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

Form #3 ◘

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Insurance Commissioner TITLE NUMBER: 114

CITE AUTHORITY: W. Va. Code §§ 33-2-10, 33-25C-6 and 33-25C-9

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 PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Authorized Signature

$12.70

STATE OF WEST VIRGINIA

Offices of the Insurance Commissioner

Legal Division

BOB WISE
Governor

JANE L. CLINE
Insurance Commissioner

July 25, 2001

HAND DELIVERED

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

Dear Ms. Cooper:

Enclosed please find for filing one (1) copy of the following:

1) Notice of Agency Approval of a Proposed Rule and Consent of Acting Secretary of Tax and Revenue;

2) Fiscal Note for Proposed Rule;

3) Brief Summary of Rule;

4) Statement of Circumstances;

5) Legislative Rule-Making Review Committee Questionnaire;

6) Agency approved proposed rule entitled "External Review of Coverage Denials" (Title 114, Series 58).

Please contact me if further information is required.

Sincerely,

Donna S. Quesenberry
General Counsel

DSQ/jz
Enclosures

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: External Review of Coverage Denials
Title 114, Series 58

Type of Rule: **_X_ Legislative ___Interpretive ____Procedural**

Agency: Insurance Commissioner

Address: Post Office Box 50540
1124 Smith Street, Greenbrooke Building
Charleston, West Virginia 25305-0540

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1. Effect of Proposed Rule

	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
ESTIMATED TOTAL COST	None	None	None	None	None
PERSONAL SERVICES	None	None	None	None	None
CURRENT EXPENSE	None	None	None	None	None
REPAIRS AND ALTERATIONS	None	None	None	None	None
EQUIPMENT	None	None	None	None	None
OTHER	None	None	None	None	None

2. Explanation of above estimates:

The rule will have no additional fiscal impact upon state, local or federal government.

3. Objectives of these rules:

The objective of this rule is to establish procedures for standard and expedited external review of adverse determinations by managed care plans. The rule addresses all of the matters set forth in Section six, Article twenty-five-c, Chapter thirty-three of the West Virginia Code, as amended by H.B. 2216, including procedures for approval and assignment of the entities who will conduct the external reviews, time frames for all steps during the review process, a description of the rights and responsibilities of all parties to the review, and procedures to ensure confidentiality of medical records.

Rule Title: External Review of Coverage Denials
Title 114, Series 58

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of Citizens.

There is no expected economic impact on political subdivisions or groups of citizens. All costs of the external review will be borne by the managed care plan. The managed care industry will be impacted with the cost of the reviews, however these costs are not expected to be significant to the overall operations of the managed care plans.

C. Economic Impact on Citizens/Public at Large.

None

Date: July 25, 2001

Signature of Agency Head or Authorized Representative

DONNA S. QUESENBERRY, GENERAL COUNSEL

Insurance Commissioner
Legislative Rule
Title 114, Series 58

EXTERNAL REVIEW OF COVERAGE DENIALS

TITLE 114, SERIES 58

BRIEF SUMMARY OF RULE

This proposed rule establishes policies and procedures necessary to carry out the provisions of article twenty-five-c, chapter thirty-three of the West Virginia Code, as amended, which establishes the right of an enrollee to request review by an approved external review organization of a decision by a managed care plan to deny, modify, reduce, or terminate coverage of or payment for a health care service, if the decision was based upon questions of whether the proposed health care service is medically necessary or is experimental. This rule establishes the standards, procedures, and time frames applicable to all parties in both standard and expedited external reviews and establishes standards and procedures for the approval of independent external review organizations. The rule sets forth procedures for the fair selection and assignment of external review organizations to reviews; procedures and time limits for providing relevant information and records to the external review organization for its consideration at the commencement of and during an external review; provisions for confidentiality of medical records and information; procedures and standards for the approval of external review organizations to conduct reviews; and procedures for providing fair notice to parties during the review.

Insurance Commissioner
Legislative Rule
Title 114, Series 58

EXTERNAL REVIEW OF COVERAGE DENIALS

TITLE 114, SERIES 58

STATEMENT OF CIRCUMSTANCES

Chapter thirty-three, Article twenty-five-c was amended by H.B. 2216 during the 2001 legislative session to include the right of an enrollee to request review by an approved external review organization of a decision by a managed care plan to deny, modify, reduce, or terminate coverage of or payment for a health care service, if the decision was based upon questions of whether the proposed health care service is medically necessary or is experimental. This proposed rule establishes policies and procedures necessary to carry out the provisions of article twenty-five-c, chapter thirty-three of the West Virginia Code, as amended. West Virginia Code Sections 33-25C-9 and 33-25C-6 require the Insurance Commissioner to propose rules to establish standards for external review procedures to be implemented by managed care plans and to establish standards for certification of independent external review organizations. These rules are required to address procedures for fair selection and assignment of external review organizations to reviews; procedures and time limits for providing relevant information and records to the external review organization for its consideration at the commencement of and during an external review; provisions for confidentiality of medical records and information; procedures and standards for the approval of external review organizations to conduct reviews; and procedures for providing fair notice to parties during the review.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period, Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: JULY 25, 2001

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: OFFICE OF THE INSURANCE COMMISSIONER
ATTN: Legal Division
1124 Smith Street
Post Office Box 50540
Charleston, West Virginia 25305-0540

LEGISLATIVE RULE TITLE: EXTERNAL REVIEW OF COVERAGE DENIALS (TITLE 114, SERIES 58)

1. **Authorizing statute(s) citation:**

   West Virginia Code §§ 33-2-10, 33-25C-6 and 33-25C-9

2. a. **Date filed in State Register with Notice of Hearing or Public Comment Period:**

      May 25, 2001

   b. **What other notice, including advertising, did you give of the hearing?**

      None

   c. **Date of Public Hearing(s) *or* Public Comment Period ended:**

      Public comment period ended June 25, 2001.

   d. **Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.**

      Attached ___X___ **No comments received** ____

   e. **Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)**

      July 25, 2001

f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Donna S. Quesenberry, General Counsel
West Virginia Insurance Commission
Legal Division
P.O. Box 50540
Charleston, WV 25305-0540
Phone: (304) 558-0401
Fax: (304) 558-1362
E-mail: quesed@wvnvm.wvnet.edu

g. IF DIFFERENT FROM ITEM 'f', please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Not applicable

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

Not applicable

b. Date of hearing or comment period:

Not applicable

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

Not applicable

d. Attach findings and determinations and reasons:

Not applicable

Insurance Commissioner
Title 114, Series 58

ATTACHMENT TO QUESTION 2 (d):

Two sets of comments were received during the comment period in response to the proposed legislative rule; one from the Health Insurance Association of America ("HIAA") and one from the West Virginia Health Maintenance Organization Association ("HMO Association").

