**Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**Subtitle 07 HOSPITALS**

**Chapter 11 Health Maintenance Organizations**

**Authority: Health-General Article, §19-701 et seq.; Insurance Article, §2-109(a)—(c); Annotated Code of Maryland**

*10.07.11.01*

**.01 Scope.**

The purpose of these regulations is to regulate various phases of the operations of health maintenance organizations in accordance with the mandates of Health-General Article, §§19-701—19-734, Annotated Code of Maryland.

*10.07.11.01-1*

**.01-1 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Board" means the Board of Physicians.

(1-1) "Certified nurse practitioner" has the meaning stated in Health Occupations Article, Title 8, Annotated Code of Maryland.

(2) "Commissioner" means the Insurance Commissioner of Maryland.

(3) "Department" means the Department of Health and Mental Hygiene.

(4) "Enrollee" means a person who has entered into a health care services contract or on whose behalf a contractual arrangement has been entered into with a health maintenance organization (HMO).

(5) "Governing authority" means the person or persons designated in the bylaws with the responsibility for operating the HMO.

(6) "Grievance" means any complaint by an enrollee:

(a) That the enrollee has not received any benefit or other right to which the enrollee is contractually entitled or that the enrollee has been treated unprofessionally or otherwise improperly by the HMO, or a provider engaged by the HMO;

(b) Which is not resolved formally to the satisfaction of the enrollee.

(7) "Operating year" means the consecutive 12-month period, or part thereof, during which the HMO makes available health services as delineated in its Certificate of Authority (as issued by the Insurance Commissioner), and beginning on the issuance date of this Certificate.

(8) "Out-of-area coverage" means contractual benefits provided by the HMO to its enrollees with respect to emergency health care services received by enrollees outside the primary geographical area served by the HMO.

(9) "Physician" means an individual authorized by law to practice medicine in the State.

(10) "Preventive services" means those services designed to prevent the occurrence of disease or injury or to arrest disease at an early stage before complications and serious disabilities develop.

(11) "Quality of health care" means that level of health care delivered which reflects the general health care standards and practices in the geographical area served by the HMO.

(12) "Secretary" means the Secretary of Health and Mental Hygiene.

*10.07.11.02*

**.02 Service Requirements.**

A. The HMO shall provide the services required by the Maryland Health Maintenance Organization Act of 1975, Health-General Article, §19-701(d), Annotated Code of Maryland.

B. The HMO shall make available and encourage appropriate history and baseline examinations for each enrollee within a reasonable time of enrollment set by the HMO. Medical problems that are a potential hazard to the person's health shall be identified and a course of action to alleviate these problems outlined. Progress notes indicating success or failure of the course of action shall be recorded.

C. The HMO shall offer or arrange for preventive services that include health education and counseling, early disease detection, and immunization. The HMO shall develop or arrange for periodic health education on subjects which impact on the health status of the enrollee population and shall notify every enrollee in writing of the availability of these and other preventive services.

D. Services to prevent a disease shall be offered if all of the following conditions exist:

(1) The disease produces death or disability and exists in the enrolled population;

(2) The etiology of the disease is known or the disease can be detected at an early stage;

(3) Elimination of factors leading to the disease or immunization has been proven to prevent its occurrence, or early disease detection followed by behavior modification, environmental modification, or medical intervention has been proven to prevent death or disability.

E. An HMO shall offer services through a licensed health care practitioner who is not a physician if the:

(1) Services are within the scope of practice for both:

(a) A physician; and

(b) Another licensed health care practitioner; and

(2) HMO considers the offering of the practitioner's services appropriate.

*10.07.11.03*

**.03 Quality Assurance Requirements — Program Planning and Evaluation.**

A. The HMO shall have a written program plan that is updated and reviewed at least every 3 years.

B. The plan shall include the following information:

(1) Statistics on age, sex, and other general demographic data used to determine the health care needs of its population;

(2) Identification of the major health problems in the enrolled population;

(3) Identification of enrolled special groups that have unique health problems such as the poor, the elderly, the mentally ill, and educationally disadvantaged;

(4) A description of community health resources and how they will be used.

