420-5-6.01 General

(1) Statutory Authority for Adoption of Rules. Under and by virtue of authority vested in it by the Legislature of Alabama, Code of Ala., 1975, 22-2-2(6), et seq., 22-21-20, et seq., 27-21A-1, et seq., Health Maintenance Organizations are required to be regulated by the Alabama Department of Public Health. The State Board of Health does hereby adopt and promulgate this Chapter.

(2) Applicability.

(a) These Rules shall be applicable to all persons who propose to establish and operate a health maintenance organization or who currently operate a health maintenance organization under Code of Ala., 1975, 22-21-20 et seq., and 27-21A-1, et seq.

(3) Definitions.

(a) Delegation means a formal process by which a health maintenance organization and an applicant organization gives another entity the authority to perform certain functions on its behalf, such as credentialing, utilization management, and quality improvement. Although the health maintenance organization and applicant organization can delegate the authority to perform a function, it cannot delegate the responsibility for ensuring that the function...
is performed appropriately.

(b) "Department" means the Alabama Department of Public Health.

(c) "Enrollee" means an individual who is enrolled in a health maintenance organization.

(d) "Governing Body" means a board of directors, or other individuals which have the authority to establish policy for the health maintenance organization and in which ultimate responsibility and authority for the conduct of the health maintenance organization is vested.

(e) "Health Care Services" means any services included in the furnishing to any individual of medical or dental care, or hospitalization or incident to the furnishing of such care or hospitalization, as well as the furnishing to any person of any and all other services for the purpose of preventing, alleviating, curing or healing human illness, injury or physical disability. Nothing in this definition and nothing in these Rules shall be construed to authorize any person employed by, or contracting with, a health maintenance organization to engage in the practice of medicine unless that person is licensed to practice medicine or to perform any act or render any medical service which act or service requires that the individual be licensed by an appropriate licensing agency of the State of Alabama or certified by the Secretary of Health and Human Services for Medicare participation and that person has complied with Alabama Health Planning Laws, "22-21-260, et seq. The fact that an employer purchases health care services from a health maintenance organization does not make the employer responsible for the provision of those services.

(f) "Health Maintenance Organization" means any person that undertakes to provide, or arrange for, basic health care services through an organized system which combines the delivery and financing of health care to enrollees. The organization shall provide physician services directly through physician employees or under contractual arrangements with either individual physicians or a group or groups of physicians. The organization shall provide basic health care services directly or under contractual arrangements. When reasonable and appropriate, the organization may provide physician services and basic health care services through other arrangements. The organization may provide, or arrange for, health care services on a prepayment or other financial basis.

(g) "Physician" means a doctor of medicine or doctor of osteopathy licensed to practice medicine by the Medical Licensure Commission of Alabama or licensed to practice in the locale in which the patient is treated.

(h) "Primary Care Provider" means a physician currently licensed in the state in which he/she practices who supervises, coordinates, provides initial and basic care to enrollees, maintains continuity of care for enrollees and initiates referrals for specialist care. The primary care provider is responsible for the medical management of the health maintenance organization enrollee’s health. The care of episodic illness alone does not constitute the role of a primary care provider. A physician's assistant or a certified registered nurse practitioner may perform certain of the above activities with appropriate physician oversight as prescribed by law.

(i) "Provider" means any physician, hospital or other person or organization licensed and practicing within the scope of such a license or
otherwise authorized in the state in which he/she practices to furnish health care services.

(j) "State Health Officer" means the executive officer of the Alabama Department of Public Health.

420-5-6.02 Content of Application for Certificate of Authority.