A. HIAA submits the following comments by letter dated and received on June 25, 2001:

1. HIAA proposes that the term "availability of ***care***" contained in the definition of "adverse determination" in Section 2.1 be changed to "availability of ***coverage***" due to the concept that HMOs provide coverage rather than care. The Commissioner agrees with HIAA and therefore changes Section 2.1 to read as follows:

> *"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. HIAA proposes that the definition of "authorized representative" in Section 2.2 be amended to avoid conflicting information from two individuals acting on behalf of the HMO enrollee. The Commissioner agrees with HIAA and amends Section 2.2.c to read as follows:

> *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.*

3. HIAA proposes that the definition of "covered benefit" in Section 2.4 be amended to reflect that an enrollee is entitled to ***payment*** for health care services rather than being entitled to the

health care service. The Commissioner agrees with this clarification and amends Section 2.4 to read as follows:

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

4. HIAA proposes that the word "coverage" be included at the end of the definition of "enrollee" under Section 2.5. The Commissioner agrees to this amendment to clarify that the HMO provides coverage rather than care. Section 2.5 is therefore amended to read as follows:

> *"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 health service organization for the provision of managed health care coverage.*

5. HIAA proposes that the definition for the terms "medical necessity" and "medically necessary" be deleted from the rule. HIAA states that as currently defined, every procedure would be deemed medically necessary or of medical necessity. HIAA also contends that in adopting a definition, there is the risk that as services and health care changes, the definition will constantly need to be amended. The Commissioner disagrees with this comment. The definition of "medical necessity" and "medically necessary" is sufficiently broad that it cannot be foreseen that the definition will require amendment as services and health care change. Further, the definition is necessary to clarify what is meant by those terms as used throughout the rule. Additionally, one of the most frequent reasons given by HMOs for denial of coverage is that the treatment is not "medically necessary" or of "medical necessity." To further allow the HMOs to define the term on a case-by-case basis would not be in the best interest of the enrollees.

6. HIAA suggests that Section 5.1 be amended to specifically include that an authorization form permitting release of the enrollee's medical information be required for a preliminary determination by the Commissioner regarding a request for an external review. While the language as currently drafted is sufficiently broad to include a medical release authorization form, the Commissioner does not object to the amendment for clarification purposes. Section 5.1.a is therefore amended to read as follows:

> *If the enrollee has provided all the information and forms necessary to process the external review request*

including, but not limited to, the authorization permitting disclosure of protected health information;

7. HIAA points out that Section 5.11 permits the enrollee or the enrollee's authorized representative to submit additional information to the external review organization after receipt of an index of documents submitted by the managed care plan. As currently drafted, the rule does not require the enrollee to submit a copy of the additional information to the managed care plan. HIAA contends that if this information is not submitted to the managed care plan, then the managed care plan will not be able to evaluate this new information and independently determine if the claim should be paid and external review terminated. The Commissioner is in agreement with this comment and amends Section 5.11 to read as follows:

At the same time the information required by Section 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 same 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.

8. HIAA proposes that Section 5.12 be amended to reflect that the external review organization note those instances in which it has requested additional information from the managed care plan and whether the additional information requested was in fact received. The Commissioner does not object to this comment and amends Section 5.12 to read as follows:

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, 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.

9. HIAA suggests that Section 5.13.d be amended by striking reference to the Health Care Financing Administration ("HCFA") and correcting the name of the Agency for Health Care Policy, Research and Quality. The Commissioner agrees to the latter technical change but elects to leave the reference to HCFA in the rule. It is necessary from a consumer protection standpoint that all reliable, available health information be considered. Therefore Section 5.13.d is amended to read as follows:

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.

10. HIAA suggests an amendment to Section 5.13.e requiring the published opinions from national recognized medical experts be peer reviewed. HIAA offers no rationale for its suggested amendment, and therefore the Commissioner does not agree to the amendment.

11. HIAA suggests that Section 5.15 be amended to clarify that the 45-day time period in which the external review organization is required to make a decision should not begin to run until all documentation has been received from the Commissioner. The Commissioner disagrees with this comment and elects not to amend this Section.

12. HIAA proposed that Section 5.16.f be deleted. HIAA states that the responsibility for advising the enrollee that the external review decision is binding on the enrollee and the managed care plan should be with the Commissioner and not with the external review organization. The Commissioner believes that a notice of the decision containing all pertinent information, including the binding nature of the decision, should be contained in one

document, and therefore elects to leave the provision as currently drafted.

13. HIAA points out that Section 5.17 provides that the managed care plan may elect at any time to cover the proposed health care service and request termination of the external review process. HIAA believes that if the managed care plan makes the determination based on new information provided by the enrollee's health care provider that had not been supplied earlier, the external review appeal should not be recorded as an external appeal. HIAA however makes no suggested revisions to Section 5.17, and the Commissioner elects to leave the language as currently drafted.

14. HIAA makes the same comments with respect to Section 6.9 pertaining to expedited external reviews as made with respect to Section 5.11. The Commissioner is in agreement with this comment and amends Section 6.9 to be consistent with the amendment to Section 5.11. Section 6.9 is therefore amended to add Subdivisions a and b as follows:

> *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.*

Additionally, HIAA proposes an amendment to Subsection 6.13 consistent with the comment to Subsection 5.17. Again HIAA has provided no suggested revisions to Subsection 6.13, and the Commissioner elects to leave the language as currently drafted.

