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Chapter 408
Certificate of Quality Assurance of Managed Care Health Insurance Plan Licensees.

PART I.
Definitions and General Information

12 VAC 5-408-10 Definitions.

The following words and terms, when used in this regulation, shall have the following meaning unless the context clearly indicates otherwise:

"Adverse decision" means a utilization review determination by the utilization review entity that a health service rendered or proposed to be rendered was not or is not medically necessary, when such determination may result in noncoverage of the health service or health services.

"Appeal" means a formal request by an enrollee or a provider on behalf of an enrollee for reconsideration of a decision, such as a utilization review recommendation, a benefit payment, an administrative action, or a quality-of-care or service issue.

"Basic health care services" means those health care services described in §38.2-5800 of the Code of Virginia which are required to be provided, arranged, payed, or reimbursed by the managed care health insurance plan licensee for its covered persons.

"Board" means the Board of Health.

"Bureau of Insurance" means the State Corporation Commission acting pursuant to Title 38.2 of the Code of Virginia.

"Center" means the Center for Quality Health Care Services and Consumer Protection of the Virginia Department of Health.

"Complaint" means a written or oral expression of dissatisfaction received from an enrollee or provider on behalf of an enrollee.

"Department" means the Virginia Department of Health.

"Disease management program" means an integrated population based system approach to deliver health care services. Disease management programs use information based processes to improve the entire continuum of care, from prevention and patient education, to diagnosis and treatment, to follow-up and ongoing maintenance, with the intention of producing the best clinical outcomes. A disease management program performs the following functions: i) classifying patients by disease state; ii) identifying patients with specific chronic diseases in a covered population, iii) encouraging intervention at the most beneficial medical junctures, iv) offering long-range strategies to prevent and control each disease, v) providing feedback on outcome to physicians, and vi) emphasizing preventive care and patient education.

"Emergency services" means those health care services that are rendered by affiliated or nonaffiliated providers after the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent layperson who possesses an average knowledge of health and medicine to result in (i) serious jeopardy to the mental or physical health of the individual, (ii) danger of serious impairment of the individual's bodily functions, (iii) serious dysfunction of any of the individual's bodily organs, or (iv) in the case of a pregnant woman, serious jeopardy to the health of the fetus. Emergency services provided within an MCHIP's service area shall include covered health services from nonaffiliated providers only when delay in receiving care from a provider affiliated with the MCHIP could reasonably be expected to cause the enrollee's condition to worsen if left unattended.

"Enrollee" means an individual residing in the Commonwealth, whether a policyholder, subscriber, covered person, or member of a managed care health insurance plan, who is entitled to health care services or benefits provided, arranged for, paid for or reimbursed pursuant to a managed care health insurance plan under Title 38.2 of the Code of Virginia.

"Evidence of coverage" means any certificate, individual or group agreement or contract, or identification card or related document issued in conjunction with the certificate, agreement or contract, issued to an enrollee setting out the coverage and other rights to which an enrollee is entitled.

"Final adverse decision" means a utilization review determination made by a physician advisor or peer of the treating health care provider in a reconsideration of an adverse decision, and upon which a provider or patient may base an appeal.

"Fully accredited" means the highest or most comprehensive level of accreditation granted as defined by the nationally recognized accrediting body.

"Grievance" means a process available to enrollees to request a second reconsideration of an adverse decision in order to resolve a disagreement about the MCHIP's responsibilities and obligations.

"Health care data reporting system" means the state contracted integrated system for the collection and analysis of data used by consumers, employers, providers, and purchasers of health care to continuously assess and improve the quality of health care in the Commonwealth.

"Managed care health insurance plan" or "MCHIP" means an arrangement for the delivery of health care in which a health carrier as defined in §38.2-5800 of the Code of Virginia undertakes to provide, arrange for, pay for, or reimburse any of the costs of health care services for a covered person on a prepaid or insured basis which (i) contains one or more incentive arrangements, including any credentialing requirements intended to influence the cost or level of health care services between the health carrier and one or more providers with respect to the delivery of health care services; and (ii) requires or creates benefit payment differential incentives for covered persons to use providers that are directly or indirectly managed, owned, under contract with or employed by the health carrier. Any health maintenance organization as defined in §38.2-4300 of the Code of Virginia or health carrier that offers preferred provider contracts or policies as defined in §38.2-3407 of the Code of Virginia or preferred provider subscription contracts as defined in §38.2-4209 of the Code of Virginia shall be deemed to be offering one or more managed care health insurance plans. For the purposes of this definition, the prohibition of balance billing by a provider shall not be deemed a benefit payment differential incentive for covered persons to use providers who are directly or indirectly managed, owned, under contract with or employed by the health carrier. A single managed care health insurance plan may encompass multiple products and multiple types of benefit payment differentials; however, a single managed care health insurance plan shall encompass only one provider network or set of provider networks.

"Managed care health insurance plan licensee" or "licensee" means a health carrier subject to licensure by the Bureau of Insurance under Title 38.2 of the Code of Virginia who is responsible for a managed care health insurance plan in accordance with Chapter 58 (§38.2-5800 et seq.) of Title 38.2 of the Code of Virginia.

"Medical necessity or medically necessary" means appropriate and necessary health care services which are rendered for any condition which, according to generally accepted principles of good medical practice, requires the diagnosis or direct care and treatment of an illness, injury, or pregnancy-related condition, and are not provided only as a convenience.

"Person" means any individual, aggregate of individuals, association, business, company, corporation, joint-stock company, Lloyds type of organization, other organization, partnership, receiver, reciprocal or inter-insurance exchange, trustee or society.

"Plan of correction" means a MCHIP'S written plan, approved by the Department, that outlines the action the MCHIP will take to address compliance issues identified during an administrative review or on-site examination conducted by the Department.

"Preferred provider organization" means a managed care health insurance plan that does not require covered medical services to be coordinated or managed through a primary care physician. A managed care health insurance plan licensee that is responsible for a managed care health insurance plan, commonly recognized as a "preferred provider organization," may delegate by contract to provide all or some of the preferred provider system components, which include the provider network, utilization review, credentialing, and claims administration, while retaining direct contact with the enrollee regarding the coordination of benefits.

"Service area" means a geographic area as defined in §38.2-5800 of the Code of Virginia.

"Timely" means the provision of services so as not to impair or jeopardize the integrity of the enrollees' diagnosis or outcomes of illness.

"Treating health care provider" or "provider" means a licensed health care provider who renders or proposes to render health care services to an enrollee.

"Utilization review" means a system for reviewing the necessity, appropriateness, and efficiency of hospital, medical or other health care services rendered or proposed to be rendered to a patient or

group of patients for the purpose of determining whether such services should be covered or provided by an insurer, health services plan, managed care health insurance plan licensee, or other entity or person. For purposes of this chapter, "utilization review" shall include, but not be limited to, preadmission, concurrent and retrospective medical necessity determination, and review related to the appropriateness of the site at which services were or are to be delivered. "Utilization review" shall not include (i) review of issues concerning insurance contract coverage or contractual restrictions on facilities to be used for the provision of services, (ii) any review of patient information by an employee of or consultant to any licensed hospital for patients of such hospital, or (iii) any determination by an insurer as to the reasonableness and necessity of services for the treatment and care of an injury suffered by an insured for which reimbursement is claimed under a contract of insurance covering any classes of insurance defined in §§ 38.2-117 through 38.2-119, 38.2-124 through 38.2-126, 38.2-130 through 38.2-132 and 38.2-134 of the Code of Virginia.

"Utilization review entity" or "entity" means a person or entity performing utilization review.

"Utilization review plan" or "plan" means a written procedure for performing a utilization review.

12 VAC 5-408-20 Responsibility of the Department.

A. The Code of Virginia allows the Board of Health to adopt regulations for the certification of quality assurance for managed care health insurance plans licensees. The Department of Health is charged with the responsibility for examining the quality of health care services provided by managed care health insurance plans according to regulations adopted by the Board and any additional requirements that may be specified by the Code of Virginia. The Center for Quality Health Care Services and Consumer Protection acts as agent for the Department for certifying managed care health insurance plans, which includes investigating complaints made against a MCHIP.