(1) Each application for a certificate of authority under Code of Ala., 1975, "27-21A-1, et seq., shall be made to the Commissioner of the Department of Insurance and to the State Health Officer. "Certificate of Authority" means the document issued by the State Insurance Commissioner permitting a person to establish, maintain and operate a health maintenance organization. The application specific to the Alabama Department of Public Health shall contain the following:

(a) Copies of the basic organizational documents such as the certificate of incorporation, bylaws, rules, articles of association, partnership agreement, trust agreement or other applicable documents and agreements regulating the conduct of the internal affairs of the applicant and all amendments thereto;

(b) A list and organization chart of the names and addresses and official positions of the members of the board of directors, officers, controlling persons, owners, or partners, the medical director and the administrator of the proposed health maintenance organization and any other persons responsible for the health services system of the health maintenance organization;

(c) A resume of the medical director, administrator and all department managers;

1. "Administrator" means a person who demonstrates competence and experience in health maintenance organization management; who is assigned the responsibility for the interpretation, implementation, and proper application of policies and programs established by the governing body; is assigned responsibility for the establishment and maintenance of effective management, control, and operation of the services provided; and, is responsible for coordination of activities and communication between the Department, the governing body, and the health delivery systems. The administrator shall be available and accessible to the Department. In the absence of the administrator, an individual shall be designated, in writing, who shall be authorized to act on the administrator's behalf.

2. "Medical Director" means a physician who oversees medical aspects of the plan, supervises the quality improvement and utilization management programs and advises the governing body on the adoption and enforcement of policies concerning medical services. A medical director must have a current license to practice medicine granted by the Medical Licensure Commission of Alabama. Alternately, an HMO may employ for no longer than 12 months an individual as medical director provided that the individual is eligible in all respects for licensure as an Alabama physician and the individual has a current active application for licensure on file with the Medical Licensure Commission of Alabama.

(d) A detailed description of the proposed health maintenance organization's potential ability to assure both the availability and accessibility of adequate personnel and facilities to serve enrollees in a manner enhancing availability, accessibility, and continuity;
(e) A description of the service area of the proposed health maintenance organization (geographic boundaries, demographic data, and identification of population groups of enrollees);

(f) Information regarding proposed practice site locations and hours of operation;

(g) A list of proposed providers with physical address and phone number;

(h) A copy of the applicant's proposed contracts and marketing documents with enrollees and group contracts with employers, unions, trustees, or other organizations, setting forth the corporation's contractual obligation to provide a minimum of basic health services;

(i) Applicant's provider contracts with physicians, groups of physicians organized on a group practice or individual practice basis, hospitals, and other providers of health care services enabling it to provide basic and frequently utilized specialty health services to an enrolled population;

(j) A detailed description of the applicant's proposed complaint system whereby the complaints of the enrollees may be acted upon promptly and satisfactorily;

(k) A detailed description of the applicant's arrangements for ongoing quality-of-health-care assurance program;

(l) A detailed description of the applicant's capability to collect and analyze necessary data relating to the utilization of health care services;

(m) Job descriptions of the medical director, administrator and department managers;

(n) A procedure for referral of enrollees to nonparticipating specialists;

(o) A copy of written procedures for provision and payment of emergency services;

(p) A copy of the written procedures regarding the method for providing frequently utilized services required by 420-5-6.06(11);

(q) An organizational chart demonstrating the delegation of authority and control of the health services delivery system from the highest authority (governing body) to the physician, with support documentation demonstrating that all personnel at each level of authority have the requisite expertise for their particular area of authority.

(r) A detailed description of how medical records will be maintained;

(s) Evidence that the proposed health maintenance organization has complied with Alabama Health Planning Laws, '22-21-260 et seq.;

(t) Any other pertinent information; and

(u) A health maintenance organization shall not materially alter, amend,
modify, suspend, or delete any of the provisions of any document submitted in connection with an application for a Certificate of Authority unless in accordance with Code of Ala., 1975, '27-21A-2(d)(1). The State Health Officer will forward in a timely manner a recommendation to the Commissioner of Insurance that the requested alteration, modification, amendment, suspension, addition or deletion be approved or disapproved in accordance with Code of Ala., 1975, '27-21A-17(a)(1).

420-5-6.03 Review by the Department.

(1) Within the statutory time frames, the Department will determine whether the information submitted in the application for a Certificate of Authority is complete. If the information is not complete, the Department will send notification in writing to the applicant stating that additional information is needed. In this event, the Department may require the organization to provide proof that all Department of Insurance requirements have been satisfied before accepting further Certificate of Authority submissions. Failure to meet all Alabama Department of Public Health requirements for a properly completed application in a ten-month period may result in the organization being required to begin the application process again.

