WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

Form #3

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

AGENCY: Insurance Commission TITLE NUMBER: 114

CITE AUTHORITY: W. Va. Code §§ 33-2-10, 33-25A-4(1)(b), and 33-25A-17a

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: Series 53

TITLE OF RULE BEING PROPOSED: Quality Assurance

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.

Robin C. Capehart, Cabinet Secretary

July 29, 1998

Date

$8.40

IL H. UNDERWOOD
GOVERNOR

STATE OF WEST VIRGINIA
DEPARTMENT OF TAX AND REVENUE
Charleston, West Virginia
P. O. Box 963
Charleston, WV 25324-0963
Ph. (304) 558-0211 - Fax (304) 558-2324

ROBIN C. CAPEHART
SECRETARY

CONSENT TO PROPOSAL OF RULE

To Whom It May Concern:

Pursuant to West Virginia Code §5F-2-2(a)(12), the undersigned hereby grants consent to the proposal of the following rule proposed by the Insurance Commissioner of the State of West Virginia: Title 114, Series 53, relating to Quality Assurance.

Dated this 25th day of June, 1997.

Robin Capehart
Secretary of Tax and Revenue

Insurance Commissioner
Legislative Rule
Title 114, Series 53

QUALITY ASSURANCE

TITLE 114, SERIES 53

BRIEF SUMMARY OF RULE

This proposed rule implements the provisions of the Health Maintenance Organization Act, W. Va. Code §§ 33-25A-1 et. seq., which was amended during the 1996 legislative session by House Bill 4511. The rule sets forth the standards for quality assurance programs which must be met by each health maintenance organization as a condition precedent to the issuance of a Certificate of Authority to transact insurance in the State of West Virginia effective May 1, 1998.

This is one of the rules which has been through the entire rulemaking process, but which was not ratified by the legislature during the 1997-98 session due to the failure to pass House Bill 4177.

Insurance Commissioner
Legislative Rule
Title 114, Series 53

QUALITY ASSURANCE

TITLE 114, SERIES 53

STATEMENT OF CIRCUMSTANCES

During the 1996 legislative session, the West Virginia Legislature passed House Bill 4511, which amended the Health Maintenance Organization Act, W. Va. Code §§ 33-25A-1 et. seq. This rule sets forth the standards for quality assurance programs which must be met by each health maintenance organization as a condition precedent to the issuance of a Certificate of Authority to transact insurance in the State of West Virginia effective May 1, 1998.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Quality Assurance
Title 114, Series 53

Type of Rule: **XX** Legislative ____Interpretive ____Procedural

Agency: Insurance Commissioner

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

==========

1. Effect of Proposed Rule

	ANNUAL FISCAL YEAR				
	Increase	Decrease	Current	Next	Thereafter
ESTIMATED TOTAL COST	243,771			464,468	464,468
PERSONAL SERVICES	123,680			197,630	197,630
CURRENT EXPENSE	43,116			160,637	160,637
REPAIRS AND ALTERNATIONS	NONE			NONE	NONE
EQUIPMENT	38,900			38,900	25,000
OTHER	38,075			67,301	67,301

2. Explanation of above estimates:

The Consumer Advocacy Division will require additional employees to regulate the quality assurance requirements imposed by this rule and House Bill 4511. These additional employees include: one (1) Office Assistant I, two (2) Nurse 4s, one (1) Health Care Analyst 2 and one (1) Paralegal.

Rule Title: Quality Assurance
Title 114, Series 53

3. Objectives of these rules:

The objective of this proposed rule is to set forth the standards for quality assurance programs required to be established by health maintenance organizations pursuant to the requirements of House Bill 4511.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None, other than those indicated in Question 1.

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

Will have economic impact on health maintenance organizations required by House Bill 4511 to undergo a review of quality assurance programs by a nationally recognized accreditation and review organization approved by the Commissioner.

C. Economic Impact on Citizens/Public at Large.

None.

Date: 7/23/98

Signature of Agency Head or Authorized Representative

B. KEITH HUFFMAN, GENERAL COUNSEL

DATE: JULY 23, 1998

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: OFFICE OF THE INSURANCE COMMISSIONER

LEGISLATIVE RULE TITLE: QUALITY ASSURANCE, SERIES 53

1. Authorizing statute(s) citation: West Virginia Code §§ 33-2-10, 33-25A-4(1)(b) and 33-25A-17a.

2. a. Date filed in State Register with Notice of Hearing: June 3, 1998

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

      None

   c. Date of hearing(s): The public comment period ended on July 6, 1998.

   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 30, 1998

   f. Name and phone number of agency person to contact for additional information:

      Donna S. Quesenberry
      Associate Counsel
      (304) 558-0401

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: 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:

Attached: Not applicable

Insurance Commissioner
Title 114, Series 53

ATTACHMENT TO QUESTION 2(d):

One comment, from Steven J. Summer, President of the West Virginia Hospital Association, was received during the comment period. The Hospital Association suggests that subsection 5.6 be amended to reflect that practice guidelines and quality improvement criteria should be based upon nationally recognized standards which have been demonstrated to improve and measure quality. Practice guidelines include protocols which may be specific to a particular hospital. Therefore, to provide flexibility to accommodate local practices, the Commissioner does not amend this subsection.