B. In developing or revising these regulations, the Department adheres to the requirements of the Administrative Process Act (§ 9.6-14:1 of the Code of Virginia) and the public participation process. The Department solicits input from MCHIPs, associations of MCHIPs, providers, experts in related fields, advocacy organizations, consumers and the general public in the development or revision of this chapter through informal and formal comment periods and public hearings.

C. The Department shall coordinate its activities with the Bureau of Insurance to ensure an appropriate level of regulatory oversight and to avoid undue duplication of effort or regulation.

D. The Department will be guided by its own interpretive guidelines when determining compliance with this regulation.

12 VAC 5-408-30 The certificate of quality assurance.

A. A certificate for quality assurance shall be issued for managed care health insurance plan licensees. The Department shall issue or renew a certificate of quality assurance if the MCHIP licensee is in compliance with the applicable law and this chapter.

B. No certificate of quality assurance may be transferred or assigned without approval of the Department.

C. Every certified MCHIP licensee shall file for its certificate of quality assurance with the Department biennially, subject to payment of a fee and receipt of all material required by law and this chapter.

D. Upon request, the Center will provide an application form for a certificate of quality assurance. The Center shall consider the application complete when all the information requested and the application fee are submitted with the required form. If the Center finds the application incomplete, the applicant will be notified in writing of receipt of the incomplete application.

E. The Department shall send an application for renewal of a certificate to the licensee at least 60 days prior to the expiration date of the current certificate.

F. The Department shall examine or review each applicant for an initial certificate of quality assurance and periodically for renewal thereof.

G. Upon the issuance or renewal of a certificate, the Department shall provide a certificate of quality assurance to the MCHIP licensee and a copy to the Bureau of Insurance.

H. Upon determining to deny or refuse to renew a certificate, the Department shall notify the applicant in writing stating the reasons for the denial of the certificate. A copy of the notification of denial shall be provided to the Bureau of Insurance.

I. Appeals from a notification of denial shall be brought by a certificate applicant pursuant to the process set forth in 12 VAC 5- 408-140.

12 VAC 5-408-40 Fees.

A. The center shall collect a fee for each initial application and each renewal application. Fees shall accompany the application and are not refundable.

B. Fees shall be sufficient to cover reasonable costs for the administration of the quality assurance program.

C. Fees shall be based upon a percentage, not to exceed one-tenth of one percent, of the proportion of direct gross premium income on business done in this Commonwealth attributable to the operation of managed care health insurance plans in the preceding biennium not to exceed $10,000 per licensee.

After July, 2000, new applicants proposing to offer MCHIP plans in the Commonwealth shall be assessed a flat fee of $5,000 for the initial application.

12 VAC 5-408-50. Preferred Provider Organization Exemption.

A. Managed care health insurance plan licensees, when operating a preferred provider organization as defined in this Chapter, must comply with all of the regulations of this chapter with the exception of the following:

1. 12 VAC 5-408-220 of Part III, Quality Improvement Program;
2. 12 VAC 5-408-250 and 12 VAC 5-408-290 of Part IV, Coordination and Continuity of Care; and
3. 12 VAC 5-408-300 et seq., of Part V, Clinical Performance Evaluation.

B. In lieu of compliance with the regulations noted above, the licensee shall demonstrate that the preferred provider organization is in compliance with one of the following:

1. The Health Networks Standards (version 3.0) of the American Accreditation HealthCare Commission/URAC for Health Networks;

2. The Joint Commission on Accreditation of Healthcare Organizations' Accreditation Manual for Preferred Provider Organizations (1997); or

3. Other nationally recognized accreditation standards for preferred provider organizations accepted by the Department.

C. If the licensee can demonstrate that, by complying with the above accreditation standards, that it meets or exceeds other MCHIP quality assurance regulations than are noted in subsection A, it may offer evidence of that compliance for consideration by the Department.

12 VAC 5-408-60 General examination process

A. MCHIP licensees shall be examined or reviewed by the Department according to Article 1.1 of Chapter 5 of Title 32.1 of the Code of Virginia to:

1. Verify that a MCHIP qualifies for an initial or renewal certificate of quality assurance;

2. Investigate a complaint filed against a MCHIP;

3. Determine compliance with this chapter and applicable law; and

4. Determine if the MCHIP has successfully implemented corrective action following an examination, or as a result of disciplinary action, or sanction.

B. Examinations shall be conducted onsite at a MCHIP's headquarters and at the site of any contractors. At its discretion, the Department may choose to conduct an administrative review to evaluate the MCHIP for compliance with applicable law and this chapter. The MCHIP's examination may also include contractors with whom the licensee has agreements, contracts, or other arrangements to provide health care services for the MCHIP.

C. Any examiner authorized by the Department shall, so far as necessary for the purposes of the examination or review, have access during regular business hours to the premises and to any books, records, files, or property of the licensee as far as they directly relate to the quality of care provided by the MCHIP.

All material copied, recorded, or received by the Department from the MCHIP shall be privileged and confidential and shall not be subject to subpoena.

D. The MCHIP licensee shall be responsible for ensuring that all examination materials are submitted to the Department at the time specified for submission and that they are complete. Failure to submit all of the examination materials as required may delay processing or result in the denial of the issuance or renewal of the quality assurance certificate.

E. A summary report of a MCHIP licensee's examination shall become part of the Department's public file on the MCHIP. A copy of the summary report shall be provided to the Bureau of Insurance.

F. The Department shall consider a MCHIP licensee's initial examination for a certificate of quality assurance as a baseline evaluation of the MCHIP's quality improvement program in order to determine if it has the structure, organization, and policies and procedures in place to provide and support quality improvement activities. If the MCHIP has been operating outside the geographic boundaries of Virginia, it shall demonstrate that it has a record of successfully implementing its quality improvement program to the benefit of the enrollees that it serves.

G. Information provided during any examination conducted regarding compliance with this chapter shall be accurate and truthful. The MCHIP shall not provide the Department with falsified information during any aspect of the examination process. The Department shall construe any effort to provide falsified information as violation of the statute, and the MCHIP shall be subject to disciplinary action. Falsification is defined for the purpose of this chapter as fabrication, in whole or in part, of any information provided by the MCHIP or the MCHIP licensee to include, but not be limited to, any redrafting, reformatting, or content deletion of documents.

H. The refusal of any licensee, by its officers, directors, employees or agents, to submit to examination or review or to comply with any reasonable written request of the examiners shall be grounds for suspension, revocation, denial, or nonrenewal of a certificate of quality assurance held by the licensee.

12 VAC 5-408-70 Administrative review

A. In most instances, the initial examination shall be an administrative review of the application for certificate of quality assurance and supporting documentation that includes:

1. The items listed in 12 VAC 5-408-160 F;

2. A copy of the most recent accreditation report issued to the MCHIP, or to the MCHIP's licensee, from a nationally recognized accreditation organization that evaluates the quality of health care services provided by health care plans. The written corrective action response if any, shall also be submitted;

3. A copy of the most recent report of an examination of the MCHIP under similar laws and regulations governing managed care plans of another state or states and a copy of the written corrective action response if any; and

4. The most recent report of any examination of the quality of health care provided by the MCHIP issued by a federal regulatory agency. The written corrective action plan, if any, shall also be submitted.

The Department shall also consider any information that the Bureau of Insurance, in its review of the MCHIP licensee's application for licensure, determines is pertinent to the Department's examination for issuance of a certificate of quality assurance. The Department shall coordinate with the Bureau of Insurance to obtain information necessary to complete its review.

B. The administrative review examination shall be conducted within 45 business days of the receipt of the documentation required by the Department. The MCHIP licensee shall be notified in writing if additional information is needed to clarify the information submitted and the specific time period in which to submit the materials.

C. The MCHIP licensee shall be notified of the results of the administrative review examination within 60 business days from the receipt by the Department of all of the required documents.

D. The Department, at its discretion, may conduct an onsite examination of the MCHIP's quality improvement program or aspects integral to the quality improvement program if, during its conduct of the administrative review examination, the Department determines that an onsite examination is warranted in order to determine the MCHIP's compliance with applicable law or this chapter.

