WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION

Form #6

Do Not Mark In This Box

FILED

2002 APR -8 P 1:49

OFFICE WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: Insurance Commission 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: 58

TITLE OF RULE BEING PROPOSED: External Review of Coverage Denials

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

AUTHORIZATION IS CITED IN (house or senate bill number) S.B. 397

SECTION 64-7-2(c), PASSED ON March 9, 2002

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: July 1, 2002

Bill Kostin

Authorized Signature

SCANNED

$6.20

STATE OF WEST VIRGINIA

Offices of the Insurance Commissioner

Legal Division

BOB WISE
Governor

JANE L. CLINE
Insurance Commissioner

April 8, 2002

FILED
2002 APR -8 P 1:49
OFFICE WEST VIRGINIA
SECRETARY OF STATE

HAND DELIVERED

Ms. Judy Cooper, Director
Administrative Law Division
Office of Secretary of State
State Capitol
Charleston, West Virginia 25305

Dear Ms. Cooper:

Attached for filing with your office is the "final filing" form for the rule Series 58 titled "External Review of Coverage Denials." This rule was authorized in Senate Bill 397 and passed by the Legislature on March 9, 2002.

We are also providing your office with a computer disk containing the aforementioned rule and a hard copy of the promulgation history of that rule. The filing date and effective date have already been inserted onto the computer disk.

If you have any questions about the enclosed forms or the computer disk, please do not hesitate to call me.

Sincerely,

Mary Jane Pickens

Mary Jane Pickens
Associate Counsel

MJP/jz
Attachments

Post Office Box 50540
Charleston, West Virginia 25305-0540

Telephone (304) 558-0401
Facsimile (304) 558-1362

PROMULGATION HISTORY

WEST VIRGINIA INSURANCE COMMISSION

TITLE

EXTERNAL REVIEW OF COVERAGE DENIALS

TITLE 114, SERIES 58

05/25/01	Notice of Comment Period Filed
06/25/01	Last Date Comments Were Received
07/25/01	Agency Approved Legislative Rule Filed
12/10/01	Date Reviewed by Legislative Rule-Making Review Committee
04/08/02	Filing Date
07/01/02	Effective Date

114CSR58

WEST VIRGINIA LEGISLATIVE RULE
INSURANCE COMMISSIONER

SERIES 58

EXTERNAL REVIEW OF COVERAGE DENIALS

Section

TITLE 114
WEST VIRGINIA LEGISLATIVE RULE
INSURANCE COMMISSIONER

SERIES 58
EXTERNAL REVIEW OF COVERAGE DENIALS

§114-58-1. General.

1.1. Authority. -- This rule is promulgated pursuant to the authority granted by West Virginia Code §§33-2-10 and 33-25C-6 and 33-25C-9.

1.2. Scope. -- The purpose of this rule is to provide standards for the external review process set forth in West Virginia Code §33-25C-6, including the procedures for selection of and assignment of external review organizations.

a. Except as otherwise provided, this rule applies to:

1. Health maintenance organizations and prepaid limited health service organizations; and

2. External review organizations seeking approval by the commissioner to conduct external reviews on behalf of managed care plans.

b. This rule does not apply to:

1. Coverage provided by managed care plans to medicaid recipients under West Virginia Code §33-25A-27;

2. Coverage provided by managed care plans to beneficiaries enrolled in medicare programs operated under Title XVIII of the Social Security Act, 42 Stat. 620 (1935), 42 U.S.C. §1851, as amended; or

3. Workers' compensation insurance under West Virginia Code §§23-2-1 et seq.

1.3. Filing Date. – April 8, 2002

1.4. Effective Date. – July 1, 2002

§114-58-2. Definitions.

2.1. "Adverse determination" means a determination by a managed care plan or its designated utilization review organization that an admission, availability of coverage, continued stay

or other health care service that is a covered benefit has been reviewed and, based upon the information provided, does not meet the managed care plan's requirements for medical necessity, or is experimental.