15. HIAA suggests a revision to Subsection 6.12 which provides that when a request for an expedited external review is received, the external review organization notify ***the appropriate representative of*** the managed care plan, rather than notifying ***the managed care plan***. Because time is of the essence in an expedited external review and the potential exists for a delay by the managed care plan in arguing that the appropriate representative had not been notified, the Commissioner elects not to amend this

Subsection. The managed care plan should have internal safeguards in place to assure that when a notice of expedited external review has been received by the plan it be forwarded to the appropriate representative.

16. HIAA believes that Section 7.2 should be deleted. HIAA argues that the language is confusing and arguably conflicts with House Bill 2216. House Bill 2216 in § 33-25C-7(a) provides in pertinent part that "a managed care plan must comply with the decision rendered in an external review under this article and may be held civilly liable for all damages proximately caused to an enrollee for its failure to so comply." While House Bill 2216 does not specifically provide for a cause of action, the language in the rule is consistent with the concept contained in the bill. The Commissioner therefore does not agree to delete Section 7.2.

17. HIAA proposes that the reference in Section 9.2 to "in-state" health care providers be deleted. HIAA argues that health care providers may have conflicts whether they are in-state or out of state and therefore, the reference should not be included. The Commissioner is in agreement with this comment and amends Section 9.2 to read as follows:

> *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 no conflict exists.*

18. HIAA proposes an amendment to the reporting requirements in Subsection 10.2.a.5. HIAA argues that it is important for the Commissioner to know which decisions to terminate external review and pay a claim were made by the managed care plan based on new information provided by the provider or the enrollee. The Commissioner agrees with this comment and amends Subsection 10.2.a.5 to read as follows:

> *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 and whether this reconsideration was as a result of information provided by the enrollee and/or the treating provider as part of the external review that had not been provided to the plan prior to the external review; and*

B. The HMO Association submits the following comments by letter dated and received on June 25, 2001:

1. The HMO Association points out that the citation contained in Section 1.2.b.2 for the Social Security Act appears to be incorrect. Therefore, the Commissioner agrees to correct the citation to read as "Title XVIII of the Social Security Act, 42 Stat. 620 (1935), 42 U.S.C. § 1851."

2. The HMO Association proposes an amendment to Subsection 2.6.a which would stress the ***effectiveness*** of experimental treatment rather than the ***benefit***. The Commissioner agrees to the amendment of this provision. Furthermore, the Association proposes a new Subdivision 2.6.b which stresses the issue of the ***safety*** of experimental treatment. The Commissioner agrees to this amendment, but instead designates this change as 2.6.c and renumbers the remaining subdivisions. Therefore, Subsection 2.6 in its entirety is amended to read as follows:

> *"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 of proven effectiveness by medical or scientific testing or evidence to be effective in treating the medical condition, illness or diagnosis for which it 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.*

3. The HMO Association suggests amendments to Subsection 2.12 for clarification purposes only. The Commissioner agrees and amends Subsection 2.12 to read as follows:

"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.

4. The HMO Association suggests that the definition of "medical necessity" or "medically necessary in Subsection 2.14 be amended to a stricter definition. The Commissioner disagrees with this comment and suggests that the definition must be sufficiently broad to accomplish the purposes of the rule without necessitating a need for amendment as health care services and the criteria for determining appropriate health care change.

5. The HMO Association suggests that the definition of "utilization review" contained in Subsection 2.18 be amended to reflect the goal of "cost effective care" reflected in 114CSR56. The Commissioner is in agreement with this proposed change and amends Subsection 2.18 to read as follows:

"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.

6. The HMO Association suggests that Subsection 3.1 be amended for clarification purposes. The Commissioner agrees that the managed care plan must only notify the enrollee of the right to external review if the enrollee has exhausted the managed care plan's internal review process. Subsection 3.1 is therefore amended to read as follows:

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:

7. The HMO Association proposes an amendment to Subsection 4.1 which will provide for a method of verifying the one thousand dollar threshold for external review provided for in that subsection. The Commissioner agrees and amends Subsection 4.1 to read as follows:

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.

8. The HMO Association proposes that Subsection 4.2 be amended to delete the phrase "Except for request for an expedited external review made pursuant to Section 6." The Association contends that the statute does not allow for an exception to the requirement that requests for external review be in writing. However, when read in its entirety, Subsection 4.2 does not provide for an exception to the writing requirement. The relevant phrase only permits the request to be made electronically, followed by written confirmation. This is necessary as time is crucial when dealing with expedited external reviews. The Commissioner therefore does not amend Subsection 4.2.

9. The HMO Association proposes that a new Subsection be added to Section 4 which provides that an external review shall not be made until the enrollee has provided 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. The Commissioner agrees and therefore adds Subsection 4.5 to Section 4 which is to read as follows:

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.

10. The HMO Association proposes an amendment to Subdivision 4.4.b. The Association argues that the managed care plan should not be penalized if the enrollee or his representative cause a delay, or if the Commissioner grants an extension for good cause shown. The Commissioner agrees with the HMO Association's assertion that the managed care plan should not be penalized if the enrollee or his representative cause a delay, but does not agree that the Commissioner has the discretion pursuant to statute to grant an extension of time for extending the time periods prescribed by W. Va. Code § 33-25A-12. Therefore, Subdivision 4.4.b is amended to read as follows:

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 W. Va. Code § 33-25A-12, without reaching a decision.

11. Subsection 5.1 requires the Insurance Commissioner to make a preliminary determination within seven days of whether an external review shall proceed. The HMO Association believes that this determination should first be reached by the managed care plan and that the plan should submit its conclusion within seven days to the Insurance Commissioner for consideration. The Commissioner disagrees. Pursuant to Subsection 4.2, all requests for external review are made in writing to the Commissioner and the managed care plan after the enrollee has exhausted the managed care plan's internal grievance process. The managed care plan has been actively involved in the grievance up to this point, and the enrollee's next step is the external review. It should be the Commissioner who makes the preliminary determination of whether the standards for external review have been met. To provide otherwise, would merely delay the process.

The HMO Association also recommends an amendment to Subsection 5.1.a referencing the requirement for an authorization to disclose protected health information. This amendment has already been made in response to HIAA's comments.