E. Licensees with MCHIPs that successfully complete the examination shall be issued a certificate of quality assurance.

Licensees with MCHIPs that do not successfully complete the examination shall be denied a certificate of quality assurance.

12 VAC 5-408-80 Renewal application.

A. Every MCHIP licensee shall request renewal of its certificate of quality assurance biennially with the Department. The purpose of the renewal examination shall be to determine if the MCHIP has maintained compliance with applicable laws and regulations since the last certificate of quality assurance was issued or renewed, and whether the MCHIP is making substantive progress in meeting its quality improvement expectations.

Failure of the MCHIP licensee to adequately document that its quality improvement program is dynamic rather than static and that it responds to the health care needs of its enrollees will be a factor in the renewal of the certificate of quality assurance.

B. The renewal examination shall include an administrative review of the renewal application and supporting documentation that includes:

1. The items listed in 12 VAC 5-408-160 F;
2. The annual complaint reports;
3. The MCHIP's formal written evaluations of its quality improvement program expectations for the time period since the MCHIP's last application for a certificate of quality assurance;
4. A copy of the most recent accreditation report issued to the MCHIP or to the licensee from a nationally recognized accreditation organization that evaluates the quality of health care services provided by health care plans if the report was issued after the issuance of the current certificate from the Department. The written corrective action plan in response to the report, if applicable, shall also be submitted;
5. A copy of the most recent report of an examination of the MCHIP under similar laws or regulations governing managed care plans of another state or state regulatory agency in which the MCHIP is domiciled, issued since the certificate of quality assurance was last issued or renewed; and

6. A copy of the report of any examination of the MCHIP by a federal regulatory body issued since the certificate of quality assurance was last issued or renewed.

C. In addition, the Department shall consider the following in its renewal examination:

1. The report of any comprehensive onsite examination of the MCHIP, if one was conducted during the renewal period;

2. Any disciplinary actions or sanctions issued by the Department pursuant to §32.1-137.5 of the Code of Virginia, these regulations, or by the Bureau of Insurance in keeping with §32.1-137.2 E of the Code of Virginia; and

3. A summary report of the analysis of any data provided to the Health Care Data Reporting System.

12 VAC 5-408-90 Comprehensive Onsite Examination

A. The comprehensive onsite examination represents a periodic quality improvement evaluation process designed to validate that not only does the MCHIP have appropriate systems in place to ensure quality of health care, but that the systems are successfully implemented and result in the improvement of enrollees' health outcomes and the delivery of their care.

B. A comprehensive onsite examination shall be conducted at least once every two years with the exception of MCHIPs that meet the Quality Improvement Acknowledgment Criteria specified in 12 VAC 5-408-100. The comprehensive onsite examination shall be conducted every four years for plans that meet the Quality Improvement Acknowledgment Criteria.

Recognition of compliance with the Quality Improvement Acknowledgment Criteria shall not prevent onsite investigations for complaints, monitoring, certificate examinations, enforcement activities, or other onsite examinations that the Department determines are necessary to verify compliance with applicable law and this chapter.

C. The comprehensive onsite examination may take place:

1. In conjunction with a Bureau of Insurance market conduct examination of the company;

2. At the request of the MCHIP licensee and in conjunction with a full accreditation survey of the MCHIP conducted by a nationally recognized accreditation organization that examines health care plans for quality of health care;

3. At the request of the MCHIP licensee following the completion of the initial administrative review and receipt of the examination results in order to document the corrective action taken in response to the examination results;

4. When the Department, at its discretion, participates in a coordinated survey in conjunction with the Bureau of Insurance or a nationally recognized accreditation organization; or

5. At the Department's discretion, in response to complaints against the MCHIP or other MCHIP activities in order to determine continued compliance with applicable laws and regulations.

D. The MCHIP licensee shall be notified in writing at least 60 days in advance of the comprehensive onsite examination and shall be provided with information regarding the parameters of the examination.

The final determination of when a comprehensive onsite examination shall be conducted rests with the Department. However, the Department will take into consideration mitigating circumstances presented by the MCHIP licensee.

E. The MCHIP licensee or the Department may request a preexamination conference for the purpose of discussing preparations for the examination. The conference shall not be used for determining whether a plan needs to be examined or the frequency of an onsite comprehensive examination.

F. In the period before the comprehensive onsite examination, the Department shall conduct or arrange for member satisfaction input regarding the plan by conducting or reviewing the results of a member satisfaction survey or by making examiners available to receive comments from enrollees following notice to enrolleess and providers of a scheduled examination through public notice to the plan's enrollees, of upcoming examinations. The plan shall provide the Department with the member mailing list for Virginia enrollees, upon request, to be used to select samples of the plan's membership for the surveys or for public notice of the examination.

G. The MCHIP shall be notified of the results of the comprehensive onsite examination within 60 business days of the final day of the examination. The Department may

choose to notify the plan earlier than 60 days and require immediate corrective action or initiate administrative disciplinary hearings for findings of serious or substantial noncompliance with the law or the regulations that could jeopardize enrollees' health or safety.

H. Depending on the examination findings, the Department may:

1. Require a corrective action plan with a time frame in which corrective action shall be completed and verified by the Department;
2. Proceed with disciplinary action or sanctions; or
3. Notify the MCHIP that it is fully and completely in compliance with all applicable regulations.

12 VAC 5-408-100 Quality Improvement Acknowledgment Criteria

A. A MCHIP licensee may qualify for a comprehensive onsite examination every four years as determined by the Department based upon the MCHIP's ability to meet the following criteria:

l. The MCHIP is fully accredited by a nationally recognized accreditation organization that evaluates the quality of health care provided by managed care plans and the accreditation organization is accepted by the Department;
2. The MCHIP generates few complaints and utilization review appeals relative to its enrollee population and the complaints and appeals it receives are resolved in compliance with this chapter;
3. There has been no change in ownership, merger, or consolidation of the plan since its last examination;
4. There has been a stable executive administration of the plan with no frequent changes in administration in excess of normal turnover rates;
5. Reports from other state regulatory agencies or federal regulatory agencies that evaluate the plan's quality of care demonstrate that the MCHIP is in substantial compliance with those agencies' regulations and that substantial compliance is consistent;
6. The MCHIP licensee is in substantial compliance with the applicable licensure requirements of the Bureau of Insurance;
7. The MCHIP is able to demonstrate through clinical studies, the evaluation of its quality improvement program, and from input from providers and enrollees that its performance expectations are being met and patient outcomes are being achieved. There is no

evidence of recurring areas of noncompliance by the MCHIP with its own quality improvement program expectations as noted by the MCHIP's internal evaluation process or by external reviewers.

8. The MCHIP successfully and in a timely manner completes its requirements for initial and renewal examination and complaint examinations;

9. The MCHIP demonstrates how it successfully integrates its program activities with public and community health goals; and

10. The MCHIP provides a summary of its quality improvement program in its marketing materials and makes the findings of its quality improvement program available to its providers and enrollees.

B. It shall be the responsibility of the MCHIP licensee that wishes to qualify for this option to submit the necessary documentation to support its compliance.

12 VAC 5-408-110 Corrective action procedures

A. At the conclusion of an examination, or within 30 business days thereafter, the Department shall provide the MCHIP licensee with a written summary of violations of the regulations or laws and any factual findings used as a basis to determine that a violation has occurred.

B. The Department may require the MCHIP licensee to submit a written plan of correction specifying how each violation will be corrected along with the time frames for completion of each corrective action. A single plan of correction may address all events associated with a given violation. The plan of correction, when required, shall be submitted by the MCHIP licensee within 20 business days of receipt of the notice of violation, or sooner, if the Department determines that the violations jeopardize the safety of enrollees.

C. The plan of correction shall be approved when the MCHIP demonstrates to the satisfaction of the Department that compliance will be achieved. If the plan of correction is not approved, the Department may request that an amended plan of correction be submitted within ten business days, or sooner if the Department determines that the violations jeopardize the safety of enrollees.