2.2. "Authorized representative" means:

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

b. A person authorized by law to provide substituted consent for an enrollee, including, but not limited to, a guardian or agent under a power of attorney; or

c. A family member of the enrollee or the enrollee's treating health care professional with the express written permission of the person, or, if incapacitated, a family member, if a situation exists which would warrant an expedited review pursuant to subsection 6.1 of this rule.

2.3. "Commissioner" means the Commissioner of Insurance of the State of West Virginia.

2.4. "Covered benefit" means a health care service for which an enrollee is entitled to payment under the terms of a health care plan.

2.5. "Enrollee" is a natural person on whose behalf a contractual arrangement has been entered into or who has entered into an agreement with a health maintenance organization or prepaid limited health service organization for the provision of managed health care coverage.

2.6. "Experimental" means medical technology or a new application of existing medical technology, including medical procedures, drugs or devices for treating a medical condition, illness or diagnosis that is:

a. Not proven by medical or scientific testing or evidence to be effective in treating the medical condition, illness or diagnosis for which its use is proposed;

b. Not generally recognized by informed health care professionals as effective or appropriate in treating the medical condition, illness or diagnosis for which its use is proposed;

c. Not of proven safety by medical or scientific testing or evidence in treating the medical condition, illness or diagnosis for which its use is proposed;

d. Provided or performed in special settings for research purposes or under a controlled environment or clinical protocol; or

e. Determined to be experimental under the terms of the health benefit plan.

2.7. "External review" means a process, independent of all affected parties, to determine if a health care service is medically necessary or experimental.

2.8. "Health care plan" means a plan that establishes, operates, or maintains a network of health care providers that have entered into agreements with the plan to provide health care services to enrollees to whom the plan has the ultimate obligation to arrange for the provision of or payment for services through organizational arrangements for ongoing quality assurance, utilization review programs, or dispute resolution. For purposes of this rule, "health care plan" shall not include indemnity health insurance policies including those using a contracted provider network.

2.9. "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.

2.10. "Health care provider" or "provider" means a health care professional or an institution which is licensed or otherwise authorized in this state to provide health care services or supplies.

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

2.12. "Health information" means information or data in any form that relates to:

a. The past, present or future physical, mental or behavioral health or condition of an individual;

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

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

2.13. "Managed care plan" or "plan" means any health maintenance organization or prepaid limited health service organization; provided, that this rule only applies to prepaid limited health service organizations to the extent of coverage and services these organizations offer.

2.14. "Medical necessity" or "medically necessary" means the determination that a health care service recommended by a health care provider is:

a. The most appropriate available supply or level of service for the enrollee, considering potential benefits and harms to the individual; and

b. Known to be effective in improving health outcomes

based on professional standards accepted in and commonly available in the United States for treatment of sickness and injury as determined by the health care plan in accordance with its medical appropriateness criteria. The fact that a health care provider may prescribe, recommend or approve a procedure does not, in itself, make that procedure medically necessary.

2.15. "Protected health information" means information:

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

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

2.16. "Religious nonmedical provider" means an individual or institution that provides no medical care but provides only religious nonmedical treatment or religious nonmedical nursing care.

2.17. "Retrospective review" means a review of medical necessity conducted after services have been provided to an enrollee, but does not include the review of a claim that is limited to an evaluation of reimbursement levels, veracity of documentation, accuracy of coding or adjudication for payment.

2.18. "Utilization review" means a formal system for the evaluation of the necessity, appropriateness, efficiency and cost effectiveness of the use of health care services, procedures and facilities, as defined in section 2 of series 51, Title 114 of the West Virginia Code of State Rules. For purposes of this rule, utilization review shall also include reviews for the purpose of determining coverage based on whether or not a health care service is considered experimental in a given circumstance.

§114-58-3. Notice of Right to External Review.