C. Priorities and Objectives. The HMO shall state its priorities and objectives in writing, describing how the priorities and objectives relating to the health problems and needs of the enrolled population will be provided for.

D. Services. At the time membership is solicited, the HMO shall provide a general description of services available to enrollees including:

(1) Benefit limitations and exclusions;

(2) Location of facilities or providers; and

(3) Procedures by which a member would obtain medical services.

E. On each enrollment card or application, the HMO shall:

(1) Place the following statement in bold print: "If you have any questions concerning the benefits and services that are provided by or excluded under this agreement, please contact a membership services representative before signing this application or card"; and

(2) Provide information on how a prospective member may contact a membership services representative.

F. The plan shall contain evidence that:

(1) Programs and services offered are based on the health problems of, and the community health services available to, the enrolled population;

(2) There is an active program for preventing illness, disability, and hospitalization among enrollees;

(3) Services designed to prevent the major health problems identified among child and adult enrollees and to improve their general health are provided by the HMO.

*10.07.11.04*

**.04 Peer Review.**

A. Internal Review. The HMO shall have an internal peer review system that will evaluate the utilization of services and the quality of health care provided enrollees. The review system shall:

(1) Provide for review by appropriate health professionals of the process followed in the provision of health services;

(2) Use systematic data collection of performances and patient results;

(3) Provide interpretation of this data to the practitioners;

(4) Review and update continuing education programs for health professionals providing services to enrollees;

(5) Identify needed change and proposed modifications to implement;

(6) Maintain written records of the internal peer review process;

(7) Conduct focused studies directly related to major health problems and preventive health needs identified in Regulation .03B and C of this chapter; and

(8) Assure that at least three focused studies related to the HMO specific plan under Regulation .03 of this chapter are conducted each year.

B. External Review.

(1) The Department shall conduct an external review of the quality of health care services of the HMO when and in a manner the Department considers appropriate.

(2) The external review shall be conducted by:

(a) A panel of physicians and other health professionals consisting of persons who:

(i) Have been approved by the Department;

(ii) Have substantial experience in the delivery of health care in an HMO setting but who are not members of the HMO staff or performing professional services for the HMO concerned;

(iii) Reside outside the area serviced by the HMO; or

(b) The Department.

(3) The final decision on which type of external review is to be employed rests solely with the Department.

(4) The external review shall consist of a review and evaluation of the following:

(a) Internal peer review system and reports;

(b) The HMO program plan to determine if it is adequate and being followed;

(c) The professional standards and practices of the HMO in every area of services provided;

(d) The grievances relating specifically to the delivery of medical care, including their final disposition;

(e) The physical facilities and equipment; and

(f) A statistically representative sample of enrollee records.

(5) A health maintenance organization accredited by an accreditation organization approved by the Secretary in accordance with Health-General Article, §19—2302, Annotated Code of Maryland, shall be exempt from the external review.

*10.07.11.05*

**.05 Medical Records.**

A. The HMO shall maintain an individual record for each patient according to accepted professional principles and the provisions of these regulations, with entries kept current, dated, and signed by a physician or other medical professional.

B. All information contained in the medical records and information received from physicians, surgeons, certified nurse practitioners, or hospitals, incident to the health care practitioner-patient or hospital-patient relationship, shall be kept confidential, and, except for use incident to bona fide medical research and education, or for the Department's review under these regulations, or as reasonably necessary in connection with the administration of the member's contract, may not be disclosed without the consent of the patient.