D. The summary of violations and the plan of correction shall not be released as public information until the Department has received the plan of correction or, in the event no

plan of correction is required, after 20 business days of receipt of the summary of violations by the MCHIP, whichever is sooner.

E. Unless otherwise documented, the Department will presume receipt of the summary of violations by the MCHIP licensee by the seventh business day if sent by regular mail.

F. Failure of the MCHIP to successfully implement the written plan of correction within a specified time period may result in an administrative sanction.

12 VAC 5-408-120 Changes to geographic service areas

A. Any changes to a MCHIP's geographic service areas shall be submitted in writing to the Department 45 days prior to the proposed effective date of the changes.

B. The request for a change in a geographic service area shall include:

l. A description of the current geographic service area including a map of the current service area, a list of current primary care and specialty physicians and other providers, and the number of enrollees by service area;

2. An explanation as to whether the MCHIP is requesting an expansion or a reduction in its service area;

3. Notification that the MCHIP licensee has inquired of the Bureau of Insurance as to whether or not the service area request constitutes a material change and the Bureau's determination, if available;

4. If a service area expansion is proposed, then the following is required:

a. A description of the proposed area that includes a map of the proposed geographic area expansion, projections of new enrollment, a listing of new primary care and specialty providers and other providers and their locations, and physician capacity to accept the anticipated enrollment;

b. Information necessary to determine if the MCHIP will be capable of conforming to the access, availability, and travel requirements of 12 VAC5-408-260 and 12 VAC 5-408-270; and

c. The methodology used to determine that the current health care system in the proposed service area can support the expansion.

5. If a MCHIP is reducing or eliminating a service area, the following information is required:

a. A description of the service area being reduced or eliminated;

b. The reason for the reduction or elimination of the service area and the effective date on which health care services will no longer be available through the MCHIP; and

c. Any information required by the Department to determine that MCHIP enrollees are ensured continuity of care during the transition.

C. If the Department fails to act on a request within 30 business days of receipt of all requested information, the proposed changes shall be deemed approved. The Department, at its discretion, may extend, for up to an additional 30 days, the period of time within which to approve or disapprove the proposed changes. Licensees shall be notified in writing of any such extensions.

12 VAC 5-408-130 Complaint system, complaint examination and investigation.

A. Each MCHIP licensee shall establish and maintain for each of its MCHIPs a complaint system approved by the Department and the Bureau of Insurance to provide reasonable procedures for the resolution of complaints.

B. The Department, in cooperation with the Bureau of Insurance, shall examine the complaint system for compliance of the system with applicable statutes and regulations and shall require corrections or modifications as necessary. The effectiveness of the complaint system in allowing enrollees, or their duly authorized representatives, to have issues regarding quality assurance appropriately resolved shall be assessed by the Department.

C. The Department has the responsibility to investigate complaints regarding alleged quality of care violations filed by, or on behalf of, enrollees.

D. Every person from whom information is sought, in an investigation of a complaint against a MCHIP licensee, shall cooperate in producing, or allowing reasonable access during regular business hours, to the books, records, files, accounts, papers, documents, and any or all computer or other recordings of the licensee being examined or those of any person delivering health care services under contract, affiliation, delegation or other arrangement directly relevant to the investigation. Information shall be limited to that which is relevant to the investigation in question.

E. Deficiencies found during a complaint investigation shall be corrected as required in 12 VAC 5-408-110.

F. When the investigation is complete, the MCHIP and the complainant will be notified of the findings of the investigation.

12 VAC 5-408-140 Administrative sanctions

A. Nothing in this part shall prohibit the Department from exercising its responsibility and authority to enforce applicable law and this regulation including proceeding directly to imposition of administrative sanctions.

B. The Department, in consultation with the Bureau of Insurance, may impose such administrative sanctions or take such actions as are appropriate for violation of any of the regulations or laws. Such sanctions include:

1. Imposing civil monetary penalties, which shall not exceed $1,000 per incident of noncompliance, to a maximum of $10,000 for a series of related incidents of noncompliance;
2. Placing a certificate holder on probation;
3. Temporarily suspending a certificate of quality assurance;
4. Temporarily restricting or prohibiting new enrollments into a MCHIP, with the concurrence of the Bureau of Insurance;
5. Revoking or not renewing a certificate of quality assurance and certifying to the Bureau of Insurance that a MCHIP licensee or its managed care health insurance plan is unable to fulfill its obligations to furnish quality health care services; or
6. Other remedies as provided by state or federal law.

C. The MCHIP licensee shall receive a written notice describing the reasons for the imposition of sanctions and a report specifying the findings of noncompliance. Upon receipt of the notice, to impose a sanction, the MCHIP shall have the right and the opportunity to appeal the sanction according to § 32.1-137.5 of the Code of Virginia. A copy of the Department's notice shall be provided to the Bureau of Insurance.

12 VAC 5-408-150 Surrender of certificate.

A. Upon revocation or suspension of a certificate, or loss of license, the MCHIP licensee must surrender its certificate to a representative of the Center.

B. In the event a MCHIP licensee voluntarily ceases operation, it shall provide at least 90 business days advance written notice to all enrollees, employers, providers, the Department, and the Bureau of Insurance. The notice shall identify the storage location of business and medical records, where applicable, and procedures for obtaining copies of such records.

PART II.
Administrative Services.

12 VAC 5-408-160 Management and administration.

A. No person shall establish or operate a managed care health insurance plan in Virginia without first obtaining a license from the Bureau of Insurance and a Certificate of Quality Assurance from the Department.

B. The licensee must comply with:

1. This regulation (12 VAC 5-408 et seq.);
2. Other applicable federal, state or local laws and regulations; and
3. The licensee's own policies and procedures.

C. The licensee shall submit, or make available, reports and information as described in §32.1-137.4 of the Code of Virginia necessary to establish compliance with these standards and applicable laws.

D. The licensee shall permit representatives from the Center to conduct examinations or reviews to:

1. Verify application information;
2. Determine compliance with these standards;
3. Review necessary records, including contracts for delegated services and capitated rate information; and
4. Investigate complaints and review grievance and appeals procedures.

E. The licensee shall notify the Center and providers in writing, 30 days prior to implementing any changes affecting the plan, including:

1. Mailing address;
2. Ownership;
3. Health care services provided, including any delegated services;
4. Medical Director;
5. MCHIP or licensee name;
6. Significant provider network changes; and

7. Any systematic changes in the quality assurance plan, complaint process, or utilization review process.

If more advance notice of a specific change is required by law for notices to providers or enrollees, notice given to the Department under this section shall be no less than notice given to enrollees under the law.

F. All applications, including those for renewal, shall require:

1. A description of the geographic area to be served, with a map clearly delineating the boundaries of the service area or areas;
2. A description of the complaint system required under to § 32.1-137.6 of the Code and 12 VAC 5-408-130 of this chapter;
3. A description of the procedures and programs established by the licensee to assure both availability and accessibility of adequate personnel and facilities and to assess the quality of health care services provided; and
4. A list of the licensee's managed care health insurance plans.

In addition, applications shall include:

5. A description of the MCHIP's disease management program;
6. The MCHIP's drug formulary;
7. A description of the quality improvement plan;
8. The utilization review plan including a description of the criteria, clinical and therapeutic guidelines, and their derivation or source;
9. The credentialing process;
10. The current provider directory identifying providers by speciality and by service area, including those providers who are not currently accepting new patients;
11. A copy of the evidence of coverage or insurance plan coverage limitations and exclusions and other information provided to enrollees;
12. A description of all types of payment arrangements that the licensee uses to compensate providers for health care services rendered to enrollees, including, but not limited to, withholds, bonus payments, capitation, processing fees, and fee-for-service discounts; and
13. A list of clinical outcome studies, with abstracts of study design, objectives, and if available, results.

G. The licensee shall provide, or arrange, for access to basic health care services which shall be appropriately integrated throughout the MCHIP's service area. Services shall be based upon prevailing nationally recognized standards of medical practice.