3.1. At the time the managed care plan sends written notice to the enrollee of an adverse determination, the managed care plan shall, if the enrollee has exhausted the managed care plan's internal review process, also notify the enrollee in writing of the enrollee's right to request an external review and shall include in the required notice:

a. The specific criteria and standards on which the adverse determination was based. Use of generalized terms such as "experimental procedure not covered," or "not medically necessary" is not sufficient to comply with this requirement;

b. A description of both the standard and expedited external review procedures;

c. The circumstances under which the enrollee or the enrollee's authorized representative may use either procedure;

d. The procedures for requesting an external review, including the time within which an external review must be requested;

e. The procedures giving the enrollee or the enrollee's authorized representative the opportunity to submit additional information;

f. The disclosure that the enrollee will not be responsible for the cost of the external review; and

g. All forms necessary to process an external review, including a form by which the enrollee or the enrollee's authorized representative may authorize the plan to disclose pertinent protected health information concerning the enrollee to the external review organization.

§114-58-4. Request for External Review.

4.1. An enrollee or the enrollee's authorized representative may make a request for external review of an adverse determination only where the denial, reduction, modification or termination of payment for health care services or course of health care services would result in payment of at least one thousand dollars if the health care services were paid for by the enrollee. The enrollee must submit documentation from his or her provider verifying that the cost of the health care services would result in payment of at least one thousand dollars if paid for by the enrollee.

4.2. Except for a request for an expedited external review made pursuant to section 6, all requests for external review shall be made in writing to the commissioner and the managed care plan. A request for an expedited external review may be made by electronic means to the commissioner and the managed care plan, followed by written confirmation not later than three business days after the electronic request is made.

4.3. Requests for external review shall be made:

a. Within sixty calendar days after the managed care plan has exceeded the time periods for grievances provided in West Virginia Code §33-25A-12, without reaching a decision; or

b. Within sixty calendar days after receiving written notice of an adverse determination by the managed care plan.

4.4. A request for external review of an adverse determination shall not be made until the enrollee has exhausted the managed care plan's internal grievance process. An enrollee shall be considered to have exhausted the managed care plan's internal grievance process if:

a. The internal grievance process has been completed timely and the enrollee has received an adverse determination; or

b. Except to the extent the enrollee or the enrollee's authorized representative requested or caused a delay, the managed care plan has exceeded the time periods for grievances provided in West Virginia Code §33-25A-12, without reaching a decision.

4.5. External review shall not be made until the enrollee has provided to the managed care plan and the commissioner an authorization allowing the plan to disclose pertinent protected health information concerning the enrollee to the external review organization.

§114-58-5. Standard External Review.

5.1. Within seven calendar days after receiving the written request for external review from the enrollee, a preliminary determination shall be completed by the commissioner to determine:

a. If the enrollee has provided all the information and forms necessary to process the external review request including, but not limited to, an authorization permitting disclosure of protected health information;

b. If the enrollee has received an adverse determination as defined in section 2 this rule;

c. If the adverse determination by the managed care plan would result in payment of at least one thousand dollars for health care services or a course of health care services if paid for by the enrollee;

d. If the individual is or was an enrollee in the plan at the time the health care service was requested, or in the case of a retrospective review, was an enrollee in the plan at the time the health care service was provided;

e. If the enrollee has exhausted all of the managed care plan's available internal grievance procedures; and

f. If the health care service that is the subject of the adverse determination reasonably appears to be a covered benefit under the plan. If the commissioner determines that the resolution of a medical issue is required for this determination, and if the request otherwise meets the requirements of this subsection, the commissioner shall certify the request for external review and proceed with assignment of an external review organization.