(2) Before the Department certifies to the Insurance Commissioner that the proposed health maintenance organization meets the requirements of 420-5-6.02, it will conduct a thorough assessment to ascertain whether the proposed health maintenance organization, the plan under which it proposes to operate, and the services which it proposes to provide are consistent with the purposes and provisions of Code of Ala., 1975, '27-21A-1, et seq., and this Chapter.

(3) Within 90 days of receipt of a properly completed application for a Certificate of Authority, the State Health Officer will do either of the following:

(a) Certify to the Insurance Commissioner that the proposed health maintenance organization meets all requirements of the State Board of Health; or

(b) Disapprove the application, specifying in writing to the proposed health maintenance organization and Insurance Commissioner the reasons for such disapproval.

420-5-6.04 Basic Health Care Services

(1) A health maintenance organization shall provide at least basic health care services: basic health care services means emergency care, inpatient hospital and physician care, and outpatient medical services.

(a) Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part. Emergency care must be available in and out of the service area and shall include ambulance services for emergency care dispatched by 911, if available, or by the local government authority. Emergency care shall be available 24 hours a day, seven
(b) Inpatient Hospital Care. Medically necessary hospital services affording inpatient treatment to enrollees in a hospital. Inpatient hospital care includes, at a minimum, room and board; general nursing care; special diets when medically necessary; newborn care; use of intensive care unit and services; x-ray; laboratory, and other diagnostic tests; drugs, medications, biologicals, anesthesia, and oxygen services; special duty nursing when medically necessary; radiation therapy; administration of whole blood and blood plasma; short term physical medicine and rehabilitative services. A health maintenance organization which contracts with the Alabama Medicaid Agency shall provide the maximum medically necessary inpatient hospital stay required by Medicaid for Medicaid enrollees. A health maintenance organization which contracts with the Alabama Medicaid Agency shall implement written protocols and shall make arrangements which may be outside the health maintenance organization for medically necessary care of Medicaid enrollees who require care beyond the maximum hospital stay required by Medicaid for Medicaid enrollees;

(c) Physician Care. Generally accepted and medically necessary health services performed, prescribed, or supervised for registered bed patients, including diagnostic and therapeutic care. Medically necessary and maintenance health services performed, prescribed, or supervised by physicians for patients who are not confined to bed in an institution or at home. These services may be provided in a nonhospital-based health care facility, at a hospital, or in a physician's office. Physician care shall include consultant and referral services; and

(d) Outpatient Medical Services. Services shall include, at a minimum, maternity coverage including risk-appropriate prenatal care, intrapartum and postpartum care, and transportation, including air transportation, where necessary, for the medically high risk pregnant woman; pediatric care from birth including pediatric maintenance visits, treatment visits, and immunizations according to written schedules; adult care including periodic physical examinations provided with the goal of protection against and early detection and minimization of the ill effects and causes of disease or disability and including adult immunizations, and other maintenance services as appropriate.

(2) Basic health care services shall be provided according to, at a minimum, standards certified by the State Health Officer.

(3) A health maintenance organization shall provide basic health care services and frequently utilized specialty services and ancillary services to its enrollees as needed and without unreasonable limitations as to the time and cost. For the purposes of this rule, Ancillary services@ means those covered services customarily provided by a participating ancillary provider (including for example: laboratory, durable medical equipment, pharmacy) in his or her office or place of business, or as applicable, in a physician's office, enrollee home setting (such as home health), mobile vehicle (diagnostic providers) as well as services customarily provided by participating ancillary providers to institutionalized patients.

(a) Frequently Utilized Specialty Services@ means those covered specialized physician services that the health maintenance organization has identified as high volume specialties based on utilization and demographics of the enrollees.
(4) Reasonable exclusions, such as are customarily found in group health insurance policies, will be permitted. Examples of reasonable exclusions are cosmetic surgery unless medically necessary, custodial or domiciliary care, and durable medical equipment for home use.