Additionally, the HMO Association recommends an amendment to Subsection 5.1.d for the purpose of clarifying that the enrollee

was a member of the plan when the requested health care service was provided. The Commissioner disagrees as this would not be appropriate in those instances in which the basis for the external review was the denial of a requested treatment or procedure, and therefore does not agree to amend Section 5.1.d.

12. The HMO Association proposes that Subsection 5.2 be amended to permit the Insurance Commissioner to designate two or three external review organizations which are acceptable and permit the managed care plan to have the option of choosing the external review organization which will perform the external review. No justification is given for this suggested amendment other than "this is the approach that Ohio follows." The Commissioner sees no benefit to this suggested amendment and elects not to amend this subsection. Additionally, § 33-25C-11 refers to the "enrollee's right to an external review by an external review organization certified and ***selected*** by the commissioner." (emphasis added) To allow the managed care plan to select the external review organization would be contrary to the statute.

13. Consistent with the recommended change to Subsection 5.2.b, the HMO Association recommends an amendment to Subsection 5.5. The Commissioner has elected not to amend Subsection 5.2.b as set forth in paragraph 12 above, and therefore the amendment to Subsection 5.5 is unnecessary.

14. The HMO Association proposes an amendment to Subsection 5.6 which will make it clear that all that the external review organization will consider in a review of experimental treatment is whether the proposed treatment is experimental under the plan. The Commissioner disagrees with this assertion. Consistent with Subsection 5.13, the external review organization is to consider "the standards, criteria, and clinical rationale used by the managed care plan to make its decision," but shall also consider other findings, studies, and research as spelled out in that subsection. This is to assure that all up-to-date relevant criteria is used when determining whether a particular treatment or course of treatment is experimental. Therefore, Subsection 5.6 is not amended.

15. The HMO Association requests an addition to Subsection 5.8 which provides for a signed authorization by the enrollee to disclose personal health information. This provision is already contained in Subsection 5.8.c and is therefore unnecessary.

16. The HMO Association proposes an amendment to Subsection 5.11 which would require the enrollee to provide to the managed care plan any additional information submitted to the external

review organization. The Commissioner has already agreed to this amendment in response to the comments received by HIAA.

17. The HMO Association recommends amendment to Section 5.12 consistent with House Bill 2216. The Commissioner believes that this proposed amendment is already covered by Section 5.12 which provides for an extension of time in the second sentence. However, for the sake of clarity, the Commissioner agrees to amend the sentence in question to read as follows:

> *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 of the information.*

18. The HMO Association suggests that the forty-five day calendar period by which external review must be completed begin when the matter is assigned to the external review organization and not from the time that the Commissioner receives a request for external review. The HMO Association also proposes that the Commissioner have the authority to extend this time frame. The Commissioner agrees with these comments and accordingly amends Subsection 5.15 to read as follows:

> *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:*

Additionally, the HMO Association suggests deletion of Subdivision d of Section 5.1 which requires this information to be sent to the enrollee's health care provider. The Commissioner disagrees with the comment and feels it is necessary to notify the provider whether the treatment in question has been approved by the external review organization. Subdivision d therefore is not deleted.

19. The Association proposes an amendment to Subdivision 5.16.e which specifies the safety, efficacy, medical appropriateness and cost effectiveness criteria upon which the external review organization based its decision. The Commissioner does not agree to this amendment. Subsection 5.13 provides that an external review organization shall consider safety, efficacy, appropriateness and cost effectiveness in making its decision.

However, as provided in Subsection 5.13, these are not, and should not be, the only considerations in reaching a decision.

20. The HMO Association also proposes the deletion of Subdivision 5.16.f. HIAA also proposed the deletion of this Subdivision. The Commissioner disagrees as previously referenced.

21. The HMO Association proposes an amendment to Subsection 6.2 which requires the provider to explain in some detail why the enrollee's condition requires expedited treatment. The Commissioner agrees and amends Subsection 6.2 to read as follows:

> *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.*

22. The HMO Association recommends that the time period specified in Subsection 6.3 be expanded to two or three business days. The Commissioner agrees and amends Subsection 6.3 to read as follows:

> *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:*

23. Likewise, the HMO Association recommends that the time period specified in Subsection 6.8 be expanded to two or three business days. The Commissioner agrees that in some instances one day may be unreasonable, but also is aware that time is of the essence in an expedited review. The Commissioner therefore agrees to amend Subsection 6.8 to read as follows:

> *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 within 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.

24. The HMO Association recommends that Subdivision 6.8.a be amended to allow the time frame for the submission of information and documents by the managed care plan to be expanded by the Commissioner upon good cause shown. The Commissioner disagrees with the proposed amendment as unnecessary and points out that W. Va. Code § 33-25C-6 (*l*) already provides a means for the managed care plan to request additional time in which a party may forward records to the external review organization. Subdivision 6.8.a addresses failure of the managed care plan to meet the time frame in the event an extension has not been requested or has not been granted.

25. The Association proposes that the second sentence of Section 6.9 be amended to provide for an extension of time by the Commissioner for good cause shown. The Commissioner agrees that the proposed amendment is consistent with H.B. 2216 and therefore amends Section 6.9 to read as follows:

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.

26. The HMO Association proposes that Section 6.14 be amended for clarification purposes. The Commissioner is in agreement and amends Section 6.14 to read as follows:

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.

27. The HMO Association proposes that Section 7.2 is misleading and should be amended. The Commissioner disagrees and elects to leave Section 7.2 as currently drafted.

28. The HMO Association proposes that the last word in Section 7.4 be changed for clarification purposes from "contract" to "plan." The Commissioner agrees and therefore, Section 7.4 is amended to read as follows:

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.

29. The HMO Association suggests amending Subsection 8.3.c to include investigation of complaints by external reviewers regarding external reviews. The Commissioner agrees and amends Subsection 8.3.c to read as follows:

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

30. The HMO Association believes that the requirements of Subdivisions 9.1.b.1 and 2 are onerous and unnecessary. The Commissioner disagrees and believes that such procedures are necessary, especially in cases involving an expedited external review. The Commissioner elects not to amend or delete these subdivisions.

31. The HMO Association believes that the criteria set forth in Subdivision 9.1.c is too stringent. The Commissioner disagrees and believes that expertise in the treatment of the medical condition and clinical experience with the proposed health care service at issue is crucial to obtaining an accurate and proper decision. The Commissioner elects not to amend or delete this Subdivision.