C. Contents and Procedures. The medical record shall contain at least the following information and be maintained under the following procedures:

(1) Identification and summary sheets;

(2) Prior medical findings and referral information;

(3) Information necessary to support the diagnosis and justify the treatment given as shown in the individual written plan of treatment;

(4) Progress notes by a medical staff member, as appropriate; a physician shall review and approve the progress notes within 24 hours of entry;

(5) Dated record of all treatments, medications, laboratory tests, X-rays, operative reports, anesthesia records, and measurements;

(6) Consultation report, if appropriate;

(7) Record of any emergency care treatment rendered to patient; and

(8) Discharge summary of inpatient hospitalization to include condition at time of discharge and post operative instructions given to the patient.

D. It is the responsibility of each attending clinical staff member to complete and sign the medical records of each ambulatory patient the staff member treats, within 72 hours of treatment.

Agency Note: The requirements of other related health programs will be considered when reviewing this requirement.

E. The HMO shall maintain a system for identifying and filing records which provides for:

(1) A universal identifier; and

(2) Adequate space and equipment for filing and prompt retrieval of medical records.

F. The HMO shall have established policies assuring that medical records of current enrollees and enrollees who leave the HMO plan are completed, promptly filed, and retained in safekeeping according to acceptable professional practices and State statutes.

G. When the HMO provides services directly to its enrollees at several locations, it shall ensure, through the coordination of medical records and the use of other appropriate operating procedures, that the services it furnishes at those various locations are organized in this manner as to facilitate continuity of care. A central patient record keeping system shall be maintained as required by the Department.

H. The HMO shall designate a member of the staff qualified by reason of training or experience, or both, who is responsible for the implementation of medical record policies and for the maintenance of the medical record system.

*10.07.11.06*

**.06 Statistics.**

The HMO shall provide the Department with full access to all operational and statistical data to enable the Department to verify the HMO's compliance and to enable the Department to conduct specific statistical studies with respect to current status of various segments of the enrolled population.

*10.07.11.07*

**.07 Personnel.**

A. When applicable, each staff member of the HMO shall be licensed as required by State and local law, and meet acceptable professional qualifications or have qualified by means of an occupational proficiency examination or through acceptable training. Provider staff patterns shall be designed to meet enrollee needs.

B. The HMO shall provide orientation for all new employees and require continuing education of all professional and supportive personnel which reflects advances in medical knowledge and enrollee health education.

C. The HMO shall establish a formal written process for:

(1) Appointment of a physician or certified nurse practitioner to the clinical staff of the HMO;

(2) Employment of a physician or certified nurse practitioner by the HMO; or

(3) Selection of a physician or certified nurse practitioner to provide services to the enrollees under contract with the HMO.

D. Information Concerning a Physician's or Certified Nurse Practitioner's Background and Training.

(1) As part of the formal written process in §C of this regulation, the HMO shall collect, review, and verify the information concerning a physician's or certified nurse practitioner's background and training in §D(2) and (3) of this regulation.

(2) Information that shall be collected, reviewed, and verified for a physician or certified nurse practitioner includes:

(a) Evidence of education;

(b) Evidence of current license to practice in the State;

(c) Evidence of internship, residency training, or other pertinent training;

(d) Evidence of specialty certification;

(e) Evidence of Drug Enforcement Administration or Controlled Dangerous Substances registration;

(f) Evidence of malpractice insurance coverage;

(g) Physical and mental status;

(h) List of all hospitals where the physician or certified nurse practitioner has current privileges or is employed;

(i) Evidence of any adverse action or restriction of privileges imposed by any hospital or Board;

(j) Delineation of services to be provided to patients at the HMO;

(k) Past malpractice claims history;

(l) Verification of status through the federal National Practitioner Data Bank; and

(m) Cooperative arrangement with a physician for each certified nurse practitioner.

(3) For a physician who has privileges in a licensed Maryland hospital, the HMO may verify, through the hospital, the credentials described in §D(2)(a)—(f) of this regulation.

E. Reevaluation of Physicians or Certified Nurse Practitioners.

(1) The HMO shall establish a formal written process for the reevaluation of appointment, employment, or selection of a physician or certified nurse practitioner.

