c. In a situation in which a covered person is unable to provide consent, a family member of the covered person or the covered person's treating health care professional;

2.3.d. A health care professional when the covered person's health benefit plan requires that a request for a benefit under the plan be initiated by the health care professional; or

2.3.e. In the case of an urgent care request, a health care professional with knowledge of the covered person's medical condition.

2.4. "Best evidence" means evidence based on:

2.4.a. 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 ("randomized clinical trial");

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

2.4.c. If subdivisions 2.4.a and 2.4.b are not available, an evaluation of a series of patients with a particular outcome, without the use of a control group ("case-series"); or

2.4.d. If subdivisions 2.4.a, 2.4.b and 2.4.c are not available, 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 ("expert opinion").

2.5. "Certification" means a determination by an issuer or its designee utilization review organization that an admission, availability of care, continued stay or other health care service that is a covered benefit under the issuer's health benefit plan has been reviewed and, based on the information provided, satisfies the issuer's requirements for medical necessity, appropriateness, health care setting, level of care and effectiveness.

2.6. "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by the issuer to determine the medical necessity and appropriateness of health care services.

2.7. "Commissioner" means the West Virginia Insurance Commissioner.

2.8. "Concurrent review" means utilization review conducted during a patient's stay or course of treatment in a facility, the office of a health care professional or other inpatient or outpatient health care setting.

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

2.10. "Covered person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan; whenever this rule provides for action by or notice to a covered person, it shall be deemed to include action by or notice to such covered person's authorized representative.

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

2.12. "Emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect that the absence of immediate medical attention would result in serious impairment to bodily functions or serious dysfunction of a bodily organ or part, or would place the person's health or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy.

2.13. "Emergency services" means with respect to an emergency medical condition:

2.13.a. A medical screening examination that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

2.13.b. Such further medical examination and treatment, to the extent they are within the capability of the staff and facilities available at a hospital, to stabilize a patient.

2.14. "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.

2.15. "Facility" means an institution providing health care services or a health care setting, including but no limited to hospitals and other licensed inpatient centers, ambulatory

surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

2.16. "Final adverse determination" means an adverse determination that has been upheld by the issuer at the completion of the internal grievance procedures or an adverse determination with respect to which the internal grievance procedures have been exhausted.

2.17. "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by an issuer to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including short term and catastrophic health insurance policies and a policy that pays on a cost-incurred basis, but excluding the excepted benefits defined in 42 U.S.C. § 300gg-91 and as otherwise specifically excepted in this rule.

2.17.a. "Health benefit plan" does not include:

2.17.a.1. Coverage only for accident, or disability income insurance or any combination thereof;

2.17.a.2. Coverage issued as a supplement to liability insurance;

2.17.a.3. Liability insurance, including general liability insurance and automobile liability insurance;

2.17.a.4. Workers' compensation or similar insurance;

2.17.a.5. Automobile medical payment insurance;

2.17.a.6. Credit-only insurance;

2.17.a.7. Coverage for on-site medical clinics; and

2.17.a.8. Other similar insurance coverage specified in federal regulations issued pursuant to Pub. L. No. 104-191, under which benefits for medical care are secondary or incidental to other insurance benefits.

2.17.b. "Health benefit plan" does not include the following benefits if they are provided under a separate policy, certificate or contract of insurance or are otherwise not an integral part of the plan:

2.17.b.1. Limited scope dental or vision benefits;

2.17.b.2. Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof; or

2.17.b.3. Other similar, limited benefits specified in federal regulations issued pursuant to Pub. L. No. 104-191.

2.17.c. "Health benefit plan" does not include the following benefits if the benefits are provided under a separate policy, certificate or contract of insurance, there is no coordination between the provision of the benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor, and the benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor:

2.17.c.1. Coverage only for a specified disease or illness; or

2.17.c.2. Hospital indemnity or other fixed indemnity insurance.

2.17.d. "Health benefit plan" does not include the following if offered as a separate policy, certificate or contract of insurance:

2.17.d.1. Medicare supplemental health insurance as defined under Section 1882(g)(1) of the Social Security Act;

2.17.d.2. Coverage supplemental to the coverage provided under Chapter 55 of Title 10, United States Code (Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)); or

2.17.d.3. Similar supplemental coverage provided to coverage under a group health plan.

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

2.19. "Health care provider" or "provider" means a health care professional or a facility.

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

2.21. "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:

2.21.a. The past, present or future physical, mental, or behavioral health or condition of an individual or a member of the individual's family;

2.21.b. The provision of health care services to an individual; or

2.21.c. Payment for the provision of health care services to an individual.

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

2.23. "Issuer" means an entity required to be licensed under the insurance laws and regulations of West Virginia 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 sickness insurance company, a health maintenance organization, a nonprofit hospital or health service corporation, fraternal benefit society, or any other entity providing a health benefit plan.

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

2.24.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;

2.24.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);

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

2.24.d. The following standard reference compendia:

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

2.24.d.2. Drug Facts and Comparisons;

2.24.d.3. The American Dental Association Accepted Dental Therapeutics; and

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

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

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

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

2.24.e.3. The National Cancer Institute;

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

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

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

2.24.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

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

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

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

2.27. "Prospective review" means utilization review conducted prior to an admission or the provision of a health care service or a course of treatment in accordance with an issuer's requirement that the health care service or course of treatment, in whole or in part, be approved prior to its provision.