H. The licensee shall have a written policy stating the MCHIP's commitment to treating enrollees in a manner that respects their rights as well as its expectations of provider and enrollee responsibilities. The services shall be accessible to all enrollees, including those with diverse cultural and ethnic backgrounds, and with physical and mental disabilities.

12 VAC 5-408-170 Provider credentialing and recredentialing

A. The licensee shall establish and maintain a comprehensive credentialing verification program to ensure its providers meet the minimum standards of professional licensure or certification. Written supporting documentation shall include, but is not limited to:

1. Current valid license and history of licensure or certification;
2. Status of hospital privileges, if applicable;
3. Valid DEA certificate, as applicable;
4. Information from the National Practitioner Data Bank as available;
5. Education and training, including post graduate training, if applicable;
6. Speciality board certification status, if applicable;
7. Practice or work history covering at least the past five years; and
8. Current, adequate malpractice insurance and malpractice history of at least the past five years.

B. Policies for credentialing and recredentialing shall include, but are not limited to the:

1. Criteria used to credential and recredential;
2. Process used to make credentialing and recredentialing decisions;
3. Type of providers covered under the credentialing and recredentialing policies;
4. Process for notifying providers of information obtained that varies substantially from the information provided by the provider; and
5. Process for receiving input from participating providers to make recommendations regarding the credentialing and recredentialing process.

The policies shall be made available to participating providers and applicants upon written request.

C. The credentialing process shall be completed before the provider:

1. Begins seeing enrollees;
2. Enters into the employment or contractual relationship with the MCHIP; and
3. Is included in the listing of health care providers as a participating provider in any marketing and enrollee materials.

D. The providers shall be recredentialed at least every two years. Recredentialing documentation shall include:

1. Current valid license or certification;
2. Status of hospital privileges, if applicable;
3. Current valid DEA registration, if applicable;
4. Speciality board eligibility or certification status, if applicable;
5. Data from enrollee complaints and the results of quality reviews, utilization management reviews and enrollee satisfaction surveys, as applicable; and
6. Current, adequate malpractice insurance and history of malpractice claims and professional liability claims resulting in settlements or judgements.

E. All information obtained in the credentialing process shall be subject to review and correction of any erroneous information by the health care provider whose credentials are being reviewed.

F. Providers shall be required by the MCHIP to notify the MCHIP of any changes in the status of any credentialing criteria.

G. The licensee shall not refuse to initially credential, or refuse to re-verify the credentials, of a health care provider solely because the provider treats a substantial number of patients who require expensive or uncompensated care.

H. The licensee shall have policies and procedures for altering the conditions of the provider's participation with the MCHIP. The policies shall include a range of actions to be taken to improve performance prior to termination and an appeals process for instances when the MCHIP chooses to alter the condition of provider participation based on issues of quality of care or service. Providers shall have complete and timely access to all data and information used by the licensee to identify or determine the need for altering the conditions of participation.

I. The licensee shall retain the right, based on quality issues, to approve new providers and sites, and to terminate or suspend individual providers. Termination or suspension of individual providers shall be supported by documented records of noncompliance with specific plan expectations and requirements for providers. The provider shall have a prescribed system of appeal of this decision available to them as prescribed in the MCHIP contract with the provider.

J. Providers shall be informed of the appeals process. Profession specific providers actively participating in the plan shall be included in reviewing appeals and making recommendations for action.

K. The MCHIP shall notify appropriate authorities when a provider's application or contract is suspended or terminated because of quality deficiencies by the health care provider whose credentials are being reviewed.

L. There shall be an organized system to manage and protect the confidentiality of personnel files and records. Records and documents relating to a provider's credentialing application shall be retained for at least seven years.

12 VAC 5-408-180 Complaint system.

A. Every MCHIP shall establish and maintain a system for the resolution of complaints brought by enrollees, or by providers acting on behalf of an enrollee and with the enrollee's consent, regarding any aspect of an MCHIP's health care services, including, but not limited to, complaints regarding quality of care, choice and accessibility of providers, and network adequacy.

The system shall include, but is not limited to:

1. Written notification to all enrollees of the procedures, including phone numbers and addresses, for contacting the MCHIP with a complaint and phone numbers and addresses of advocate programs to help with complaints, grievances or appeals;

2. A description of the process used to investigate and resolve complaints, including specific time lines for each step in the complaint process; and

3. A description of the process used to document and track the status of all complaints and compile the complaint information required to be reported to the Department under § 32.1-137.6 C of the Code of Virginia.

B. Time lines for responding to complaints shall accommodate clinical urgency and shall not exceed 30 days from receipt of the complaint. Resolution of complaints shall not exceed 60 days from date of reciept of the complaint.

C. The MCHIP shall keep records of complaints filed, including, but not limited to:

1. Complaint identifier, using a unique identification code assigned consistently to the enrollee;

2. Date complaint received;

3. A general description of the reason for the complaint;

4. Date of each review and hearing (if any);

5. The number of days to gather the information necessary to resolve the complaint;

6. Date closed;

7. Resolution of the complaint;

8. Record of internal actions necessary as a result of the complaint resolution, as applicable; and

9. Notification to the enrollee of the resolution.

D. No enrollee who exercises the right to file a complaint or a grievance shall be subject to disenrollment or otherwise penalized due to the filing of a complaint or grievance.

E. Complaint records shall be maintained from the date of the licensee's last examination and for no less than five years.

F. A description of the systems for filing complaints, grievances, and appeals shall be provided to enrollees at the time of enrollment and upon request thereafter.

12 VAC 5-408-190 Enrollee education and communication

A. The MCHIP shall make available to each enrollee, at the time of enrollment or at the time the contract or evidence of coverage is issued, as required by law, and upon request thereafter, policies and procedures applicable to the enrollee including, but not limited to:

1. A statement of enrollee's rights and responsibilities;
2. Procedures for obtaining care including:
   a. Referral and authorization requirements;
   b. Primary care services;
   c. Speciality care and hospital services;
   d. Behavioral services, when the complexity of the enrollee's condition requires the knowledge base and expertise beyond those of the primary care provider;
   e. Emergency services and after-hours coverage, including access to emergency care, including any requirements for prior authorization and payment for out-of-service areas;
   f. Care and coverage when out of the service area;
   h. Pharmacy services.
3. Procedures for appealing decisions adversely affecting enrollee coverage benefits;
4. Procedures for changing primary care and specialty care providers including any restrictions on changing providers;
5. All necessary mailing addresses and telephone numbers for seeking information or authorization;
6. The toll-free number for the Complaint Unit of the Center; and
7. Notice of the right to obtain information on types of provider payment arrangements used to compensate providers for health care services rendered to enrollees, including, but not limited to, withholds, bonus payments, capitation, processing fees, and fee-for-service discounts.

B. Lists of all network providers by specialty and by location and indicating which providers are accepting new patients shall be available to all enrollees on request.

C. There shall be a mechanism for providing enrollee information in plain language that is clearly understood and in the languages of the major population groups served.

D. Enrollees shall be provided an opportunity for input into matters of policy and operation through the establishment of advisory panels, the use of advisory referenda on major policy decisions, or by other mechanisms.

E. There shall be a mechanism for assisting enrollees affected by changes in the MCHIP's service areas or network providers.

12 VAC 5-408-200 Data Management

A. The information system shall collect data on enrollees and provider characteristics, and on services furnished to enrollees, as needed, to guide the selection of the quality assurance activities and to meet the data collection requirements of quality assurance projects.

B. The data management system, which includes medical records, shall be safeguarded against loss, destruction, tampering, and unauthorized access or use.

12 VAC 5-408-210 Medical Records

A. The licensee shall maintain an organized medical record system assuring the availability of information required for effective and continuous enrollee care and for quality review. Written policies and procedures, based on accepted standards of practice, shall specify retention, reproduction, access, storage, content, and completion of each record.

B. Medical records shall be confidential. Only authorized personnel shall have access as specified in § 32.1-127.1:03 of the Code of Virginia. Written procedures shall govern the use and removal of medical records and the conditions for release of information. The enrollee's written consent shall be required for release of information as required by law.