32. The HMO Association proposes a minor change to Subdivision 9.1.d.1 to which the Commissioner agrees. Subdivision 9.1.d.1 is therefore amended to read as follows:

The enrollee who is the subject of the review;

33. The HMO Association proposes an amendment to Section 9.2 which sets forth a procedure by which the managed care plan and the enrollee may agree to a clinical peer who might otherwise have a conflict of interest. The Commissioner agrees and Section 9.2 is amended to read as follows:

For purposes 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.

34. The HMO Association believes that the reports set forth in Subdivision 10.2.1 may violate the confidentiality of the health records of the enrollee. The Commissioner does not believe this to be the case in that the rule provides that the information be submitted in the aggregate. It is not anticipated that individual health information will be submitted. Any individual health information that may be submitted would be protected from disclosure by the Freedom of Information Act.

35. The HMO Association suggests that Section 11 which sets forth certain immunities from liability for the external review organization and any person who participates with the organization is without any statutory authority and may not have any force and effect. The Commissioner disagrees and feels that this provision is necessary in order to have effective participation in the external review process. Additionally, H.B. 2216 provides in § 33-25C-6(o) that the Commissioner shall propose rules which establish procedures for external reviews and certification of external review organizations. In the development of the rule, the Commissioner is directed to consider the latest version of the NAIC's Health Carrier External Review Model Act. Section 14 of the model act addresses the issue of liability of external review organizations and clinical peer reviewers. The Commissioner contends that Section 11 is therefore with specific statutory authority. Additionally, W. Va. Code § 33-2-10 authorizes the Commissioner to promulgate such rules as are necessary to effectuate the provisions of Chapter 33. The Commissioner therefore has general statutory authority to promulgate the provisions contained in Section 11.

36. The Association believes that a new Section 12 should be established which sets forth the procedure for a managed care plan to obtain an exemption from the requirements of the external review procedures as set forth in W. Va. Code § 33-25C-6. The Commissioner agrees and adds Section 12, entitled "Exemption from External Review Requirements," which will read as follows:

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 W. Va. 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 W. Va. Code § 33-25A-17a;

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.

37. The HMO Association suggests that a general reference to the effect that an internet correspondence or facsimile transmission satisfies the written requirements contained in the rule. The Commissioner agrees and adds a new section, Section 13, entitled "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.

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June 25, 2001

VIA HAND DELIVERY

Office of the West Virginia Insurance Commissioner
Att'n: Donna S. Quesenberry, General Counsel
1124 Smith Street
Charleston, WV 25305

RE: Comments to 114CSR 58
External Review of Coverage Denial

Dear Ms. Quesenberry:

This letter outlines my client's, the Health Insurance Association of America's ("HIAA") position on the proposed West Virginia Rules Governing External Review of Coverage Denial (Title 114, Series 58). The HIAA is a trade association representing approximately 300 commercial health insurance companies. These companies provide health, long term care, dental, disability and supplemental coverage to approximately 123 million Americans.

HIAA's comments to 114CSR58 are as follows:

1. Section 2.1 is the definition of "adverse determination." It provides, in pertinent part, that adverse determination means "the determination by a managed care plan or its designated utilization review organization that an admission, availability of care. . . is a covered benefit. . ." HIAA proposes that the term "availability of care" be changed to "availability of coverage." Health maintenance organizations provide coverage rather than care.

2. Section 2.2 is the definition of "authorized representative." HIAA would propose that 2.2.c. be amended as follows:

> 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.

If this language is not included, then the health maintenance organization or external review organization might receive conflicting information from two individuals acting on behalf of the individual who is covered by the HMO.

3. HIAA proposes that Section 2.4 be amended as follows:

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

An enrollee is not entitled to health care service, but is entitled to payment for health care services.

4. HIAA proposes that the word "coverage" be included at the end of Section 2.5 which is the definition of "enrollee," as follows:

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

5. HIAA proposes that "medical necessity" and "medically necessary" as contained in Section 2.14 not be defined in the regulations. As defined in Subsection 2.14, virtually every procedure would be deemed medically necessary or of medical necessity. This clearly is not the intent of the law or the policies that are adopted by health maintenance organizations. HIAA's review indicates that neither Medicaid nor Medicare, for example, incorporate a specific definition of medical necessity or medically necessary into their programs. House Bill 2216 does not include a definition of medical necessity or medically necessary. Further, in adopting a definition, there is the risk that as services and health care changes, the definition of medical necessity will constantly need to be amended. Accordingly, HIAA would suggest that no definition for medical necessity or medically necessary be included in the regulations.

6. Section 5.1 sets forth the materials which an enrollee must provide to the Commissioner in order for external review to proceed. HIAA would propose that 5.1.a. include the authorization form which permits a release of the enrollee's medical information. 5.1.a. would be amended as follows:

a. If the enrollee has provided all the information and forms necessary to process the external review request, including

but not limited to, the authorization permitting disclosure of protected health information;

This authorization is critical and should be provided by the enrollee before external review may commence.

7. Section 5.11 requires the managed care organization to submit a copy of the index of documents submitted by the managed care plan to the external review organization also to the enrollee. The enrollee or the enrollee's authorized representative is also permitted to 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. This information which the enrollee submits to the external review organization should also be delivered to the managed care plan. If this information is not submitted to the managed care plan, then the managed care plan will not be able to evaluate this new information and independently determine if the claim should be paid and external review terminated.

8. Section 5.12 allows the external review organization to request additional information in writing. It further allows the external review organization to proceed with its review without the information. The external review should note the absence of the material and its request for the information. We would propose that the following sentence be added at the end of 5.12.

The external review organization shall make record of its request for additional information and whether the additional information requested was received.

9. HIAA would propose that 5.13.d. be amended as follows:

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 & Drug Administration, ~~the Health Care Financing Administration of the United States Department of Health and Human Resources~~ and the Agency for Health Care Policy, ~~and~~ Research and Quality.