5.2. Within seven calendar days after receiving the written request for external review from the enrollee, the commissioner shall send to the enrollee and the managed care plan notification:

a. If the criteria for the preliminary determination set forth in subsection 5.1 have not been met, that the request is denied; or

b. If the criteria for the preliminary determination set forth in subsection 5.1 have been met and the request is complete, that the request has been certified for external review. If certified by the commissioner, the notice shall include the names, addresses, and telephone numbers of two randomly selected external review organizations which have been approved pursuant to section 8 and which do not have a conflict of interest as described in subdivision (d) of subsection 9.1 from which the managed care plan will choose one to conduct the external review. The managed care plan will notify the commissioner and the enrollee of its choice within two business days.

5.3. The notification required to be given by the commissioner under subsection 5.2 may be provided by telephone, facsimile, or electronic means followed by a written confirmation to the enrollee and the managed care plan within two business days.

5.4. If the commissioner cannot make the preliminary determination required by subsection 5.1 because the request for external review is incomplete, the notice shall so state and shall describe the information or materials needed to make the request complete.

5.5. The standard of review in an external review shall be whether the health care service denied by the managed care plan was medically necessary or experimental within the meaning of subsections 2.6 and 2.14 under the terms of the plan. In reaching a decision, the external review organization shall not be bound by any decisions or conclusions reached during the managed care plan's internal grievance procedure.

5.6. External review determinations are to be made by physician or provider panels.

a. External reviews concerning questions of medical necessity will be conducted by at least one physician, or other provider appropriate to the health care service under consideration, who is knowledgeable about the proposed health care service.

b. External reviews concerning whether a proposed health care service is experimental will be conducted by a panel of at least three physicians, or other providers appropriate to the health care service under consideration, who are knowledgeable about the proposed health care service.

c. External reviews concerning questions of both medical necessity and whether a proposed health care service is experimental will be conducted by a panel of at least three physicians, or other providers appropriate to the health care service under consideration, who are knowledgeable about the proposed health care service.

d. The opinion of a majority of the panel members is binding on the managed care plan with respect to that enrollee. If the opinions of the panel members are evenly divided, the decision shall be in favor of coverage. If less than a majority of the panel members recommends coverage, the managed care plan may, in its discretion, provide coverage, subject to the terms and conditions of the plan.

5.7. Within seven calendar days from the date the managed care plan receives notice from the commissioner that the request has been certified for external review, the managed care plan shall deliver to the assigned external review organization all documents and information in its possession that are relevant to the enrollee's medical condition and considered in making the managed care plan's adverse determination, including, but not limited to, the following:

a. All information used by the managed care plan during the internal grievance process to determine whether the proposed health care services were medically necessary or experimental, including medical and scientific evidence and clinical review criteria;

b. A copy of all denial letters issued by the managed care plan concerning the case under review;

c. A copy of the signed authorization permitting disclosure of protected health information; and

d. An index of all submitted documents.

5.8. Upon delivery of the required information and documentation to the external review organization, the managed care plan shall also provide to the commissioner written verification of its compliance with subsection 5.8.

5.9. The failure of the managed care plan to provide the information and documents set forth in subsection 5.8 within the stated time frame may result in the termination of the external review and a decision to reverse the adverse determination.

5.10. At the same time the information required by subsection 5.8 is delivered to the external review organization, the managed care plan shall also deliver to the enrollee a copy of the index of documents submitted. The enrollee or the enrollee's authorized representative may submit additional information to the external review organization within seven calendar days from the date the enrollee receives the index from the managed care plan. At the time any additional information is submitted by the enrollee to the external review organization, the enrollee shall also submit a copy of the information to the managed care plan.

5.11. The managed care plan, the enrollee, or the enrollee's health care provider shall provide any additional information the external review organization requests to complete the review. The additional information shall be provided within five calendar days of the request, which time may be extended upon written request to the commissioner, for good cause shown. The external review organization may make the request for additional information in writing, by telephone, by facsimile, or by electronic means followed by written confirmation of the request within five calendar days. If the requested additional information is not provided within the time specified, and the time is not extended by the commissioner, the external review organization shall proceed with its review without the information. The external review organization shall make record of its request for additional information and whether the additional information requested was received.