(5) A health maintenance organization may provide, in addition to basic health services, other health services such as outpatient substance abuse services, residential treatment for substance abuse or mental health at recommended levels of 30 days for adults and 60 days for adolescents, cosmetic surgery, prescription drug coverage, dental coverage, and similar services which an enrolled population may require to maintain physical and mental health.

420-5-6.05 Organization.

(1) The health maintenance organization shall be organized in a manner which allows the accomplishment of its stated mission which shall include, as a minimum delivery of basic health care services, as well as covered frequently utilized specialty services and ancillary services.

(2) The plan shall possess organizational and administrative capacity to provide services and the ability to monitor provision of such services.

(3) The plan shall demonstrate separation of medical services from fiscal management sufficient to assure that medical decisions will not be inappropriately influenced by fiscal management.

(4) The governing body of the health maintenance organization shall be responsible for establishment and oversight of the health maintenance organization's health delivery system. The responsibilities of the governing body of the health maintenance organization shall include, but not be limited to, the following:

(a) Adoption and enforcement of all policies governing the health maintenance organization's management of health care services delivery, quality improvement and utilization review programs including annual meetings for the purpose of evaluation and improvement of the health services of the health maintenance organization and to react to recommendations and findings of the quality improvement committee;

1. The governing body shall keep minutes of meetings and other records to document the fact that the governing body is effectively discharging the obligations of its office regarding health services.

(b) Authority to hire and terminate the administrator and medical director;

(c) Adoption of the health maintenance organization's procedures for maintenance and control of all books, records, and audits which are related to the health services system;

(d) Assurance that the health maintenance organization's medical director is performing the duties of that position and in a manner that results in the operation of a quality improvement program that is effective and otherwise in
compliance with the standards of 420-5-6.07;

(e) Assurance that the health maintenance organization's administrator is performing the duties of that position;

(f) Independent adoption of policies affecting the delivery of health care services;

(g) Assurance that the health maintenance organization complies with applicable laws and regulations;

(h) Provision of reasonable access to the Board for input by the Medical Director at the request of the Medical Director.

(5) Health maintenance organizations operating or contracting with hospitals, independent clinical laboratories, rehabilitation centers, ambulatory surgical treatment facilities, end stage renal disease treatment and transplant centers, abortion or reproductive health centers, skilled nursing facilities, domiciliaries, and other related health care institutions when such institution is primarily engaged in offering to the public generally, facilities and services for the diagnosis, treatment, or both, of injury, deformity, disease, surgical or obstetrical care, shall ensure compliance with Code of Ala., 1975, ‘‘22-21-20, et seq.

420-5-6.06 Assurance of Access to and Continuity of Care.

(1) A health maintenance organization shall have available sufficient personnel to meet the standards set forth in this Chapter and its contractual obligations.

(2) When health care services are not provided directly, a health maintenance organization shall develop and maintain written executed contracts for the provision of the health services contracted for by its enrollees.

(3) The Department may grant a waiver from the requirement for executed provider contracts in certain areas of health care, if the Department determines that:

(a) The specific services are services which, because of an emergency, it was medically necessary to provide to the enrollee other than through contracted providers; or

(b) The specific service or services being reviewed are unusual or infrequently used health services.

(4) In those specialities which are generally available and frequently utilized in the geographic area served by the health maintenance organization, services of qualified specialty practitioners shall be provided through executed provider contracts between the health maintenance organization and the practitioner, assuring enrollee access to medically necessary specialty care.

(5) Medically necessary specialty services other than those described in paragraphs (3) and (4) shall be provided by participating or nonparticipating specialists.

(6) A health maintenance organization may expand the service area approved
in the Certificate of Authority process at any time through submission of information validating the ability to provide basic health care services, frequently utilized specialty services, and any other covered benefit. Service area expansions require the approval of the Alabama Department of Public Health and the Department of Insurance.

(7) A health maintenance organization may require that all health care services be coordinated and supervised by a primary care provider. In such circumstances, a health maintenance organization may either assign, or each enrollee may select, a primary care provider to supervise and coordinate the health care of the enrollee. An enrollee who is dissatisfied with the assigned or selected primary care provider shall be allowed to select another primary care provider. However, the health maintenance organization may impose a reasonable waiting period to accomplish this transfer. A list of primary care providers and enrollees assigned to each shall be maintained.

