114CSR53

WEST VIRGINIA LEGISLATIVE RULE

INSURANCE COMMISSIONER

SERIES 53

QUALITY ASSURANCE

Section.

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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. -- April 3, 2003.

1.4. Effective Date. -- April 3, 2003.

§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. “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.

2.17. “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.

2.18. “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 three 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.

§114-53-10. 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.