The Health Care Financing Administration ("HCFA") is primarily responsible for studies and research concerning Medicare. All health maintenance organizations have not chosen to follow the Medicare approach. Therefore, it is unfair to include HCFA as part of the studies, research and other documents of HCFA as a basis for external review. Finally, the Agency for Health Care Policy and Research is more correctly called the "Agency for Health Care Policy, Research and Quality.

10. HIAA would also propose 5.13.e. be amended as follows:

> Relevant findings and peer review medical or scientific literature peer reviewed published opinions from nationally recognized medical experts, and clinical guidelines adopted by relevant national medical societies; and

The published opinions from nationally recognized medical experts should also be peer reviewed.

11. HIAA would propose that Section 5.15 be amended as follows:

> As soon as possible, but not more than 45 calendar days after the date the request and all necessary documentation for external review is received by the Commissioner, the assigned external review organization shall send written notice of its decision to uphold or reverse the managed care plans adverse determination to:

The 45 day period should not commence until such time as the external review organization receives all documentation from the Commissioner.

12. HIAA believes that 5.16.f. should be deleted. The responsibility for advising the enrollee that the external review decision is binding on the enrollee and the managed care plan should be with the Commissioner and not with the external review organization.

13. Section 5.17 provides that the managed care plan may elect at any time to cover the proposed health care service and request termination of the external review process. If the managed care plan makes the determination based on new information provided by the enrollee's health care provider that it had not been supplied earlier, the external review appeal should not be recorded as an external appeal.

14. HIAA would offer the same comments to the expedited review criteria as it would to the normal external review process. In particular, in Subsection 6.9, any additional information provided to the external review organization by the enrollee shall also be provided to the managed care plan. Likewise, in Subsection 6.13, if a managed care plan makes a determination to pay a claim and terminate external review based on information that was not previously provided to it by the provider, then the process should not be considered external review.

15. In Subsection 6.12, HIAA would propose the following amendment:

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 appropriate representative of the managed care plan and the Commissioner of its decision to uphold or reverse the managed care plan's adverse determination. . . .

16. HIAA believes that Section 7.2 should be deleted. House Bill 2216 does not specifically provide that the enrollee may have other remedies available and this language is confusing and arguably conflicts with House Bill 2216.

17. HIAA would propose that the reference in 9.2 to "in-state" health care providers is inappropriate. This requirement should apply to all providers regardless of where they reside. Health care providers may have conflicts whether they are in-state or out of state and therefore, this reference should not be included.

18. HIAA would propose an amendment to Subsection 10.2.a.5, as follows:

5. 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 and whether this reconsideration was as a result of information provided by the enrollee and/or the treating provider as part of the external review that had not been provided to the plan prior to external review.

It is important for the Commissioner to know what decisions to terminate external review and pay a claim were made by the managed care plan based on new information provided by the provider or the enrollee.

If you have any questions regarding the foregoing comments or request amplification or additional information, please do not hesitate to contact me.

Sincerely yours,

T. Randolph Cox, on behalf of the
Health Insurance Association of America

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167689

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June 25, 2001

VIA HAND-DELIVERY

Office of the West Virginia Insurance Commissioner
Att'n: Donna S. Quesenberry, General Counsel
1124 Smith Street
Charleston, WV 25305

RE: Comments to 114CSR58 West Virginia Legislative Rule External Review of Coverage Denials

Dear Ms. Quesenberry:

The West Virginia Health Maintenance Organization Association (the "WV HMO Association" or "Association") is a voluntary non-profit association established under West Virginia laws. The WV HMO Association consists of three health maintenance organizations that are authorized to do business in West Virginia; Carelink, The Health Plan, and Optimum Choice.

The WV HMO Association's comments to 114CSR58 are as follows:

1. The citation contained in Section 1.2.b.2 for the Social Security Act appears to be incorrect. The current cite should be "Title XVIII of the Social Security Act, 42 Stat. 620 (1935), 42 U.S.C. § 1851.

2. Subsection 2.6 contains the definition for "experimental." The WV HMO Association proposes the following changes to Subdivision 6(a):

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

The Association would add a new Subdivision b (2.6.b) as follows:

b. 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.

The choice of "effectiveness" versus "benefit" is (a) an attempt to clarify one of the deficiencies of experimental treatment. Another concern of experimental treatment is the element of safety. Thus, the proposed Subdivision (b).

3. The Association would propose the following amendments to Subsection 2.2, which contains the definition of "health and information."

b. Information or data relating to the provision of health care services to an individual; or

c. Information or data relating to payment for the provision of health care services to an individual.

These changes are for clarification purposes only.

4. The Association would propose that a more precise definition of "medical necessity" or "medically necessary" be chosen. The Association believes that this is critical considering the importance this definition will play in the external review process, and believes that a more precise definition will provide clearer standards for the external review organizations in their review of medical necessity questions.

2.14 "Medical Necessity or "medically necessary" means services or supplies received while covered, which are determined by a managed care plan to be: (1) appropriate and necessary for the symptoms, diagnosis or direct care and treatment of a covered medical condition; (2) provided for the diagnosis or direct care and treatment of the covered medical condition; (3) within standards of good medical practice within the organized medical community; (4) meet national criteria adopted by the managed care plan; (5) not primarily for the convenience of the member, the member's physician or another provider; and (6) most appropriate and cost effective supply or level of service which can safely be provided. For hospital stays, this means that acute care as an inpatient is necessary due to the kind of services the member is receiving or the severity of the member's condition and that safe and adequate care cannot be received as an outpatient or in a less intensified medical setting. The fact that a provider/physician may prescribe, order, recommend or approve a service or supply does not, of itself, make that service or supply medically necessary.

5. The Association would propose that Subsection 2.18 be amended as follows:

> "Utilization review" means a formal system for the evaluation of the necessity, appropriateness, efficiency, and cost effectiveness of the use of the health care services, procedures and facilities as defined in Section 2 of series 51, Title 114 of the West Virginia Code of State Rules.

This change is consistent with 114CSR56. 3.1.d which suggests that a goal of utilization review is "cost effective care."

6. The Association would propose that Subsection 3.1 be amended as follows, for clarification purposes:

> 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:

The amendment to Subsection 3.1 makes it clear that the plan only has to notify the enrollee of his right to external review if the enrollee has exhausted the managed care plan's internal review process, otherwise no notice is required.