(2) The reevaluation shall include an ongoing process for verifying:

(a) Current State Licensure;

(b) Current Controlled Dangerous Substances or Drug Enforcement Administration registration; and

(c) Evidence of current malpractice insurance.

(3) Every 3 years, the reevaluation also shall include the following for all physicians and certified nurse practitioners:

(a) An update of the requirements of §D of this regulation;

(b) An assessment of the performance pattern based on an analysis of:

(i) Complaints filed through the grievance system;

(ii) Malpractice claims filed;

(iii) Utilization, quality, and risk data;

(iv) Adherence to policies, bylaws, and procedures; and

(v) Physician and certified nurse practitioner practice patterns as reviewed through the HMO's quality assurance program.

F. Administrator.

(1) At least one administrator shall be appointed by the governing body and delegated the responsibility for the internal operation of the HMO according to established policies. The administrator's responsibility for procurement and direction of personnel shall be clearly defined. An individual competent and authorized to act in the absence of the administrator shall be designated.

(2) The HMO shall notify the Department of the name of the person appointed administrator and of any change in the appointment.

G. Medical Director. The HMO shall have a medical director who is licensed to practice medicine in the State. A physician authorized to act in the absence of the medical director shall be designated. The medical director shall oversee the quality of care provided to the HMO's patients. If the medical director becomes aware of unethical or unprofessional conduct on the part of any health provider, the medical director shall take appropriate action to prevent future occurrences of this conduct.

H. The HMO shall have a licensed registered nurse present to perform nursing services at all times that these services are required.

*10.07.11.08*

**.08 Policy Formulation.**

A. The HMO shall have written policies governing the provision of the HMO services according to stated objectives of the HMO. The policies shall be developed in consultation with the executive officer, representative professionals, including one or more physicians, nursing service personnel associated with the service, and one or more enrollee representative or representatives. Policies shall be approved by the governing authority and reviewed and revised annually as required. These approvals shall be affirmed in writing and dated by an authorized representative of the governing authority.

B. Patient Care Policies. The policies shall cover at least the following:

(1) Inpatient admission and discharge policies;

(2) Physician (Independent Practice Association) services, including medical staff organization;

(3) Provision of or arrangements for other services not directly provided by the HMO;

(4) Continuity and availability of care through an established referral mechanism and ongoing contract with other health services providers.

*10.07.11.09*

**.09 Access and Availability of Services.**

A. Regular Hours. With respect to all services it furnishes, whether direct or through contractual arrangements, an HMO shall provide for regular hours during which an enrollee may receive services. It is also required to have an orderly system for scheduling the provision of services to enrollees in a timely manner, taking into account the immediacy of need for services.

B. Outside of Regular Hours. The HMO shall have a system for providing the enrollee with 24-hour access to a physician in cases where there is an immediate need for medical services. To meet this requirement, the HMO's arrangements for off-hour services may provide for access to physicians who do not have a contract with the HMO and facilities such as hospital emergency rooms. When a physician who does not have a contract with the HMO is used, the HMO shall develop and publicize procedures assuring that the HMO is notified of the services and receives adequate documentation from the physician or facility within a reasonable period of time.

*10.07.11.10*

**.10 Physician Availability.**

A. The HMO shall have a physician available at all times to provide diagnostic and treatment services. The HMO shall assure that every enrollee seen for a medical complaint is evaluated under the direction of a physician and that every enrollee receiving diagnostic evaluation or treatment is under the direct medical management of an HMO physician who provides continuing medical management.

B. Each enrollee shall have an opportunity to select a primary physician from among those available to the HMO.

*10.07.11.11*

**.11 Complaint System for Quality of Care Issues.**

A. The HMO shall have a:

(1) Written procedure to assist and respond to enrollees, families, and providers on complaints concerning quality of care issues; and

(2) Designated department to handle complaints.