(8) All health maintenance organizations shall have a system in place to ensure that enrollees receive medically necessary referrals. Referrals, except in emergency situations, shall be made by the enrollee's primary care provider (if the primary care provider concept is utilized by the health maintenance organization) or by a physician under contract or other arrangement with the health maintenance organization. If a requested referral is denied, the provider or enrollee may seek referral from the medical director who may, after consultation with appropriate providers, grant or deny the referral.

   (a) The health maintenance organization shall have a process to ensure requests for referrals are processed in a timely fashion with appropriate medical director oversight, as well as a process for expedited referrals.

   (b) In those cases in which a health condition of ongoing or chronic status has been established and the need for specialized care has been determined, the referring physician may authorize in advance a number of visits to a specialty physician so that the enrollee may proceed directly to the specialty physician without first meeting with the referring physician.

(9) Utilization decisions shall be made within seven (7) calendar days of receipt of all necessary information, unless the attending physician indicates that the enrollee’s life, health or ability to regain maximum function could be seriously jeopardized, in which event the decision shall be expedited. Each health maintenance organization shall have policies and procedures addressing these processes and will communicate the policies and procedures to providers through the provider manual.

   (a) All decisions shall be communicated to the provider within a time period reasonably calculated to accommodate the clinical urgency of the situation.

   (b) In the event of denial based on medical necessity, the health maintenance organization must give the provider initiating the request for authorization, and the enrollee if he or she requests it, a written denial response that identifies by name, title and telephone number the medical director or other physician who made the denial decision and the name of the person, address and telephone number to whom a request for an informal complaint, formal complaint, or expedited formal complaint may be made.
In the event of denial based on reasons other than medical necessity, such as non-covered services, the health maintenance organization must give the provider initiating the request for authorization, and the enrollee if he or she requests it, a written denial response that indicates where to initiate a request for an informal complaint or a formal complaint. The written denial response shall include the address, telephone number and title of the individual or the specific department within the health maintenance organization to whom the request may be made.

(c) An expedited formal complaint may be requested verbally or in writing by the enrollee or the provider. For a request made or supported by a physician, the health maintenance organization must provide an expedited response if the physician indicates that applying standard response time provided in paragraph (9) above could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. The expedited formal complaint process is described at Rule 420-5.6.08(6)(h).

(10) The health maintenance organization shall have in effect an adequate system of documentation of services requested by providers which shall include:

(a) A log shall be kept of all medical necessity requests from participating providers where reimbursement for requested services was denied. The log shall include the name of the enrollee, name and address of the requesting provider, type of service requested, date of the request, date of the denial, and the name of the health maintenance organization medical director who made the decision. Sufficient documentation must exist to establish a clear picture of the process and outcome. The log may be maintained through a backed-up automated system.

(11) The health maintenance organization shall have in effect an adequate system of documentation of referrals to noncontracted providers which shall include:

(a) A log which includes all referrals by contracted physicians to noncontracting providers and hospitals. The log shall include the name of the enrollee, name and address of the referring contracting physician, an authorization number, and the date of referral. The log may be maintained through an automated system and

(b) Transfer of adequate information from the health maintenance organization to the referral physician with assigned responsibility for follow-up.

(12) When an enrollee is referred by a health maintenance organization or by a health maintenance organization physician to a nonparticipating specialist for covered services, the enrollee shall incur no financial liability above that which he would have incurred had he been referred to a participating specialist except when such referral occurs pursuant to noncontractual provider arrangements as defined by Code of Ala., 1975, '27-21A-29(b).