Part III.
Quality Improvement Program

12 VAC 5-408-220 Purpose

A. The MCHIP shall have a comprehensive, systematic, and organized quality improvement program for the purpose of:

1. Improving enrollees' health outcomes;
2. Enhancing the quality of the clinical care and service provided to enrollees;
3. Increasing enrollee satisfaction;
4. Maximizing opportunities for MCHIP improvements and minimizing opportunities for errors;
5. Monitoring and evaluating quality of care issues; and
6. Reporting incidences to the appropriate entities.

B. The quality improvement program shall ensure that the MCHIP provides health services that, at a minimum:

1. Are i) consistent with prevailing nationally recognized medical standards of care, ii) adequately available, iii) accessible, iv) appropriate for enrollees' clinical conditions, and v) guided by a combination of utilization review guidelines, treatment protocols, accepted practice guidelines, and clinical case data that ensures balanced clinical decision-making;
2. Target acute and chronic illnesses;
3. Promote prevention;
4. Provide for the treatment of enrollees with similar medical conditions while recognizing individual case differences;
5. Allow for a variety of treatment options that are commensurate with the MCHIP's benefit coverage;
6. Offer enrollee guidance for treatment out of network if treatment is not available through the MCHIP;
7. Recognize identified public health goals;
8. Allow for the evaluation and use of new technology or the new application of existing technology; and
9. Provide for a multi-disciplinary treatment approach that addresses the physical and psychological function and functional status of the MCHIP's enrollees.

12 VAC 5-408-230 Program Structure

A. The MCHIP shall have an operational unit to administer the quality improvement program.

B. The operational unit shall have the primary responsibility for all aspects of the MCHIP's quality improvement program, including, but not limited to:

1. Establishing performance expectations designed to improve the quality of health care services provided by the MCHIP;
2. Developing a quality improvement plan to implement the expectations;
3. Measuring and assessing the MCHIP's performance in meeting the expectations;
4. Implementing activities based upon the assessments to improve and maintain performance;
5. Integrating the quality improvement activities of all other organizational units, providers, delegated health service providers, and the governing body into the quality improvement program and providing feedback to those entities;
6. Enlisting enrollee input through sources such as satisfaction surveys, reviews of complaints, appeals, and requests to change providers, and utilizing enrollee and provider participation in the program;
7. Identifying the resources necessary for the MCHIP to successfully pursue improvement priorities;
8. Maintaining and documenting the plan's compliance with state and federal laws, as well as private accreditation requirements, if applicable, that govern the MCHIP's quality improvement program; and
9. Ensuring that the MCHIP's quality improvement expectations are communicated to all organizational units of the plan, enrollees, providers and delegated health service providers.

C. The quality improvement program shall be managed by professional personnel qualified by training and experience to implement the MCHIP's program expectations. The organizational relationship and responsibilities for quality improvement shall be clearly defined.

D. The quality improvement program shall be structured to include, but is not limited to:

1. A quality improvement program operational unit accountable for the quality improvement program;
2. A quality improvement program advisory committee whose members include enrollees and representatives from the operational units responsible for quality improvement, utilization management, provider affairs, credentialing, complaints and grievances, customer service, medical records, and data management;
3. A medical director of the MCHIP;
4. Committees established accountable to the quality improvement program operational unit that meet to address specific ongoing aspects of the quality improvement program; and
5. Committees established to provide the quality improvement program unit with periodic input regarding the quality improvement program from Virginia providers active in the plan and enrollees.

E. The MCHIP shall designate a Board certified physician to serve as medical director.

F. The medical director shall provide supervision and oversight of the quality improvement program including, but not limited to:

1. Defining the responsibilities and interrelationships for professional services;
2. Coordinating, supervising and overseeing the functioning of professional services;
3. Input into the medical performance of providers;
4. Overseeing the continuing in-service education of the MCHIP's professional staff;
5. Providing clinical direction and leadership to the continuous quality improvement program;
6. Establishing policies and procedures covering all health care services provided to enrollees; and
7. Ensuring review of provider credentials, including, but not limited to:
   a. Delineating qualifications for participating in the MCHIP;

b. Establishing a system for verification of providers' credentials, recredentialing, performance reviews; and

c. Obtaining information about any disciplinary action against the provider.

G. The quality improvement program advisory committee shall:

1. Recommend policies for quality improvement;
2. Review and approve the quality improvement program;
3. Evaluate the results of the quality improvement program;
4. Initiate quality improvement activities; and
5. Ensure implementation of the quality improvement program.

H. All determinations and actions made by the committee shall be recorded in minutes that are dated, approved and are current.

I. The quality improvement program operational unit shall maintain written descriptions of the responsibilities of each of the operational units of the licensee and the governing body in the planning, development, implementation and evaluation of the plan's quality improvement program. The description shall clearly delineate the responsibilities of each unit, to whom the resposibilities are delegated, and the organizational relationship that each operational unit has with another to provide quality health care.

J. The director of the quality improvement program operational unit shall report directly to the executive management of the MCHIP.

K. A written report shall be issued annually by the quality improvement operational unit to the MCHIP's executive management and to the governing body. The purpose of the report shall be to evaluate the MCHIP's quality improvement program activities including, at a minimum:

1. The MCHIP's achievements in meeting its quality improvement expectations;
2. Those areas where expectations were not met or where improvements are still needed;

3. The impact on enrollee's health services and the MCHIP as a result of meeting and needing to continue improving upon expectations;

4. New areas identified through the quality improvement assessment process that will be incorporated in the next annual quality improvement program plan; and

5. Resources identified as necessary to assist in meeting the MCHIP's quality improvement expectations.

L. The governing body shall retain the ultimate authority for the MCHIP's quality improvement program. Documentation shall be maintained by the MCHIP that the governing body has reviewed the annual quality improvement program report and has provided direction to the program and, as necessary, other operational units in response to the report.

M. A summary of the program shall be provided to appropriate managers, providers and staff members of the MCHIP, and shall be available to enrollees of the MCHIP upon request. The program shall be made available to all other managers, providers, and staff upon request.

N. There shall be a mechanism in place to inform enrollees, providers, and employers of the MCHIP's annual performance results each year, upon request.

12 VAC 5-408-240 Program plan

A. Each MCHIP shall have a written quality improvement plan. The plan shall include:

1. The quality improvement performance expectations for the MCHIP for the year and an explanation as to the rationale for targeting these expectations;

2. Delineation of the expected outcomes for the performance expectations;

3. The performance activities to implement the plan and the specific lines of authority and accountability for implementation;

4. The data collection and analysis methodologies to be used to evaluate the quality of health care services;

5. Clinical studies that target clinical diagnosis and treatments with the requirement that those diagnoses focused upon are pertinent to a substantial number of its enrollees or have been identified as major public health risks. The plan shall also include studies that are pertinent to the enrollees of the product lines that the MCHIP manages or that address major public health risks;

6. Strategies to evaluate provider performance and systems, direct corrective action, and act when corrective action has not been taken;

7. Methods to assess enrollee and provider satisfaction and respond to enrollee and provider satisfaction results regarding the provision of the quality of the health care services;

8. Evaluations of the actual outcomes of care provided to selected groups of enrollees with an analysis of variations in care;

9. Amendment of treatment protocols and clinical practice guidelines, as necessary, to make them current and the development of new protocols and clinical practice guidelines, as necessary, to address clinical conditions;

10. Examination of the overutilization and underutilization of services and interventions when either are identified;

11. Strategies to evaluate the coordination and continuity of care that enrollees receive;

12. Analysis of the accessibility of enrollee services including emergency services and after-hour care; and

13. Strategies to evaluate experimental treatment procedures.

Part IV.