The Hospital Association requests clarification of subsection 5.7. Specifically, whether subdivision a refers to plan performance or provider performance. The Commissioner is in agreement, and amends that subdivision accordingly. Also, it is suggested that subdivision c be amended by striking the word "detecting" and substituting "reviewing." No explanation is given as to why this suggested amendment is being proposed. The Commissioner does not feel this amendment is necessary. Accordingly, subsection 5.7 is amended to read as follows:

5.7. An HMO shall develop and implement mechanisms for:
   a. Assessing plan and provider performance against practice guidelines;
   b. Evaluating member continuity and coordination of care;
   c. Detecting under- and over-utilization; and
   d. Assessing patient outcomes.

The Hospital Association suggests that subsection 6.1 be amended to include language requiring the HMO to comply "with established access standards developed by the Commissioner". The Association is concerned that "there is no clear guarantee that HMO enrollees are assured reasonable access to care". The Commissioner disagrees that such an amendment is necessary. Pursuant to statute, W.Va. Code § 33-25A-4(1), availability and accessability of adequate personnel and facilities is a requirement for licensure in this State.

The Hospital Association also suggests a change in the terminology in subdivision b of subsection 6.4. The Association believes that their "terminology better describes the behavioral conditions which may affect an individual provider's ability to practice." The Commissioner is in agreement and amends subdivision b of subsection 6.4 to read as follows:

b. Lack of substance abuse or chemical dependency.

The Hospital Association recommends that subsection 6.7 be amended to allow "HMOs to contract with organizations which demonstrate compliance with federal Medicare conditions of participation, as certified by the Office of Health Facilities Licensing and Certification." It is the opinion of the Commissioner that such an amendment is unnecessary. The proposed rule, as currently drafted provides for flexibility by requiring the HMO to be in good standing with state and federal regulatory bodies. Additionally, this subsection contains requirements for the HMO "if the health delivery organization has not been approved by a recognized accrediting body."

Finally, the Association suggests an amendment to subdivision a of subsection 9.1 requiring standards for medical records to be consistent with state law and regulations. The Commissioner does not believe this amendment is necessary due to the language contained in subsection 4.1 of the proposed rule which states that "a health maintenance organization shall develop a quality assurance program which adheres to all applicable state and federal laws, federal regulations and state rules." Medical records are therefore required by this provision to be maintained in a manner consistent with state law.

WEST VIRGINIA
HOSPITAL ASSOCIATION

100 Association Drive
Charleston, WV 25311-1571
(304) 344-9744
FAX: (304) 344-9745
Web Page: www.wvha.com

July 6, 1998

RECEIVED
JUL 6 1998
LEGAL DIVISION
W. VA. INS. DEPT.

B. Keith Huffman
General Counsel
Offices of the Insurance Commissioner
Legal Division
P.O. Box 50540
Charleston, West Virginia 25305-0540

Hand Delivered

Dear Mr. Huffman:

On behalf of the West Virginia Hospital Association and its 67 member hospitals and health systems, we appreciate the opportunity to provide comments in response to the proposed Quality Assurance Rule, Title 114, Series 53. The suggested changes are indicated by strike-throughs and underlines, and comments are in italics.

§114-53-5.6. A health maintenance organization shall adopt and use nationally recognized practice guidelines or explicit criteria that are based on reasonable, nationally recognized scientific evidence.
Practice guidelines and quality improvement criteria should be based upon nationally recognized standards which have been demonstrated to improve and measure quality.

§114-53-5.7. An HMO shall develop and implement mechanisms for:

a. Assessing performance against practice guidelines
Does this refer to plan performance or provider performance? This needs clarification.

b. Evaluating member continuity and coordination of care;

c. Reviewing ~~detecting~~ under and over-utilization;

d. Assessing patient outcomes.

§114-53-6.1. A health maintenance organization shall ensure that its network has sufficient numbers and types of providers, through compliance with established access standards developed by the Commissioner. The HMO shall have a written access plan outlining its strategy for maintaining an adequate network and shall implement mechanisms designed to assure the availability of primary care and specialty providers.
Since HMOs are not required to achieve accreditation through the National Commission on

Quality Assurance, there is no clear guarantee that HMO enrollees are assured reasonable access to care. WVHA believes that there must be public accountability for assuring access to services and compliance with access standards in order for an HMO to maintain a Certificate of Authority to operate in specific counties. At a minimum, the same HMO access standards which are required by the federal Health Care Financing Administration for Medicaid managed care enrollees should be upheld for all consumers. Furthermore, the development of access standards should be through a public review and comment process with input from other state agencies, providers, and consumers. The requirement that an HMO merely outline its strategy for assuring availability to providers is insufficient in protecting consumers and assuring quality.