5.12. In making its decision, an external review organization shall consider safety, efficacy, appropriateness, and cost effectiveness. It shall take into account all of the information submitted by the managed care plan, the enrollee, and the enrollee's health care provider, including:

a. The enrollee's medical records;

b. The standards, criteria, and clinical rationale used by the managed care plan to make its decision;

c. The recommendation of the enrollee's health care provider;

d. Findings, studies, research, and other relevant documents of government agencies and nationally recognized medical professional organizations, including the National Institutes of

Health or any board recognized by the National Institutes of Health, the National Cancer Institute, the National Academy of Sciences, the United States Food and Drug Administration, the Health Care Financing Administration of the United States Department of Health and Human Services, and the Agency for Health Care Policy Research and Quality;

e. Relevant findings in peer-reviewed medical or scientific literature, published opinions of nationally recognized medical experts, and clinical guidelines adopted by relevant national medical societies; and

f. The terms of coverage under the enrollee's managed care plan.

5.13. Nothing in this rule shall be construed to require the external review organization to utilize medical professionals or criteria in making decisions in external reviews regarding coverage for care by religious nonmedical providers.

5.14. As soon as possible, but not more than forty-five calendar days after the date the request for external review is assigned to the external review organization, unless extended by the commissioner for good cause shown, the assigned external review organization shall send written notice of its decision to uphold or reverse the managed care plan's adverse determination to:

a. The enrollee or the enrollee's authorized representative;

b. The managed care plan;

c. The commissioner; and

d. The enrollee's health care provider.

5.15. The notice sent pursuant to subsection 5.15 shall include the following information:

a. A general description of the reason for the request for external review;

b. The date the external review organization received the assignment from the commissioner to conduct the external review;

c. The date the external review was conducted;

d. The date of the external review organization's decision;

e. The reason(s) and clinical rationale for its decision, including, at a minimum, consideration of safety, efficacy, appropriateness, the managed care plan's terms of coverage, and cost effectiveness, with references to the evidence and documentation considered in reaching the decision; and

f. An explanation that the external review decision is binding on the enrollee and the managed care plan.

5.16. The managed care plan may elect at any time to cover the proposed health care service and request termination of the external review. The managed care plan shall notify the enrollee, the health care provider, the external review organization and the commissioner of its election to provide coverage. Upon receipt of the notice from the managed care plan, the external review organization shall terminate the external review.

5.17. If the external review organization reverses the adverse determination, the managed care plan shall provide coverage for the health care services that were the subject of the adverse determination.

5.18. An enrollee shall not be required to pay for any part of the cost of the review. All costs and fees associated with the external review shall be borne by the managed care plan.

§114-58-6. Expedited External Reviews.

6.1. Except for retrospective adverse determinations, an enrollee or an enrollee's authorized representative may request an expedited external review of an adverse determination in circumstances where failure of the enrollee to immediately receive the health care service could result in placing the health of the enrollee or the health of the enrollee's unborn child in serious jeopardy, cause serious impairment to bodily functions, or serious dysfunction of any bodily organ or part. Requests for expedited external review shall be made to the commissioner and the managed care plan.

6.2. A request for an expedited external review must include a certification from the enrollee's health care provider that the enrollee's medical condition meets the criteria set forth in subsection 6.1. Such certification shall include a clinical explanation of how the enrollee's condition meets the criteria.

6.3. Within two business days of receiving a request for an expedited external review, the commissioner shall determine if the criteria set forth in subsection 5.1 have been met, and shall send notification to the enrollee and the managed care plan of the following:

a. If the criteria for the preliminary determination set forth in subsection 5.1 have not been met, that the request is denied; or

b. If the criteria for the preliminary determination set forth in subsection 5.1 have been met and the request is complete, that the request has been certified for expedited external review. If certified by the commissioner, the commissioner shall randomly select an external review organization that does not have a conflict of interest and include in the notice the name, address, and telephone number of the external review organization to which the expedited review has been assigned.