2.28. "Protected health information" means health information:

2.28.a. That identifies an individual who is the subject of the information or;

2.28.b. With respect to which there is a reasonable basis to believe that the information could be used to identify an individual.

2.29. "Retrospective review" means any review of a request for a benefit that is not a prospective review request. "Retrospective review" does not include the review of a claim that is limited to veracity of documentation or accuracy of coding.

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

2.31. "Utilization review" means a system for the evaluation of the necessity, appropriateness and efficiency of the use of health care services, procedure and facilities.

2.32. "Utilization review organization" means an entity that conducts utilization review, other than an issuer performing utilization review for its own health benefit plans.

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

3.1. An issuer shall notify the covered person in writing of the covered person's right to request an external review. Such 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;

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 section 14 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; and

3.1.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 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.

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 would seriously jeopardize the covered person's life or health or ability to regain maximum function, the covered person may file a request for an expedited external review pursuant to section 7; 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; 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 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.

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

4.1. Except for a request for an expedited external review as set forth in section 7, 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 or if the exhaustion requirement is waived by the issuer, a request for external review pursuant to section 6, 7 or 8 may 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 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 internal review of a grievance involving an adverse determination pursuant to W. Va. Code of St. R. §114-96, the covered person may file a request for an expedited external review of the adverse determination pursuant to either section 7 or 8, as appropriate.

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

5.3.b. Upon a determination made pursuant to subdivision 5.3.a 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 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 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 of 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 is made in accordance with the terms of the covered person's plan, subject to the provisions of this rule, and that it 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 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 on 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 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 one business day of receipt of any information submitted pursuant to this subdivision, the IRO shall forward a copy to the issuer.

6.5.b. Within five 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 to ensure that the independent review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the issuer;

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 6.6.a through 6.6.f 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 or the issuer's internal grievance process.

6.8. **IRO decision**. Within forty-five days after receipt of the request for an external review and no later than one business day after making the decision, 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 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 written 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 3.1.e or a notice of a final adverse determination that meets any of the conditions described in the notice required by subdivision 3.1.f.

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 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 shall include a statement informing the covered person that the initial determination 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 and must be made in accordance with the terms of the covered person's plan, subject to the provisions of this rule.

7.3. Within one 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) or after the Commissioner determines pursuant to subdivision 7.2.b that a request is eligible for external review, he or she shall immediately assign an IRO in accordance with subsection 6.5 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, 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.

7.6. As expeditiously as the covered person's medical condition or circumstances require, but in no event more than seventy-two hours after receipt of the request for an expedited external review that the assigned IRO determined has met the reviewability requirements set forth in subsection 6.2 or of a decision by the Commissioner pursuant to subdivision 7.2.b 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 electronically, by telephone or facsimile, or by any other available expeditious method.

7.7. Within forty-eight hours after providing notice of the IRO's decision provided pursuant to subsection 7.6, 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.

7.8. Upon receipt of the notice a decision pursuant to subsection 7.6 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 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 7.8.

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

8.4. Within six business days following receipt of a copy of a covered person's external review request from the Commissioner pursuant to subsection 8.3, 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 subdivision 8.4.d;

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.

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.

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

8.5.a.1. Select one or more clinical reviewers, as it determines is appropriate, pursuant to subdivision 8.5.b 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. In selecting clinical reviewers pursuant to subdivision 8.5.a, the assigned IRO shall select physicians or other health care professionals who meet the minimum qualifications described in section 11 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. 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 8.9, 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-

8.6. Within five business days after the date of receipt of the notice provided pursuant to subdivision 8.5.a., 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.a. Except as provided in subdivision 8.6.b, failure by the issuer or its designee utilization review organization to provide the documents and information within the time specified in subsection 8.6 may not delay the conduct of the external review.

8.6.b. If the issuer or its designee utilization review organization has failed to provide the documents and information within the time specified in subsection 8.6, 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 8.5 shall review all of the information and documents received pursuant to subsection 8.6 and any other information submitted in writing by the covered person. Upon receipt of any information submitted by the covered person pursuant to subdivision 6.5.a and subsection 8.5, within one business day after the receipt of the information, the assigned IRO shall forward the information to the issuer.

8.8. 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 may not delay or terminate the external review.

8.8.a. 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.b. Immediately upon making the decision to reverse its adverse determination or final adverse determination, as provided in subdivision 8.8.a, 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. Except as provided in subdivision 8.9.b, within twenty days after being selected in

accordance with subsection 8.5 to conduct the external review, each clinical reviewer shall provide an opinion to the assigned IRO pursuant to subsection 8.10 on whether the recommended or requested health care service or treatment should be covered.

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

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

8.9.a.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 than any available standard health care service or treatments and the adverse risks of the recommended or requested health care services or treatments would not be substantially increased over those of available standard health care services or treatments;

8.9.a.3. A description and analysis of any medical or scientific evidence, as that term is defined in subsection 2.24.