Coordination and Continuity of Care

12 VAC 5-408-250 Continuity of Care

A. The MCHIP shall coordinate the health care services it provides in such a way that:

1. Enrollees' individual needs are assessed on an ongoing basis, through their physician or staff and matched with the appropriate level of medical, psychological, or medical social services care. The MCHIP shall monitor the continuity and coordination of care an enrollee receives with other facets of care;

2. Enrollees' transitions through the health care delivery system are facilitated by the MCHIP and its components;

3. The MCHIP provides for enrollees' involvement in determining care and treatment and facilitates the family's involvement in treatment decisions when the enrollee is unable to do so;

4. Information necessary to support the provision of care from one plan component to another is provided in a timely manner to enrollees and providers to support the continuity of the enrollee's care;

5. Providers follow plan procedures to address enrollees' need to know specific information about their illness, condition or treatment in order for the enrollee to follow their plan of care and receive follow-up care when needed; and

6. Enrollees affected by a change or termination of benefits, services or providers are assisted in understanding how such developments impact them and the options available for dealing with them.

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B. If a utilization management decision results in denial of authorization for care, enrollees and providers shall be notified in a timely manner.

The MCHIP shall assist with denial of care issues by providing adequate information for enrollee and provider decisions regarding ongoing care, or if appropriate, discharge.

12 VAC 5-408-260 Network Adequacy

A. The MCHIP shall provide a sufficient number and mix of services, specialists, and practice sites to meet enrollees' health care needs, including providers serving high risk populations or those specializing in the treatment of costly conditions, and its contractual obligations with reasonable promptness.

B. The MCHIP shall ensure telephone access 24 hours a day, 7 days a week, to responsible and knowledgeable health care practitioners capable of assessing the enrollees' conditions, and as necessary, arranging for appropriate services.

C. The MCHIP shall incorporate strategies into their access procedures to facilitate utilization of the MCHIP's health care services by enrollees with physical, mental, language or cultural barriers.

D. When a MCHIP does not have a health care provider with the appropriate training and experience within its network capable of meeting the particular health care needs of an enrollee, the MCHIP shall ensure that the enrollee is referred, consistent with the evidence of coverage, to a health care provider outside of the MCHIP's network. The enrollee shall not be responsible for any additional costs incurred by the MCHIP as a result of this referral, consistent with the evidence of coverage, other than any applicable copayment, coinsurance or deductible.

E. The MCHIP shall make provisions for affected enrollees to be notified about the termination of a health care delivery site as soon as it becomes aware of the termination but at least 30 days before the termination or closing date. The MCHIP shall inform the affected enrollees of other participating providers available to assume their care and facilitate the enrollees' transition from a terminating provider to another provider so that the enrollee's continuity of care is not interrupted. Enrollees undergoing an active course of treatment shall have continued access to care during the transition period.

12 VAC 5-408-270 Travel and Appointment Waiting Times

A. The travel time for the enrollee to the nearest primary care delivery site or to the nearest institutional service site shall not exceed 30 minutes normal driving time from the enrollee's residence or place of business for at least 90 percent of the enrolled population within each approved service area. Pharmacy services shall also be available within this time frame.

The Department may waive this requirement for rural or urban areas if the MCHIP can successfully demonstrate that the 30-minute driving time is not feasible.

Institutional service sites include acute care hospitals, surgical facilities including licensed acute care hospitals and outpatient surgical hospitals, psychiatric inpatient facilities, licensed long term care facilities with certified skilled nursing beds, certified renal dialysis providers, home health agencies, hospice programs, and outpatient therapy providers for mental health and substance abuse conditions and other sites as determined appropriate by the Department.

B. The travel time for the enrollee to the nearest specialty care shall not excced 60 minutes normal driving time from the enrollee's residence or place of business for at least 90 percent of the enrolled population within each approved service area.

The Department may waive this requirement for rural or urban areas if the plan can successfully demonstrate that the 60-minute driving time is not feasible.

C. The travel time for the enrollee to each of the nearest health care delivery sites listed below shall not exceed 60 minutes normal driving time from the enrollee's residence or place of business for at least 90 percent of the enrolled population within each approved service area.

1. A hospital providing specialty level or above neonatal services;
2. A hospital providing tertiary pediatric services;
3. A residential substance abuse treatment center;
4. Hospital-based diagnostic cardiac cauterization services;
5. Hospital inpatient medical rehabilitation services; and
6. Laboratory, x-ray, Magnetic Resonance Imaging (MRI) services.

The Department may waive this requirement for rural or urban areas if the plan can successfully demonstrate that the 60-minute driving time is not feasible.

D. The travel time for the enrollee to each of the nearest health care delivery sites listed below shall not exceed 90 minutes normal driving time from the enrollee's residence or place of business for at least 90 percent of the enrolled population within each approved service area:

1. A hospital providing kidney and other organ transplantation services;

2. A hospital providing major trauma treatment and open-heart surgery services; and

3. Other specialty hospital services including major burn care and oncology services.

The Department may waive this requirement for rural or urban areas if the plan can successfully demonstrate that the 90-minute driving time is not feasible.

Nothing in this section shall prohibit or restrict a plan from offering such services at designated "centers of excellence" inside or outside of the geographic boundaries of Virginia.

E. Routine appointments for non-emergency or non-urgent care shall be available within two weeks of the enrollee's request.

F. Preventive care appointments, including routine physical examinations, shall be available with 60 days of the enrollee's request.

G. Consultations for specialty services shall be available as requested by the primary care provider.

12 VAC 5-408-280 Urgent care and emergency services

A. The MCHIP shall have a system in place to provide to its enrollees, on a 24-hour basis: i) access to medical care or ii) access by telephone to a physician or licensed health care professional with appropriate medical training who can refer or direct an enrollee for prompt medical care in cases where there is a need for urgent care or emergency services.

B. The MCHIP shall comply with the requirements of the Federal Emergency Medical Treatment and Active Labor Act (42 U.S.C.§ 1395 dd).

C. The MCHIP shall provide clear and understandable explanations to enrollees and providers of :

1. What constitutes emergency and urgent care;
2. The process for accessing emergency and urgent care;

3. The responsibility of the enrollee for payment for nonemergency services rendered in a hospital emergency facility; and

4. Coverage for out of network emergency medical care when a enrollee cannot reasonably access network services.

D. The MCHIP shall require its providers to clearly notify enrollees of provisions for urgent care or emergency services when the physician is not available after hours.

E. The MCHIP shall recognize primary care practitioners' authority to facilitate and authorize emergency services for enrollees.

F. Coverage of costs for emergency services shall be consistent with the evidence of coverage and shall not interfere with enrollee access to care.

G. Enrollees shall be allowed immediate access to emergency services and access within no more than 24 hours for urgent care. Urgent care access may be provided sooner with appropriate authorization.

H. The MCHIP shall monitor usage of urgent care and emergency service to determine if the services are understood and appropriately used by enrollees and providers.

12 VAC 5-408-290 Health Promotion and Disease Management

A. Annually, the MCHIP shall develop and implement at least two health guidelines for the prevention and early detection of illness and disease. Each written guideline shall:

1. Be available to enrollees upon request;

2. Describe the prevention or early detection intervention and the recommended frequency and condition under which the intervention is required and;

3. Document the scientific basis or authority upon which the guideline is based.

Guidelines may be specific to a defined population segment.

B. The MCHIP shall distribute any preventive health guideline it develops and any updates to its providers as soon as practicable after development of the guideline.

C. The MCHIP shall regularly communicate with its enrollees to encourage the use of preventive health services.

D. At least annually, the MCHIP shall measure enrollee and provider compliance with the current preventive care guidelines. The MCHIP may measure compliance by population segment if the guideline is specific to a population segment.

E. Providers who have appropriate knowledge shall be consulted in the adoption of the preventive health guidelines.

Part V.
Clinical Performance Evaluation

12 VAC5-408-290 Clinical Performance Evaluation Systems

A. The MCHIP shall have a system for the evaluation of the outcomes and processes of clinical care services delivered to the MCHIP's enrollees.

B. The MCHIP shall adopt a nationally recognized clinical performance evaluation system, such as HEDIS, that analyzes data based upon selected performance factors or shall establish a clinical performance evaluation system that uses data collection, quantitative measures, and analysis to monitor quality improvement activities.

C. The MCHIP shall notify the Department regarding its adoption of a nationally recognized clinical performance evaluation system, such as HEDIS, or that it has chosen to establish its own performance measurement system.

MCHIPs that choose not to adopt a nationally recognized system shall provide justification to the Department of their choice of performance measurement selections for the Department's approval.