§114-53-6.4 A prospective provider shall complete an application an application for membership which includes a statement by the applicant regarding:

a. Reasons for any inability to perform the essential functions of the position, with or without accommodation;

b. Lack of present ~~illegal drug use and alcohol abuse~~ substance abuse or chemical dependency.
We believe that our proposed terminology better describes the behavioral conditions which may affect an individual provider's ability to practice.

§114-53-6.7. A health maintenance organization shall have written policies and procedures for the initial and ongoing quality assessment of health delivery organizations with which it intends to contract. The HMO shall confirm that the health delivery organization has been reviewed and approved by a recognized accrediting body, and/or is in compliance with state licensure and Medicare/Medicaid certification regulations as deemed by the Office of Health Facilities Licensure and Certification ~~is in good standing with state and federal regulatory bodies.~~ If the health delivery organization has not been approved by a recognized accrediting body, the HMO must develop and implement standards of participation. Health delivery organizations shall include but are not limited to hospital, home health agencies, behavioral health agencies, nursing homes, skilled nursing facilities, and free-standing surgical centers.

a. At least every three years, the health maintenance organization shall confirm that the health delivery organization continues to be in good standing with the state and federal regulatory bodies and/or, if applicable, is reviewed and approved by an accrediting body.

In order for a health care organization to receive Medicare or Medicaid reimbursement, the organization must meet federally specified "Conditions of Participation" (COPs). The federal Health Care Financing Administration (HCFA) promulgates COPs for hospitals, home health agencies, nursing facilities, hospices, ambulatory surgical centers, renal dialysis centers, rural

health clinics, outpatient physical and occupational therapy, and rehabilitation facilities. HCFA contracts with designated state agencies in each state to perform the certification surveys. In West Virginia, the designated agency is the Office of Health Facilities Licensure and Certification. Although the majority of hospitals in West Virginia are voluntarily accredited by the Joint Commission on Healthcare Organizations (JCAHO), most health care organizations in West Virginia as listed in the rule are not accredited through their respective national accreditation organizations.
Furthermore, JCAHO accreditation is not authorized by HCFA for Critical Access Hospitals. We therefore recommend flexibility to allow HMOs to contract with organizations which demonstrate compliance with federal Medicare conditions of participation, as certified by the Office of Health Facilities Licensing and Certification.

§114-53-9a. An HMO shall set forth in writing appropriate standards for medical records consistent with state law and regulations, the systematic review for conformance and the institution of corrective action when standards are not met. Copies of all standards and goals and any updates shall be provided to all providers.

Again, thank you for the opportunity to comment and encourage you to adopt the changes as we've suggested in order to rectify some issues that may hamper the success of managed care in West Virginia.

Sincerely,

Steven J. Summer
President

114CSR53
WEST VIRGINIA LEGISLATIVE RULE
INSURANCE COMMISSION

SERIES 53
QUALITY ASSURANCE

Section

§114-53-1. General.

§114-53-2. Definitions.

§114-53-3. Goals of a Quality Assurance Program.

§114-53-4. Requirements of a Quality Assurance Program.

§114-53-5. Quality Management & Improvement.

§114-53-6. Credentialing & Recredentialing.

§114-53-7. Members' Rights & Responsibilities.

§114-53-8. Preventive Health Services.

§114-53-9. Medical Records.

§114-53-10. Severability.

114CSR53
WEST VIRGINIA LEGISLATIVE RULE
INSURANCE COMMISSION

SERIES 53
QUALITY ASSURANCE

§114-53-1. General.

1.1. Scope. -- The purpose of this rule is to set forth standards for quality assurance programs established as a component of a health maintenance organization's overall structure.

1.2. Authority. -- W. Va. Code §§ 33-2-10, 33-25A-4(1)(b), and 33-25A-17a.

1.3. Filing Date. --

1.4. Effective Date. --

§114-53-2. Definitions.

2.1. "Accountability" means the responsibility of a department or individual for achieving defined goals.

2.2. "Appropriateness" means the extent to which a particular procedure, treatment, test or service is clearly indicated, not excessive, adequate in quantity and provided in the setting best suited to the patient's/member's needs.

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

2.4. "Clinician" means a state-recognized provider including but not limited to physicians, psychologists and psychiatrists who specialize in clinical studies or practice.

2.5. "Credentialing" means the process by which a health maintenance organization authorizes, contracts with or employs clinicians, who are licensed to practice independently, to provide services to its members.

2.6 "DEA" means Drug Enforcement Administration, the Federal agency that issues licenses to prescribe and dispense scheduled drugs.

2.7. "Delegation" or "delegated" means the formal process by which a health maintenance organization gives a contractor the authority to perform certain functions on its behalf, such as credentialing, utilization review and quality assurance. A

health maintenance organization can delegate the authority to perform a function but cannot delegate the responsibility for assuring the function is performed properly.