6.4. If the commissioner cannot make the preliminary determination required by subsection 5.1 because the request for external review is incomplete, the notice shall so state and shall describe the information or materials needed to make the request complete.

6.5. The notification required by subsection 6.3 shall be provided by telephone, facsimile, electronic means, or any other expeditious method, followed by written confirmation no later than the next business day.

6.6. The standard of review in an expedited external review shall be as set forth in subsection 5.6.

6.7. Expedited external reviews shall be conducted pursuant to subsection 5.7.

6.8. Within two business days from the date the managed care plan receives the initial notice from the commissioner that the request has been certified for external review, the managed care plan shall deliver to the assigned external review organization all documents and information described in subsection 5.8. The commissioner may order the managed care plan to deliver the required documentation and information to the external review organization in one business day if the enrollee's health condition so warrants. The documents and information shall be transmitted by facsimile, electronic means or some other available expeditious method.

a. The failure of the managed care plan to provide the information and documents set forth in this subsection within the stated time frame may result in the termination of the expedited external review and a decision to reverse the adverse determination.

b. At the same time the information required by this subsection is delivered to the external review organization, the managed care plan shall also provide to the enrollee by telephone, facsimile, or electronic means the index of documents submitted. The enrollee or the enrollee's authorized representative may submit additional information to the external review organization within two business days from the date the enrollee receives the index from the managed care plan.

c. Upon delivery of the required information and documentation to the external review organization, the managed care plan shall also provide to the commissioner written verification of its compliance with this subsection.

6.9. The managed care plan, the enrollee, or the enrollee's health care provider shall provide any additional information the external review organization requests to complete the review. The additional information shall be provided to the external review organization within two business days of the request unless such time is extended by the commissioner for good cause shown. The external review organization shall make the request for additional information by telephone, facsimile, or by electronic means, followed by written confirmation no later than the next business day. If the requested additional information is not provided within the time specified, the external review organization shall proceed with its review without the information.

a. At the same time any additional information is submitted by the enrollee or the enrollee's health care provider to the external review organization, the enrollee or the enrollee's health care provider shall also submit a copy of the information to the managed care plan.

b. At the same time any additional information is submitted by the managed care plan to the external review organization, the managed care plan shall also submit a copy of the information to the enrollee or the enrollee's authorized representative.

6.10. In making its decision, an external review organization shall consider safety, efficacy, appropriateness, and cost effectiveness. It shall take into account all of the information described in subsections 5.8 and 5.13, as well as all other information submitted by the managed care plan, the enrollee and the enrollee's health care provider.

6.11. Nothing in this rule shall be construed to require the external review organization to utilize medical professionals or criteria in making decisions in expedited external reviews regarding coverage for care by religious nonmedical providers.

6.12. As soon as possible, but not more than seven calendar days after the date the request for expedited external review is received by the commissioner, the assigned external review organization shall notify the enrollee, the managed care plan, and the commissioner of its decision to uphold or reverse the managed care plan's adverse determination. The notification shall be made by telephone, facsimile, or electronic means, followed by written confirmation no later than the next business day. The written confirmation of the external review organization's decision shall include the following information:

a. The information required by subsection 5.16 of this rule; and

b. An explanation that the external review decision is the final appeal available to the enrollee under state insurance law.

6.13. The managed care plan may elect at any time during the expedited external review to cover the proposed health care service and request termination of the expedited review. The managed care plan shall notify the enrollee, the external review organization and the commissioner by telephone, facsimile, or electronic means, of its election to provide coverage, followed by written confirmation. Upon receipt of the notice from the managed care plan, the external review organization shall terminate the external review.

6.14. If the external review organization reverses the adverse determination, the managed care plan shall immediately notify the enrollee that it will provide coverage for the proposed health care services.

6.15. An enrollee shall not be required to pay for any part of the cost of the expedited review. All costs and fees associated with the expedited external review shall be borne by the managed care plan.