8.9.a.4. A description and analysis of any evidence-based standard, as that term is defined in subsection 2.14.

8.9.a.5. Information on whether the reviewer's rational for the opinion is based on paragraphs 8.10.e.1 or 8.10.e.2.

8.9.b. 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 calendar days after being selected in accordance with subsection 8.5. If the opinion provided was not in writing, within forty-eight 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 8.9.a.

8.10. In addition to the documents and information provided pursuant to subsection 8.2 or subsection 8.6, each clinical reviewer selected pursuant to subsection 8.5, 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 8.9:

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. **Decisions.**

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

8.11.a.1. The covered person;

8.11.a.2. If applicable, the covered person's authorized representative;

8.11.a.3. The issuer; and

8.11.a.4. The Commissioner.

8.11.b. For an expedited external review, within forty-eight hours after the date it

receives the opinion of each clinical reviewer pursuant to subsection 8.9, the assigned IRO, in accordance with subdivision 8.11.d, shall make a decision and provide notice of the decision orally or in writing to the persons listed in subdivision 8.11.a.

8.11.c. If the notice provided under subdivision 8.11.b was not in writing, within forty-eight hours after the date of providing that notice, the assigned IRO shall provide written confirmation of the decision to the persons listed in subdivision 8.11.a and include the information set forth in subdivision 8.11.e.

8.11.d. 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. 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.d.1. 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 this subdivision.

8.11.d.2. The additional clinical reviewer selected under paragraph 8.11.d.1 shall use the same information to reach an opinion as the clinical reviewers who have already submitted their opinions pursuant to subsection 8.9.

8.11.d.3. 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 8.5.

8.11.e. The IRO shall include in the notice provided pursuant to subdivision 8.11.a:

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

8.11.e.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.e.3. The date the IRO was assigned by the Commissioner to conduct

the external review;

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

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

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

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

8.11.f. Upon receipt of a notice of a decision pursuant to subdivision 8.11.a 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 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 pursuant to subsection 11.4.

§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. **Judicial Proceedings.**

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 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. 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.1 The expense of preparing and filing such record shall be deemed to be a cost of the underlying proceeding before the IRO.

9.2.f.2 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, 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; and

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

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

10.4. 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.

10.4.a Subject to subdivision 10.4.b, an IRO is eligible for approval under this section only if it is accredited by a nationally recognized private accrediting entity that Commissioner has determined has IRO accreditation standards that are equivalent to or exceed the minimum qualifications for IROs under section 11.

10.4.b. 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.

10.5. An approval is effective for two years, unless the Commissioner determines before its expiration that the IRO is not satisfying the minimum qualifications established under section 11. Whenever the Commissioner determines that an IRO has lost its accreditation or no longer satisfies the minimum requirements established under section 11, the Commissioner shall terminate the approval of the IRO and remove it from the list maintained pursuant to subsection 10.6.

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 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.

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, 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. **Conflicts.**

11.4.a. In addition to the requirements set forth in subsections 11.1, 11.2 and 11.3, to be approved pursuant to section 10 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, any known close relative of the covered person 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. Any administrator, fiduciary, employee or sponsor of an employee welfare benefit plan as defined in 29 U.S.C. 1002(1), if any, under which the covered person's request for external review arises;

11.4.a.5. A trade association of group health plans or issuers, or a trade association of health care providers;

11.4.a.6. 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.7. The facility at which the recommended health care service or treatment would be provided; or

11.4.a.8. 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 11.4.a, the Commissioner may disregard the mere appearance of a conflict of interest.

11.5. 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.

11.5.a. 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.b. 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. External Review Reporting Requirements.

12.1. An IRO assigned pursuant to section 6, 7 or 8 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 12.1.a.

12.1.a. Each IRO required to maintain written records on all requests for external review pursuant to 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.

12.1.b. The report shall include in the aggregate by state, and for each issuer:

12.1.b.1. The total number of requests for external review;

12.1.b.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;

12.1.b.3. The average length of time for resolution;

12.1.b.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;

12.1.b.5. The number of external reviews pursuant to subsection 8.8 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

12.1.b.6. Any other information the Commissioner may request or require.

12.1.c. The IRO shall retain the written records required pursuant to this subsection for at least three years.

12.2. 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.

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

12.2.b. The report shall include in the aggregate, by state, and by type of health benefit plan:

12.2.b.1. The total number of requests for external review;

12.2.b.2. From the total number of requests for external review reported under paragraph 12.2.b.1, the number of requests determined eligible for a full external review; and

12.2.b.3. Any other information the Commissioner may request or write.

12.2.c. The issuer shall retain the written records required pursuant to this subsection for the lesser of the current calendar year plus five calendar years or five years from the closing date of the period of review for the most recent examination by the Commissioner.

§114-97-13. Funding of External Review.

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.

§114-97-14. Disclosure Requirements.

14.1. 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.

14.2. The description required under subsection 14.1 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.

14.3. In addition to subsection 14.2, 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.

§114-97-15. Penalties.

Any issuer failing to comply with the requirements of this rule is subject to the penalties prescribed in W. Va. Code §33-3-11.