2.8. "Governing body" means an individual, group or agency with the ultimate authority and responsibility for the overall operation of the organization.

2.9 "Health care services" means any services or goods included in the furnishing to any individual of medical, mental or dental care, or hospitalization, osteopathic services, chiropractic services, podiatric services, home health, health education, or rehabilitation, as well as the furnishing to any person of any and all other services or goods for the purpose of preventing, alleviating, curing or healing human illness or injury.

2.10. "Health maintenance organization" or "HMO" means a public or private organization which provides, or otherwise makes available to enrollees, health care services, including at a minimum basic health care services, which:

a. Receives premiums for the provision of basic health care services to enrollees on a prepaid per capita or prepaid aggregate fixed sum basis, excluding copayments;

b. Primarily provides physicians' services:

1. Directly through physicians who are either employees or partners of the organization;

2. Through arrangements with individual physicians or one or more groups of physicians organized on a group practice or individual practice arrangement; or

3. Through some combination of paragraphs one and two of this subdivision;

c. Assures the availability, accessibility and quality including appropriate utilization of the health care services that it provides or makes available through clearly identifiable focal points of legal and administrative responsibility; and

d. Offers services through an organized delivery system, in which a primary care physician is designated for each subscriber upon enrollment. The primary care physician is responsible for coordinating the health care of the subscriber

and is responsible for referring the subscriber to other providers when necessary: Provided, that when dental care is provided by the health maintenance organization the dentist selected by the subscriber from the list provided by the health maintenance organization shall coordinate the covered dental care of the subscriber, as approved by the primary care physician or the health maintenance organization.

2.11. "Medical record" means the record in which clinical information relating to the provision of physical, social and mental health services is recorded and stored.

2.12. "Member," "subscriber" or "enrollee" means an individual who has been voluntarily enrolled in a health maintenance organization, including individuals on whose behalf a contractual arrangement has been entered into with a health maintenance organization to receive health care services.

2.13. "Oversight" means the monitoring and direction of a set of activities by individuals responsible for the execution of the activities resulting in the achievement of desired outcomes.

2.14. "Practice guidelines" or "protocols" means systematically developed statements to assist patient and practitioner decisions about appropriate health care for specific clinical circumstances. Practice guidelines are usually based on such authoritative sources as clinical literature and expert consensus.

2.15. "Provider" means any physician, hospital, or other person or organization which is licensed or otherwise authorized in this state to furnish health care services.

2.16. "Public health related activities" means those activities related but not limited to the prevention of epidemics and the spread of disease in communities; the protection against environmental hazards; the prevention of injuries; the promotion and encouragement of healthy behaviors; and the assurance of accessibility of health services and treatment of specific illnesses for persons in high risk and vulnerable populations.

2.17. "Quality assurance" means an ongoing program designed to objectively and systematically monitor and evaluate the quality and appropriateness of the enrollee's care, pursue opportunities to improve the enrollee's care and to resolve identified problems at the prevailing professional standard of care.

2.18. "Quality assurance work plan" means an annual plan that describes with timeliness the specific planned quality assurance activities that will be carried out within the quality assurance program.

2.19. "Quality of care" means the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

§114-53-3. Goals of a Quality Assurance Program.

3.1. The goals of a health maintenance organization's quality assurance program shall be to:

a. Assure the provision of appropriate medical services delivered to members, while simultaneously addressing the effectiveness of quality of care;

b. Monitor, evaluate and improve the quality of health care;

c. Provide a systematic process that promotes the delivery of medically appropriate care in a timely, effective and efficient manner, while maintaining the quality of health care;

d. Direct members and providers toward the goal of quality, cost effective health care.

3.2. A health maintenance organization's quality assurance program shall include a mechanism for identifying potential utilization management issues and linking them to the HMO's utilization management program.

§114-53-4. Requirements of a Quality Assurance Program.

4.1. A health maintenance organization shall develop a quality assurance program which adheres to all applicable state and federal laws, federal regulations and state rules.

a. A health maintenance organization that has obtained full accreditation or equal status from a nationally recognized accreditation and review organization approved by the commissioner pursuant to W. Va. Code § 33-25A-17a is deemed to be in compliance with this rule. If, at any time subsequent to the granting of full accreditation or equal status by a nationally

recognized accreditation and review organization, the commissioner determines that the quality assurance program of the health maintenance organization has become deficient in any significant area, the commissioner, in addition to other remedies available, may establish a corrective action plan that the HMO must follow as a condition to the issuance or maintenance of a certificate of authority.

4.2. Each application for a certificate of authority or renewal thereof filed with the commissioner pursuant to the Health Maintenance Organization Act, W. Va. Code §§ 33-25A-1 et seq., shall be accompanied by a description of a health maintenance organization's quality assurance program, which shall include, but not be limited to, the requirements of the quality assurance program set forth in this rule. The HMO's quality assurance program may be inspected by providers, enrollees or their agents at the offices of the commissioner pursuant to the provisions of the West Virginia Freedom of Information Act, W.Va. Code §§ 29B-1-1 et seq.

a. Pursuant to the requirements of W. Va. Code § 33-25A-3, a health maintenance organization shall file notice with the commissioner prior to any modification of the quality assurance program.