§114-58-7. Binding Nature of External Review Decision.

7.1. An external review decision is binding on the managed care plan.

7.2. An external review decision is binding on the enrollee except to the extent the enrollee has other remedies available under federal or state law.

7.3. An enrollee or an enrollee's authorized representative may not file a subsequent request for external review involving the same adverse determination for which the enrollee has already received an external review decision pursuant to West Virginia Code §33-25C-6 and this rule.

7.4. The external review organization may not order the managed care plan to provide a benefit or to pay a claim for a benefit that is excluded from coverage by the plan.

§114-58-8. Approval of External Review Organizations.

8.1. The commissioner shall approve external review organizations eligible to be assigned to conduct external reviews pursuant to West Virginia Code §33-25C-6 and this rule. An approval is effective for two years, unless the commissioner determines before expiration of the approval that the external review organization is not satisfying the minimum qualifications established under section 9 of this rule. The commissioner shall maintain a randomly organized roster of approved external review organizations.

8.2. An external review organization seeking approval to conduct external reviews shall submit an application on a form prescribed by the commissioner. The application shall include any documentation or information specified by the commissioner as necessary to determine if the external review organization meets the minimum qualifications established under section 9 of this rule. The external review organization will file with the application a schedule of fees and charges for approval by the commissioner.

8.3. To ensure continued compliance with this rule, the commissioner may:

a. Conduct periodic examinations and random audits of approved external review organizations. These examinations shall be at the expense of the external review organization.

b. Withdraw approval of the external review organization if the commissioner determines that an external review organization no longer satisfies the minimum requirements established under section 9 of this rule.

c. Investigate complaints by enrollees, managed care plans, and external reviewers regarding external reviews.

8.4. The commissioner, after reviewing the accreditation process and standards used by a national organization to accredit an external review organization, may determine that accreditation by the national organization satisfies the approval standards of the commissioner.

8.5. An approved external review organization may request termination of its approval by sending written notice to the commissioner at least sixty days prior to the effective date of the termination. No termination of an external review organization's approved status shall be effective until all pending external reviews assigned to the external review organization have been satisfactorily completed.

§114-58-9. Minimum Qualifications for External Review Organizations.

9.1. To be approved to conduct external reviews, an external review organization shall have and maintain written policies and procedures that govern all aspects of both the standard and expedited external review processes, which include, at a minimum:

a. A quality assurance program that:

1. Ensures that external reviews are conducted and all required notices are provided within the time frames specified in sections 5 and 6 of this rule;

2. Ensures the selection of qualified and impartial clinical peer reviewers to conduct external reviews on behalf of the external review organization and appropriate matching of clinical peers to specific cases;

3. Ensures the confidentiality of medical and treatment records, clinical review criteria, and personal information; and

4. Ensures that any person employed by or under the external review organization adheres to the requirements of this rule.

b. Procedures in place that:

1. Ensure appropriate systems, including a toll-free telephone number, are accessible twenty-four hours per day, seven days per week to receive a notice of selection for an external review and other information relating to an external review;

2. Ensure appropriate systems are available twenty-four hours per day, seven days per week to respond to a notice of selection for an external review; and

3. Ensure appropriate personnel are accessible not less than forty hours per week during normal business hours to discuss issues related to the external review.

c. Procedures to ensure the qualifications of reviewers. No party other than the external review organization shall control, directly or indirectly, the appointment of clinical peer reviewers to an external review. Each clinical peer assigned by an external review organization to conduct an external review shall:

1. Have expertise in the treatment of the medical condition of the enrollee and clinical experience in the past three years with the proposed health care service at issue;

2. Hold an unrestricted license by the state in the United States in which the clinical peer is licensed;

3. Not have been disciplined or sanctioned by a hospital or government entity based on the quality of care provided by the clinical peer; and

4. In the case of a physician, be certified by a nationally recognized medical specialty board in the area that is the subject of the review.