B. Quality of care issues include, but are not necessarily limited to:

(1) Bad outcomes related to poor care;

(2) Failure to follow-up on diagnostic procedures;

(3) Failure to provide treatment for presenting complaints consistent with standard of care;

(4) Failure to appropriately document medical records;

(5) Confidentiality and privacy issues related to medical records or provision of care;

(6) General dissatisfaction with care;

(7) Qualifications of individuals who are:

(a) Employees of the HMO; or

(b) Under contract with the HMO to provide services to enrollees;

(8) Misdiagnosis;

(9) Inappropriate referral to meet enrollees' needs;

(10) Environmental issues related to infection control and hazardous medical waste;

(11) Failure of a provider to perform adequate medical screening, assessments, or timely care in emergency situations;

(12) Failure to provide an adequate internal enrollee complaint process concerning quality of care issues;

(13) Failure to comply with policies and procedures concerning delivery of care; or

(14) Inadequate credentialing and performance appraisal for physicians.

C. The HMO shall:

(1) Submit the written procedure to the Department for approval before distributing to enrollees;

(2) Obtain Departmental approval of any revision to the written procedure before implementing the proposed change; and

(3) Distribute the approved written procedure to all enrollees.

D. The written complaint procedure shall include, at a minimum, the:

(1) Department of the HMO that the enrollee or family member may contact if the enrollee wishes to make a complaint or obtain information concerning a complaint;

(2) Complaint department's address and telephone number;

(3) Procedure for investigating the complaint;

(4) Time frame in which the HMO shall provide a final response to or resolve the enrollee's complaint, not to exceed 60 days; and

(5) Telephone number of the Maryland Insurance Administration if the enrollee wishes to pursue a complaint regarding quality of care issues outside of the HMO's complaint system.

E. The HMO shall treat the enrollee with dignity, courtesy, and due regard for the individual's privacy.

F. The HMO shall maintain a written record of complaints and responses for at least 5 years following the date the complaint was received by the HMO.

G. Investigation by the Department.

(1) The Maryland Insurance Administration is the single point of entry for all complaints to State government filed by an HMO enrollee. The Maryland Insurance Administration shall refer all quality of care complaints, as defined in §B of this regulation, to the Department for investigation.

(2) The Department may:

(a) Refer a complaint directly to an HMO for resolution; or

(b) Conduct an independent investigation.

(3) If the Department refers the complaint to an HMO, the HMO shall provide the following information in writing to the Department within 30 days of receipt of the complaint:

(a) The results of the investigation;

(b) Any change or proposed change to HMO policies or procedures as a result of the investigation; and

(c) The HMO's method to prevent recurrence of the problem.

(4) If the HMO has not completed the investigation within 30 days, the HMO shall send the Department an interim report with a summary of the investigation to date and the expected date of completion. The expected date of completion may not be longer than 60 days from receipt of the complaint.

*10.07.11.12*

**.12 Inspections.**

A. HMO to Be Open for Inspection. An HMO shall be open to inspection by representatives of the Department and by any agency designated by the Department.

B. Frequency of Inspection.

(1) The Department shall inspect each HMO periodically at reasonable times.

(2) The Department shall monitor continuously the health care services of an HMO:

(a) From the time of notice by the Commissioner that the HMO is not operating in a fiscally sound manner; and

(b) Until:

(i) The Commissioner notifies the Department that the HMO is operating in a fiscally sound manner; and

(ii) The Secretary determines that further continuous monitoring is not warranted.

C. Records and Reports. HMO's shall keep records and shall make reports as the Department shall prescribe. All records shall be open to inspection by representatives of the Department.

*10.07.11.13*

**.13 Repealed.**

*10.07.11.14*

**.14 Waiver Authority.**

The Department may grant waivers to the provisions of these regulations when this action is demonstrated to be in the best interests of the general public. Waivers may be granted for a 1-year period, are renewable, and are subject to reconsideration at any time.