4.3. A health maintenance organization shall have a program for quality assurance which clearly defines the structure, design and responsibilities of both delegated and non-delegated activities.

a. The basic components of the quality assurance program shall include:

1. Organizational arrangements and responsibilities for quality management and improvement processes;

2. A documented utilization review program;

3. Written policies and procedures for credentialing and recredentialing physicians and other licensed providers;

4. A written policy addressing members' rights and responsibilities; and

5. The adoption of practice guidelines for the use of preventive health services.

b. Utilization management rules contained in 114 CSR 51 shall be incorporated in and made a part of this rule.

4.4. If a health maintenance organization delegates any quality assurance activity to contractors, there shall be evidence of oversight and auditing of the contracted activity.

a. The HMO shall maintain a written description of the delegated activities, the contractor's accountability for the activities, the frequency of reporting to the HMO, the process by which the delegation will be evaluated and the remedies available, including revocation of delegation, if the contractor does not fulfill its obligations.

b. The HMO shall maintain evidence of its regular evaluation and approval of the delegated activities by the contractor.

c. The HMO shall be responsible for monitoring the activities of the contractor to which it delegates quality assurance activities and for ensuring that the requirements of this rule are met.

4.5. No health maintenance organization may place restrictions upon any provider or upon any primary care physician which would serve to limit the communication of medical advice or options available to the member, subscriber or enrollee or would act in any way to limit the communication between the provider or physician and his or her patient. An HMO may not prevent any provider from advising an enrollee whether or not a treatment is covered by the plan.

a. No health maintenance organization may provide to any provider or any primary care physician an incentive or disincentive plan that includes specific payment made directly or indirectly, in any form, to the provider or primary care physician as an inducement to deny, release, limit, or delay specific, medically necessary and appropriate services provided with respect to a specific enrollee or groups of enrollees with similar medical conditions.

4.6. Data or information pertaining to the diagnoses, treatment or health of a member obtained from the member or from

a provider by a health maintenance organization is confidential and shall not be disclosed to any person except:

a. To the extent that it may be necessary to carry out the purposes of these rules and as allowed by state law;

b. Upon the express consent of the member;

c. Pursuant to statute or court order for the production of evidence or the discovery thereof;

d. In the event of a claim or litigation between the member and the health maintenance organization where the data or information is pertinent, regardless of whether the information is in the form of paper, preserved on microfilm, or stored in computer retrievable form.

4.7 If any data or information pertaining to the diagnosis, treatment or health of any enrollee or applicant is disclosed pursuant to the provisions of subsection 4.6, the health maintenance organization making this required disclosure shall not be liable for the disclosure or any subsequent use or misuse of the data.

§114-53-5. Quality Management & Improvement.

5.1. Organizational arrangements and responsibilities for quality management and improvement processes shall be clearly defined and assigned to appropriate individuals.

a. There shall be a detailed written description of the program which shall be reviewed annually and updated as necessary.

b. A senior executive shall be responsible for program implementation.

c. A medical director shall be employed by the health maintenance organization and have substantial involvement in quality improvement activities.

1. Upon application to and approval by the commissioner, a health maintenance organization may employ a medical director on a part-time basis during the first two years of the HMO's operation.

2. All health maintenance organizations are

required to employ a full-time medical director no later than the first day of the third year of the HMO's operation.

d. A committee shall be created to oversee quality improvement and shall include HMO providers as active participants. The committee shall keep contemporaneous written records reflecting all of its actions.

e. The role, structure and function, including frequency of meetings, of the quality improvement committee shall be specified in the program description.

f. Adequate resources including, but not limited to, personnel, analytic capabilities and data resources shall be dedicated to meet program needs.

g. A written quality improvement work plan shall be prepared annually and shall include: the objectives, scope and planned projects or activities for the year; planned monitoring of previously identified issues, including tracking of issues over time; and planned evaluation of the quality improvement program.

5.2. The quality improvement committee shall be accountable to the governing body of a health maintenance organization. The governing body shall consist of the board of directors or a committee of senior management in instances where the board's participation with quality improvement is indirect. There must be documented evidence of a formally designated structure, accountability at the highest levels of the organization and ongoing and/or continuous oversight of quality assurance.

a. The governing body shall formally designate a subcommittee to provide oversight of quality improvement or formally decide to provide such oversight as a committee of the whole.

b. There must be written documentation that the governing body has reviewed and approved the written overall quality improvement program and the annual quality improvement work plan.

c. The governing body or designated committee shall regularly receive written reports from the quality improvement program delineating actions taken and improvements made.

d. All quality assurance information shall be considered in recredentialing, recontracting and/or annual performance evaluations.