d. Procedures in place to prevent conflicts of interest. The external review organization shall maintain policies and procedures to ensure that neither the external review organization nor any clinical peer assigned to conduct the external review has a material professional, familial, or financial conflict of interest with:

1. The enrollee who is the subject of the review;

2. The managed care plan that is the subject of the review;

3. Any officer, director, or management employee of the managed care plan that is the subject of the review;

4. The health care provider or facility that would provide or has provided the health care service; or

5. The developer or manufacturer of the principal drug, device, procedure, or other therapy that is the subject of the review.

e. Procedures in place to ensure that no compensation or anything of value, other than payment for the fees and costs of the external review, shall be accepted, permitted, or provided by or to the external review organization, its employees or agents, or any clinical peer reviewer, that, directly or indirectly, encourages the affirmation or reversal of an adverse determination.

f. An agreement to maintain and provide to the commissioner the information set forth in section 11 of this rule.

g. A fee structure that is competitive and reasonable and does not exceed the maximum rates and maximum amounts permitted by the commissioner.

9.2. For the purpose of allowing health care providers to act as clinical peers in the conduct of external reviews, an affiliation with a hospital, an institution, an academic medical center, or a provider network does not solely constitute a conflict of interest sufficient to preclude that provider from acting as a clinical peer, as long as the affiliation is disclosed to the enrollee or the enrollee's

authorized representative and the managed care plan and both parties agree that the clinical peer is acceptable to both parties.

§114-58-10. External Review Organization Reporting Requirements.

10.1. An external review organization shall maintain records in the aggregate and by managed care plan on all standard and expedited external reviews it conducts pursuant to assignment by the commissioner during each calendar year. The external review organization shall retain the records required by this subsection for at least three years.

10.2. Each external review organization conducting an external review pursuant to assignment by the commissioner shall, by the 31st day of March of each year for the preceding calendar year, submit a report on a form prescribed by the commissioner. The report required by this subsection shall include in the aggregate, for each managed care plan, and for West Virginia external reviews only, the following information:

a. The total number of requests for external review;

b. The number of requests for external review resolved and, of those resolved, the number resolved upholding the adverse determination and the number resolved reversing the adverse determination;

c. The average length of time for standard external reviews and for expedited external reviews;

d. A summary of the types of coverages or cases for which an external reviews were sought and the types of health care plans involved in the external reviews;

e. The number of external reviews that were terminated at the request of the managed care plan as the result of a reconsideration by the managed care plan, except those external reviews terminated because the enrollee and/or the treating provider presented as part of the external review information that had not been provided to the plan prior to the external review; and

f. Any other information the commissioner may request or require.

§114-58-11. Liability of External Review Organizations.

11.1. Neither the external review organization nor any person who participates in an external review by investigating, reviewing materials, providing technical expertise or rendering a decision shall be civilly liable for any action that is taken in good faith, that is within the scope of the organization's or person's duties, and that doe not constitute wilful or reckless misconduct.

§114-58-12. Exemption from External Review Requirements.

12.1. Upon written application to and approval by the commissioner a managed care plan may be exempted from the requirements for external review as specified in West Virginia Code §33-25C-6 upon a showing that:

a. The managed care plan has an established external review procedure in place;

b. The managed care plan has been reviewed by and maintains a current full accreditation from a nationally recognized accreditation and review organization approved by the commissioner, in accordance with West Virginia Code §33-25A-17a; and

c. As part of the accreditation process, the accreditation and review organization reviewed and approved the managed care plan's external review process.

12.2. The managed care plan shall immediately notify the commissioner upon any loss of accreditation or upon any corrective plan of action made or suggested to the plan's external review process by the accreditation and review organization.

§114-58-13. Electronic and Facsimile Transmissions.

13.1. Any requirement set forth in this rule which requires an action by any party to be in writing shall be satisfied by electronic or facsimile transmission.