D. The MCHIP shall annually evaluate its performance in at least three of the areas of clinical care shown below:

1. Primary care services;
2. High volume specialty services;
3. Behavioral health services; and
4. Institutional health services including inpatient hospital care, home health services, skilled nursing facility services and ambulatory surgery.

If HEDIS is used to assess clinical performance, the plan shall substitute the HEDIS "Effectiveness of Care" measures for the above.

E. The performance measurement indicators chosen by the plan shall:

1. Be objective and quantifiable;

2. Be based upon current and reliable scientific information;
3. Have an established goal or benchmark;
4. Effectively measure performance indicators; and
5. Have priority areas for measuring outcomes of clinical care and be reflective of industry-wide performance measurement goals.

F. The plan shall implement ways to improve its performance based on an analysis of its clinical performance measurements.

12 VAC 5-408-310 Data Collection and Submission

A. Data collected and analyzed for clinical service evaluation shall be:

1. From the enrollee population areas appropriate for the MCHIP to assess including: i) high risk and high volume areas, ii) areas where clinical problems are expected or have occurred in the past, iii) areas that have the potential for adverse health outcomes, and iv) areas where preventive health measures may have an impact;
2. Collected using processes that are methodologically sound;
3. Valid, reliable, complete and timely;
4. Analyzed quantitatively by personnel qualified to evaluate the data for clinical quality improvement; and
5. Protected for confidentially, easily retrievable, and transmitted for appropriate release to external parties.

In addition, the data shall allow for intra and inter system comparisons for the purpose of improving patient health outcomes and improving clinical health delivery systems.

B. The plan shall permit any organization with which it contracts to collect and analyze clinical data for performance evaluation to release that data to the Department or its designee.

Part VI.
Delegated Services

12 VAC 5-408-320 Delegated Services

A. If the licensee contracts for any of the following services, it shall retain accountability for the oversight of those services:

1. Quality assurance activities;
2. Credentialing and recredentialing;
3. Enrollee education, communication and satisfaction;
4. Utilization management;
5. Health promotion;
6. Records management;
7. Data management, to include the collection of clinical trial and the audit of all clinical trial data;
8. Providers and provider networks;
9. Claims administration; or
10. Pharmacy benefits.

B. The MCHIP shall establish and implement written procedures to evaluate the effectiveness of any delegated service.

C. Documentation that the delegated service complies with these regulations, its agreement with the MCHIP to provide services, and any applicable state and federal laws required of the MCHIP to provide the service shall be maintained by the MCHIP licensee.

D. Data and information exchanged between the delegated service and the plan shall be accomplished in a manner that is timely, efficient, and effective.

E. The MCHIP shall ensure that data held by the delegated service that is required to be shared with the state's Health Care Data Reporting System is transmitted according to collection requirements.

F. The MCHIP shall require the delegated service to provide for timely and efficient access by state examiners to data, records, and personnel necessary to determine compliance with these regulations.

12 VAC 5-408-330 Written Agreement

A. There shall be a written agreement signed by the MCHIP and the delegated service that describes the:

1. Delegated service or services;
2. Responsibilities of the MCHIP and the delegated service and the remedies available to the MCHIP if the delegated service does not fulfill its obligations; and
3. Frequency of reporting to the MCHIP and the process by which the MCHIP will evaluate the delegated service's performance.

B. The MCHIP shall ensure that the enrollees' continuity of care is not disrupted because of changes made in the written agreement between the MCHIP and the delegated service or because the relationship, as provided for in the agreement, is terminated.

12 VAC 5-408-340 Exchange of Information

A. The MCHIP shall inform its enrollees and providers which services they may need are delegated and how those services are accessed.

B. If the delegated services are health care services, then the contractor shall also inform the plan's enrollees of at least the following:

l. The procedures for filing complaints, appeals, and grievances;
2. The utilization management decision process;
3. The process for appealing claims denials;
4. How to access emergency and urgent care;
5. How to obtain services not covered in the delegated health services' benefit package;
6. The process for changing from one practitioner to another;
7. Orientation process for new enrollees;
8. Enrollee participation opportunities; and

9. Participating practitioners and providers.

C. The delegated health services shall also inform the MCHIP's providers of at least the following:

l. Opportunities for provider involvement;
2. Quality improvement program expectations;
3. Provider credentialing process;
4. Procedures for complaints, appeals, grievances;
5. Process for utilization management decisions; and
6. How to access emergency and urgent care.

12 VAC 5-408-350 Quality improvement integration

A. As it pertains to the enrollees, the MCHIP shall integrate, within its quality improvement program, monitoring of the delegated health services:

1. Quality improvement program activities;
2. Quality improvement outcomes; and
3. Complaint, grievance and appeals processes.

B. At least annually, the MCHIP shall evaluate the delegated health service's quality improvement program, and complaint, grievance, and appeals processes, and provide the delegated health service with a report of its evaluation.

C. When the MCHIP's expectations have not been met, the MCHIP shall require the delegated health service to provide:

l. A corrective action plan that addresses areas where performance expectations have not been met; and
2. Evidence that corrective action was taken in keeping with corrective action plans.

Part VII.
Utilization Review and Management

12 VAC 5-408-370 Utilization Review and Management

A. The MCHIP shall have a utilization review and management process that complies with the requirements of § §32.1-137.7 through 32.1-137.16 of the Code of Virginia and these regulations. The process shall be managed by a licensed physician.

B. In developing its utilization review program, the MCHIP shall utilize the "Standards for Utilization Management" and the "Standards for the Delegation of Utilization Management" of the National Committee for Quality Assurance's Accreditation Standards for Managed Care Organizations, effective July 1, 1999, which is incorporated by reference as the criteria for determining compliance with the utilization management and review requirements of this section except in those instances in which state requirements in law or regulation are more stringent.

C. The purpose of the utilization review process shall be to monitor access to, and utilization of, health care services with the process ensuring that the conduct of utilization review is:

1. Impartial, timely, consistent and based upon supportive medical evidence;
2. Performed by qualified personnel;
3. Comprehensive in assuring that good faith efforts to obtain all information necessary to make utilization review decisions are made;
4. Evaluated routinely so that program changes that determine the necessity, appropriateness, efficiency and efficacy of health care services provided by the plan can be made as a result of the evaluation; and
5. Reported annually to the MCHIP's governing body.

In addition, the utilization review process shall:

1. Allow for flexibility, taking into account individual cases when appropriate;
2. Provide avenues for provider input into the establishment of clinical guidelines and protocols;

3. Afford opportunity for reconsideration and appeal of adverse determinations in a manner that is easily understood and accessed by enrollees and providers; and

4. Be coordinated with other components of the MCHIP that use or could benefit from utilization review data.

D. The utilization review process shall be based upon a written plan that is reviewed annually and that shall contain, at a minimum:

1. A description of the scope of the utilization review process, both internal and external;

2. A description of the organizational responsibilities for utilization review including the qualifications of utilization review personnel;

3. The clinical review guidelines, standards, and protocols which are applied in utilization review determinations;

4. Mechanisms to evaluate uniform application of guidelines and to determine the necessity for case-by-case decision making;

5. Procedures for soliciting and implementing provider input in the development of guidelines as well as evaluating provider usage of the guidelines;

6. The process for monitoring over utilization and under utilization;

7. Provisions for notice to enrollees and providers regarding any need for precertification, concurrent certification, or retrospective review as a prerequisite for approval of payment or access to service;

8. Procedures for reconsideration of adverse decisions and appeals including expedited appeals;

9. Guidelines for the delegation of utilization review to external entities and the expectations for that delegation;

10. Guidelines for the notification in clear and understandable terms of the reasons for denial of services or payments to providers and subscribers;

11. Mechanisms for review and implementation of experimental treatments and new technology;

12. Mechanisms for soliciting and evaluating provider and enrollee satisfaction with utilization review determinations and the MCHIP's appeal process and implementing mechanisms to address areas of dissatisfaction; and

13. Procedures for the maintenance of records required under § 32.1-137.16 of the Code of Virginia.

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