5.3. All findings, conclusions, recommendations, actions taken, and results of actions taken as a result of the quality improvement process shall be documented and reported to the appropriate individuals and committees in the health maintenance organization and through established quality improvement standards.

a. Quality improvement activities shall be coordinated with other performance monitoring activities, including but not limited to utilization management, risk management and resolution, monitoring of member complaints and grievances, assessment of member satisfaction and medical records review.

b. Quality improvement shall be coordinated with other management functions of the health maintenance organization such as network changes, benefits redesign, medical management systems, practice feedback to providers and patient education.

5.4. Requirements to participate in quality improvement activities shall be incorporated into all provider contracts and employment agreements. Contracts shall specify that hospitals and other contractors will allow the health maintenance organization access to members' medical records. Contracts shall also specify that the health maintenance organization allows open provider-patient communication regarding appropriate treatment alternatives and that it does not penalize the provider for discussing medically necessary or appropriate care for the patient.

5.5. The quality improvement program must be ongoing and designed to objectively and systematically monitor and evaluate the quality and appropriateness of care and service provided members and to pursue opportunities for improvements.

a. The scope of the program shall be comprehensive and shall include quality of clinical care and quality of service.

b. Members shall be afforded opportunities to participate in and offer suggestions on quality improvement.

c. A health maintenance organization shall monitor and evaluate clinical issues in institutional and non-

institutional settings, primary care and major specialty services including mental health, high volume high-risk services, preventive care services, and the care of acute and chronic conditions. Such monitoring and evaluation shall reflect the population served in terms of age groups, disease categories and special risk status.

5.6. A health maintenance organization shall adopt and use practice guidelines or explicit criteria that are based on reasonable scientific evidence.

a. The guidelines shall be reviewed and updated as needed.

b. The guidelines and any updates shall be communicated in writing to all providers.

5.7. An HMO shall develop and implement mechanisms for:

a. Assessing plan and provider performance against practice guidelines;

b. Evaluating member continuity and coordination of care;

c. Detecting under- and over-utilization; and

d. Assessing patient outcomes.

5.8. A health maintenance organization shall establish standards for the availability of primary care providers and access which shall include but not be limited to routine, urgent and emergency care; identification of members with chronic/high-risk illnesses and the appropriate programmatic responses; telephone appointments, advice and member service lines. The availability and access standards shall conform to the minimum requirements set by the commissioner.

5.9. A health maintenance organization shall develop indicators, a data collection system and data analysis capabilities to track quality improvement.

a. Indicators shall be objective, measurable and based on current knowledge and clinical experience and shall be used to monitor and evaluate all aspects of care and services identified.

b. An HMO shall have performance goals and/or a bench marking process for each indicator.

c. Appropriate methods and frequency of data collection shall be used for each indicator.

d. Appropriate clinicians shall be used to evaluate data on the clinical performance of practitioners.

e. Multidisciplinary teams shall be used, where indicated, to analyze and address systems issues.

5.10. If a health maintenance organization receives ten or more complaints from members or enrollees within a six-month period that relate to the same or similar subject matter, the health maintenance organization shall develop a specific written plan of action as to the resolution of the complaints and file a report with the commissioner on how the complaints were successfully resolved.

§114-53-6. Credentialing & Recredentialing.

6.1 A health maintenance organization shall ensure that its network has sufficient numbers and types of providers. The HMO shall have a written access plan outlining its strategy for maintaining an adequate network and shall implement mechanisms designed to assure the availability of primary care and specialty practitioners.

6.2 A health maintenance organization shall have written policies and procedures for the credentialing of all providers that include the original credentialing, recredentialing, recertification and or reappointment of physicians and other licensed independent practitioners who fall under its scope of authority and action.

a. The governing body, or the group or individual to whom the governing body has formally delegated the credentialing function, shall review and approve credentialing policies and procedures.

b. A credentialing committee or other peer review body shall be established to make recommendations regarding credentialing decisions. The committee shall include providers, including but not limited to physicians, as voting members.

6.3 In terms of initial credentialing, an HMO shall obtain and review verification of the following from primary sources:

a. A current valid license to practice;

b. When applicable, clinical privileges in good standing at the hospital designated by the practitioner as the primary admitting facility;

c. A valid Drug Enforcement Administration (DEA) certificate, as applicable;

d. Graduation from medical school or appropriate graduate school and completion of a residency, specialty training and board certification, as applicable;

e. Complete work history;

f. Current adequate malpractice insurance according to the HMO's policy;

g. Complete professional liability claims history; and

h. Any other information deemed necessary by the HMO in determining whether to contract with a prospective provider.

6.4. A prospective provider shall complete an application for membership which includes a statement by the applicant regarding:

a. Reasons for any inability to perform the essential functions of the position, with or without accommodation;

b. Lack of substance abuse or chemical dependency;

c. History of loss of license and/or felony convictions;

d. History of loss or limitation of privileges or disciplinary activity;

e. Any other information deemed necessary by an HMO in determining whether to contract with a prospective provider; and

f. An attestation to the correctness/completeness of the application.