7. The Association would propose that Subsection 4.1 be amended by adding the following sentence at the end of the paragraph:

> The enrollee must submit documentation from his provider verifying that the cost of the health care services would result in payment of at least $1,000 if paid for by the enrollee.

There must be some method for verifying the one thousand dollar threshold for external review. The Association proposes verification from the provider.

8. The Association proposes that Subsection 4.2 be amended to delete the phrase "Except for request for an expedited external review made pursuant to Section 6." W. Va. Code § 33-25C-6(b) provides, in pertinent part, that: "A request for external review must be made in writing to the managed care plan and the Insurance Commissioner. . ." Accordingly, the statute does not permit this exception.

9. The Association would propose that a new Subsection be added to Section 4 which would provide as follows:

> 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.

It is clear that without this authorization, the Plan may not forward the enrollee's health information to the external review organization.

10. The Association would propose that Subdivision 4.4.b be amended as follows:

> 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 W. Va. Code § 33-25A-12, without reaching a decision, unless the managed care plan for just cause shown was granted an extension by the Insurance Commissioner for exceeding the time period.

The managed care plan should not be penalized if the enrollee or his representative cause a delay. In addition, if the Commissioner grants an extension for good cause shown, the managed care plan should not be penalized.

11. Section 5 deals with Standard External Review. Subsection 5.1 requires the insurance commissioner to make a preliminary determination within seven days of whether external review shall proceed. The Association believes that this process will be very difficult for the Insurance Commissioner and will require the insurance commissioner to make extensive inquiries with the Plan. The Association would propose that this determination first be reached by the Plan and that the Plan would submit its conclusion within seven days to the insurance commissioner for his consideration. In addition, we would propose the following amendments to Subsection 5.1:

> a. If the enrollee has provided all the information and forms necessary to process the external review request, including the authorization to disclose pertinent protected health information.

This amendment is self-explanatory.

> d. If the individual is or was an enrollee in the plan at the time the health care service was requested and provided, or in

> the case of a retrospective review was an enrollee in the plan at the time the health care services was provided.

The purpose of the amendment to (d) is to make it clear that the enrollee was not only was a member of the plan when he requested the health care service, but in certain instances, when the service was provided.

12. Under Subsection 5.2 as proposed, the Insurance Commissioner will assign the external review to an external review organization. The Association would propose that the Insurance Commissioner designate two or three external review organizations which are acceptable and that the managed care plan have the option of choosing the external review organization which will perform the external review from the organizations chosen by the Commissioner.

> 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 to the managed care plan shall include the name, address and telephone number of two external review organizations from which the plan may choose an external review organization to undertake the external review.

This is the approach that Ohio follows.

13. Consistent with the changes to Subsection 5.2.b, the Association would suggest that Subsection 5.5 be amended as follows:

> For each request for external review certified by the Commissioner, the Commissioner shall randomly select two external review organizations which have been approved pursuant to Section 8 and which do not have a conflict of interest as described in Subdivision e of Subsection 9.1. The managed care plan shall select one external review organization from the three proposed by the Insurance Commissioner for undertaking the external review process.

14. The Association would propose that the second sentence of Subsection 5.6 be amended as follows:

> In reviews regarding experimental treatment, the standard of review shall be whether the health care service denied by the managed care plan was experimental under the terms of the plan.

This change makes it clear that all that the external review organization will consider in a review of experimental treatment is whether the proposed treatment is experimental under the plan. If it is experimental, then the plan will have no obligation to provide the services.

15. At the end of Subsection 5.8, the Association would add a new Subdivision "e "which would provide as follows:

> e. The signed authorization by the enrollee to disclose personal health information.

This authorization must be provided if the plan is to transfer health care records to the external review organization.

16. In Subsection 5.11, the Association would propose that the enrollee be required to provide to the managed care plan any additional information which it submits to the external review organization. Accordingly, Section 5.11 would be amended by adding the following phrase to the end of the paragraph – "the enrollee shall also deliver to the managed care plan a copy of the additional information."

It seems only reasonable that if the plan also provides a copy of additional information which it provided to the external review organization to the enrollee, that the enrollee should provide a copy of the additional information to the plan.

17. The Association would amend Section 5.12 consistent with the House Bill 2216, by amending the last sentence as follows:

> 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 of the information.

18. Section 5.15 sets out a 45-day calendar period by which external review must be completed. The Association would propose that this time frame begin when the matter is assigned to the external review organization and not from the time that the Commissioner receives a request for external review. We further believe that the Commissioner should have the authority to extend this time frame. Accordingly, Subsection 5.15 would be amended as follows:

> 5.15 As soon as possible, but not more than 45 calendar days after the date the request for external review is assigned to the external review organization, unless extended by the Commissioner, the assigned external review organization shall

send written notice of its decision to uphold or reverse the managed care plan's adverse determination to:

In addition, we would delete Subdivision d of Section 5.15 which requires this information to be sent to enrollee's health care provider. The enrollee's health care provider is not necessarily the enrollee's authorized representative, and therefore is not a party to this proceeding, and therefore is not entitled to this information.

19. The Association would propose that Subdivision 5.16.e be amended as follows:

e. The reason(s) and clinical rationale for its decision with references to the evidence and documentation considered in reaching its decision which reasons and clinical rationale shall address safety, efficacy, medical appropriateness and cost effectiveness of the decision and the managed care plan's guidelines.

These criteria are the standards which the managed care plan must follow. Further, the plan's guidelines are what are approved by the Commissioner and what the plan must follow. They should be addressed in any decision reached by an external review organization.

20. The Association would also propose that Subdivision 5.16.f be deleted. This provision should come from the Commissioner, not the external review organization.

21. The Association proposes that Subsection 6.2 be amended as follows:

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 6.1. Such certification shall include a detailed clinical explanation of how the enrollee's condition meets the criteria.

The provider should explain in some detail why the enrollee's condition requires expedited treatment.

22. Subsection 6.3 requires the Commissioner, within one business day, to determine if the criteria in Subsection 5.1 have been met. The Association believes that the standard of one business day is unreasonable and proposes that this time frame be expanded to two or three business days.