6.5. A health maintenance organization shall request information on the prospective provider from recognized monitoring organizations including: the National Practitioner Data Bank; the appropriate State licensing boards such as the Board of Medicine, Chiropractic Board, Osteopathic Board and/or Dental Board; and any Medicare/Medicaid sanctioning.

6.6. Representatives from the credentialing committee or members of their staff shall make an initial visit to each potential primary care practitioner's office and to the offices of obstetricians/gynecologists and other high-volume specialists. This process shall include documentation of a structured review of the site and of medical record keeping practices to ensure conformance with the HMO's standards.

6.7. A health maintenance organization shall have written policies and procedures for the initial and ongoing quality assessment of health delivery organizations with which it intends to contract. The HMO shall confirm that the health delivery organization has been reviewed and approved by a recognized accrediting body and is in good standing with state and federal regulatory bodies. If the health delivery organization has not been approved by a recognized accrediting body, the HMO must develop and implement standards of participation. Health delivery organizations shall include but are not limited to hospitals, home health agencies, behavioral health agencies, nursing homes, skilled nursing facilities and free-standing surgical centers.

a. At least every three years, the health maintenance organization shall confirm that the health delivery organization continues to be in good standing with the state and federal regulatory bodies and, if applicable, is reviewed and approved by an accrediting body.

6.8. In terms of recredentialing, a health maintenance organization shall develop a process for the periodic verification of credentials which shall be implemented at least every two years.

a. At a minimum, recredentialing shall include verification from primary sources of:

1. A valid state license to practice;

2. Clinical privileges in good standing at the hospital designated by the practitioner as the primary admitting facility;

3. A valid Drug Enforcement Administration (DEA) certificate, as applicable;

4. Board certification, as applicable;

5. Current, adequate malpractice insurance;

6. Professional liability claims history; and

7. Any other information deemed necessary by an HMO in determining whether to re-contract with a provider.

b. The recredentialing process shall include a current statement by the applicant regarding reasons for any inability to perform the essential functions of the position, with or without accommodation and lack of present illegal drug use and alcohol abuse.

c. An HMO shall request recredentialing information from the National Practitioner Data Bank; the appropriate State licensing boards such as the Board of Medicine, Chiropractic Board, Osteopathic Board and/or Dental Board; and any Medicare/Medicaid sanctioning.

d. The recredentialing process shall also include a review of data from member complaints and grievances, results of quality reviews, utilization management, member satisfaction surveys, medical record reviews and site visits.

e. The recredentialing process shall include an on-site visit to all primary care providers, obstetricians/ gynecologists and high-volume specialists and shall involve documentation of a structured review of the site and medical record keeping practices to ensure conformance with HMO standards.

f. A health maintenance organization shall have polices and procedures in place for reducing, suspending or terminating practitioner privileges which shall include but is not limited to:

1. A mechanism for reporting to the appropriate authorities serious quality deficiencies resulting in suspension or termination; and

2. An appeal process for and notice thereof to the provider.

114-53-7. Members' Rights & Responsibilities.

7.1. An HMO shall demonstrate a commitment to treating members with respect by developing written policies giving them the right to:

a. Voice grievances about the HMO or care provided;

b. Have information concerning the HMO, its services, the practitioners providing care and members' rights and responsibilities;

c. Participate in decision-making regarding health care; and

d. Be treated with respect and recognition of their dignity and need for privacy.

7.2. An HMO shall develop a written policy addressing members' responsibilities for cooperating with those providing health care services by giving needed information to professional staff to ensure appropriate care and by following instructions and guidelines given by those providing health care services.

7.3. All policies on members' rights and responsibilities shall be provided in writing in clear and concise terms to all members and participating providers and, at a minimum, shall address the following procedures for, policies concerning or information regarding:

a. How to submit claim for covered services;

b. How to obtain primary and specialty care, behavioral health services and hospital services;

c. After-hours and emergency coverage including the HMO's policy on when to directly access emergency care or use 911 type services;

d. Benefits and services included and excluded from membership;

e. Obtaining out-of-area coverage;

f. Special benefit provisions such, as co-payment, higher deductibles and rejection of claims, that may apply to services outside the system;

g. Member charges;

h. Notification of termination or change in any benefits, services or delivery site/office;

i. Notification of termination of a primary care or specialty provider and the process for selecting a new provider;

j. Appealing decisions adversely affecting a member's coverage, benefits or relationship to the HMO;

k. Changing practitioners;

l. Disenrollment of nongroup subscribers;

m. Voicing complaints, grievances and appeals;

n. Recommending changes in policies and services;

o. Points of access to primary care, specialty care and hospital services;

p. The process by which a managed care organization determines whether or not to include new and emerging technology or treatment as a covered benefit;

q. Provider names, qualifications and titles;

r. Confidentiality; and

s. Member satisfaction surveys that assess patient complaints, requests to change practitioners and/or facilities and disenrollments.