23. Likewise, Subsection 6.8 requires the managed care plan to receive the initial notice and provide information within one business day. The Association believes that this time frame is also unreasonable and that this time should be expanded to at least two, but more realistically, three business days.

24. The Association recommends that Subdivision 6.8.a be amended as follows:

> 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, unless for good cause shown the managed care plan can demonstrate to the Commissioner its reasons for not complying with the three day requirement.

This amendment allows the time frame to be expanded by the Commissioner upon good cause shown.

25. The Association proposes that the second sentence of Section 6.9 be amended as follows:

> 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.

26. For clarification purposes, the Association would amend Section 6.14 as follows:

> 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.

27. The Association proposes that Section 7.2 as written is misleading and proposes the phrase "except to the extent the enrollee has other remedies available under federal or state law."

The enrollee only has other remedies available to it if the managed care plan does not comply with the decision. Otherwise, an enrollee has no recourse against the managed care plan.

28. The Association proposes that the last word in Section 7.4 be changed for clarification purposes from "contract" to "plan."

29. The Association would amend Subsection 8.3.c to include external reviewers. The Commissioner should investigate complaints by the enrollees, the managed care plans and the external reviewers. Subsection 8.3.c would be amended as follows:

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

30. The Association believes that the requirements of Subdivisions 9.1.b 1 and 2 are onerous and unnecessary. While it may be necessary for the external review organization to be able to receive messages 24 hours a day, it is unlikely that it will take action if it receives notice after normal business hours. Therefore, while the external review organization should have the capability of receiving messages, the requirements set forth in Section 9.1.b. 1 and 2 go beyond that requirement.

31. Subdivision 9.1.c sets forth the criteria that each clinical peer assigned by an external review organization must meet. Subsection 9.1.c.1 requires the clinical peer to have expertise in the treatment of the medical condition of the enrollee and clinical experience in the past three years with proposed health care service at issue. The Association believes that this requirement will be very difficult to achieve and will make it difficult for the external review organization, especially in instances when it must chose three providers to satisfy this requirement. Further, this requirement will unnecessarily increase the cost of external review. Accordingly, while the clinical peer should have knowledge in the area, he need not have had clinical experience within the last three years in the area.

32. The Association proposes a minor change to Subdivision 9.1.b.1, as follows: 1. The enrollee ~~that~~ who is the subject of the review;

33. Section 9.2 sets forth a procedure by which the managed care plan and the enrollee may agree to a clinical peer who might otherwise have a conflict of interest. We would propose that 9.2 be amended by deleting the last three words of 9.2 and, in their place, insert the following "that the clinical peer is acceptable to both parties."

34. Section 10 sets forth the reporting requirements for external review. We are concerned that the reports set forth in 10.2.a may violate the confidentiality of the health records of the enrollee. In particular, W. Va. Code § 33-25C-6(o)(5) provides that the Commissioner in developing these regulations must consider the confidentiality of the enrollee medical records. We believe that the information contained in the reports should remain confidential.

35. Section 11 sets forth certain immunities from liability for the external review organization and any person who participates with the organization. This Section seems to be without any statutory authority, and therefore, notwithstanding the efforts of including this protection in the regulations, it may have no force and effect since it is without authorization by the Legislature.

36. The Association believes that a new Section 12 should be established which sets forth the procedure for a managed care plan to be exempt from the requirements of the external review procedures as set forth in 33-25C-6 and in these regulations. In particular, 33-25C-6(p) sets forth that a managed care plan is exempt from the requirements of external review upon written application to and approval by the Commissioner. The criteria that the managed care plan must demonstrate is that it has an established external review procedure in place; it has been reviewed and maintains a current full accreditation from a nationally recognized accreditation review organization approved by the Commissioner, and as part of that accreditation process, the accreditation review organization reviewed and approved the managed care plan's external review process. This procedure was not included in the regulations and is an integral part of this statute. Accordingly, a procedure should be established in this rule for a managed care plan to obtain this exemption.

37. The regulations generally require certain action by the various parties involved in external review to be in writing. Does an Internet correspondence or facsimile transmission satisfy this requirement? If so, a general reference to that effect should be included in the regulations.

Sincerely yours,

T. Randolph Cox, on behalf of
the West Virginia HMO Association

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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 W. Va. 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 W. Va. 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 W. Va. 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;

3. Workers' compensation insurance under W. Va. Code §§ 23-2-1 et seq.

1.3. Filing Date. –

1.4. Effective Date. –

§ 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 of proven effectiveness 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.

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.

§ 114-57-3. 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, and does not solely use generalized terms such as "experimental procedure not covered," or "not medically necessary."

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.

§ 114-57-4. 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 W. Va. 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 W. Va. 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, the 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 name, address, and telephone number of the external review organization to which the review has been assigned.

5.3. The notification required by Subsection 5.2 may be provided by telephone, facsimile, or electronic means followed by 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. For each request for external review certified by the commissioner, the commissioner shall randomly select an external review organization which has been approved pursuant to Section 8 and which does not have a conflict of interest as described in Subdivision e of Subsection 9.1.

5.6. The standard of review in an external review shall be whether the health care service denied by the managed care plan was medically necessary under the terms of the plan. In reviews regarding experimental treatment, the standard of review shall be whether the health care service denied by the managed care plan was a covered benefit or excluded from coverage 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.

5.7. 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.

5.8. 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.

5.9. 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.

5.10. 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.

5.11. 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 same 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.

5.12. 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.

5.13. 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.

5.14. 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.

5.15. 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.

5.16. 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 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.

5.17. 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 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.

5.18. If the external review organization reverses the adverse determination, the managed care plan shall provide coverage for the health care services subject to the adverse determination.

5.19. 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.

a. The written confirmation of the external review organization's decision shall include the following information:

1. The information required by Subsection 5.16 of this rule; and

2. 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 W. Va. Code § 33-25A-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 W. Va. Code § 33-25A-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.

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.

a. 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:

1. The total number of requests for external review;

2. 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;

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

4. 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;

5. 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 and whether this reconsideration was as a result of information provided by the enrollee and/or the treating provider as part of the external review that had not been provided to the plan prior to the external review; and

6. 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 W. Va. 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 W. Va. Code § 33-25A-17a;

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.