7.4. The health maintenance organization shall make reasonable accommodations for providing to member's with disabilities the HMO's policies on members' rights and responsibilities.

7.5. A health maintenance organization shall have a procedure by which a member, upon diagnosis with a life-threatening, degenerative or disabling condition or disease, either of which requires specialized health care over a prolonged period of time, may receive a standing referral to a specialist with expertise in that condition or disease who will be responsible for and capable of providing and coordinating the member's specialty care. When a standing referral is made, the HMO shall periodically review the referral for continued necessity.

§114-53-8. Preventive Health Services.

8.1. A health maintenance organization shall adopt guidelines for the use of preventive health services which must be based on reasonable medical evidence and the full service population. The guidelines shall be developed or adopted with the participation of the HMO's providers and must include a mechanism for periodic updates.

a. The guidelines and all updates shall be provided in writing to all providers and members.

b. The guidelines shall consist of the following categories:

1. Prenatal and perinatal care;

2. Preventive care for infants up to 24 months;

3. Preventive care for children and adolescents aged two through 19 years old;

4. Preventive care for adults aged 20 through 64 years old; and

5. Preventive care for those aged 65 and older.

c. Each guideline shall describe the prevention or early detection interventions and the recommended frequency and conditions under which the interventions are required. The health maintenance organization shall document the scientific basis or authority upon which it based the preventive health guidelines.

d. Providers from the health maintenance organization who have appropriate knowledge shall be involved in the adoption of the preventive health guidelines.

e. At least annually, an HMO shall monitor, evaluate and take action upon a minimum of two of the following preventive services and take action to improve the use of preventive services as appropriate:

1. Childhood immunizations recognized by the American Academy of Pediatrics or as required by state or federal law;

2. Adult immunizations including influenza vaccine, pneumococcal vaccine, Hepatitis B vaccine, diphtheria and tetanus toxoid, rubella screening for women of childbearing age or any other immunization required by state or federal law;

3. Coronary artery disease risk factor screening and/or counseling for smoking, cholesterol, exercise and hypertension;

4. Breast and cervical cancer screening;

5. Counseling for prevention of motor vehicle injury;

6. Lead toxicity screening;

7. Sexually transmitted disease screening/prevention;

8. Prenatal care;

9. HIV/Aids counseling, screening and education;

10. Prevention of unintended pregnancy;

11. Alcohol and drug abuse screening/prevention; and

12. Any other preventive services deemed appropriate by the commissioner and any other state or federal regulatory authorities.

f. Preventive health service studies shall be enrollee population-based, measuring compliance as it relates to the total at-risk population.

§114-53-9. Medical Records.

9.1. A health maintenance organization shall require all of its providers to have an organized medical recordkeeping system. Medical records shall be maintained in a manner that is current, detailed, organized and permits effective patient care and quality review. Records shall also reflect all aspects of patient care including ancillary services.

a. An HMO shall set forth in writing appropriate standards for medical records, the systematic review for conformance and the institution of corrective action when standards are not met. Copies of all standards and goals and any updates shall be provided to all providers.

b. Records shall be available to health care practitioners at each patient visit and to nationally and state recognized reviewing bodies sanctioned by the commissioner.

§114-53-1. Severability.

10.1. This rule is subject to the anti-discrimination provisions of W.Va. Code § 33-25A-31.

10.2. If any provision of this rule or the application of this rule to any person or circumstances is for any reason held to be invalid, the remainder of the rule and the application of the provisions to other persons or circumstances shall not be affected by the holding.

Quality Assurance

Title 114, Series 53

BRIEF SUMMARY OF RULE

This proposed rule implements the privisions of the Health maintenance Organization Act, W. Va. Code §§ 33-25A-1 et. seq., which was amended during the 1996 legislative session by House Bill 4511. The rule sets forth the standards for quality assurance programs which must be met by each health maintenance organization as a condition precedent ot the issuance of a Certificate of Authority to transact insurance in the State of West Virginia effective May 1, 1998.

This is one of the rules which has been through the entire rulemaking process, but which were not ratified by the legislature during the 1997-98 session due to the failure to pass HB 4177.

STATE OF WEST VIRGINIA
Offices of the Insurance Commissioner
Legal Division

CECIL H. UNDERWOOD
Governor

HANLEY C. CLARK
Insurance Commissioner

July 30, 1998

HAND DELIVERED

Ms. Judy Cooper
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 filing with the Legislative Rule-Making Review Committee;

2) Consent of Tax and Revenue Cabinet Secretary to Proposed Rule;

3) Brief Summary of the Rule;

4) Statement of Circumstances;

5) Fiscal Note;

6) Legislative Rule-Making Review Committee Questionnaire; and

7) The Agency Approved Proposed Rule Entitled "Quality Assurance" (Series 53).

Please contact me if further information is required.

Sincerely,

B. Keith Huffman
General Counsel

BKH/ksb

Enclosures

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