(13) To insure that claims payments are not a barrier to accessibility of health care, claims shall be paid as follows:

(a) All health maintenance organizations issuing contracts to employers, unions, trustees, or other organizations and individuals within this State shall
consider claims made thereunder and, if found to be valid and proper, shall pay such claims within 45 days after the health maintenance organization receives reasonable proof of the fact and amount of loss sustained. If reasonable proof is not supplied as to the entire claim, the amount supported by reasonable proof shall be considered overdue if not paid within 45 days after such proof is received by the health maintenance organization. Any part or all of the remainder of the claim that is later supported by reasonable proof shall be considered overdue if not paid within 45 days after such proof is received by the health maintenance organization. For the purposes of calculating if any benefits are overdue, payment shall be treated as made on the date a draft or other valid instrument was placed in the United States mail to the last known address of the claimant or beneficiary in a properly addressed, postpaid, envelope, or, if not so posted, on the date of delivery period. When the claim is overdue or denied, the health maintenance organization must provide written justification within five days of the overdue or denial date to any providers involved and to the enrollee if the enrollee is financially liable for the denied claim.

(b) The above required payment time period of 45 days is not applicable if the health maintenance organization has executed provider contracts in which the health maintenance organization and the provider have agreed to a different schedule of payment in which case, all other stipulations in (a) will be applicable with the exception that the time payment period will be in accordance with the contract between the health maintenance organization and the provider.

(14) A health maintenance organization shall have written procedures governing the availability of frequently utilized services contracted for by enrollees, including at least the following:

(a) Service protocols by type of maintenance visit;

(b) Well child and adult examinations and immunizations;

(c) Emergency telephone consultation on a 24-hour a day, 7-day a week basis including qualified physician coverage for emergency services;

(d) Treatment of acute emergencies including ambulance and transport services;

(e) Treatment of acute minor illness;

(f) Treatment of chronic illness;

(g) Hours of operation of delivery sites including appointment systems;

(h) Distribution to enrollees of information concerning enrollee rights and patient education;

(i) List of referral sources; and

(j) Medical records establishment and review.

(15) Each health maintenance organization shall have a written procedure describing coverage for emergency health services received by an enrollee outside of the health maintenance organization's service area.

(a) The health maintenance organization's coverage for emergency health
services shall be clearly described in enrollee contracts and shall include disclosure of any restrictions regarding emergency services.

(16) Each health maintenance organization shall pay the provider or reimburse its enrollees for the payment of emergency services, as defined in these Rules in 420-5-6.06(13).

(a) Each health maintenance organization shall adopt procedures to review promptly all claims for reimbursement for the provision of emergency services, including a procedure for the determination of the medical necessity for obtaining these services other than through the health maintenance organization.

(b) Emergency services shall include payment to the nearest 24-hour emergency facility and ambulance services when appropriate.

(17) The health maintenance organization shall provide coordinated discharge planning including the planning of such continuing care as may be necessary, both medically and as a means of preventing possible rehospitalization.

(18) If a health maintenance organization fails to become operational within twelve months after receiving a Certificate of Authority, the Alabama Department of Public Health may request the Department of Insurance to issue a Show Cause Order why the health maintenance organization should be authorized to retain the Certificate of Authority.

(19) If at any time a formerly operational health maintenance organization ceases to provide covered services for a period of ten months, the Alabama Department of Public Health may request the Department of Insurance to issue an Order for the health maintenance organization to document why the health maintenance organization should be authorized to retain the Certificate of Authority.

(20) The distance from the health maintenance organization's geographic service area boundary to the nearest primary care delivery site and to the nearest institutional service site shall be a radius of no more than 30 miles. Frequently utilized specialty services shall be within a radius of no more than 60 miles. The Department may waive this requirement if the distance limit is not feasible in a particular geographic area.

After notification to the health maintenance organization and a reasonable opportunity to cure, the Alabama Department of Public Health may recommend to the Department of Insurance the withdrawal of a previously approved service area if required provider access is not maintained.

(21) The health maintenance organization shall insure that it has access to the medical records of enrollees upon request for review by the health maintenance organization and the Department.

420-5-6.07 Quality Improvement and Utilization Review

(1) A health maintenance organization shall develop and implement a quality improvement program subject to the approval of the State Health Officer that includes organizational arrangements and ongoing procedures for the identification, evaluation, resolution, and follow-up of potential and actual
problems in health care administration and delivery to enrollees.

(2) The quality improvement organizational arrangements and ongoing procedures must be fully described in written form, provided to all members of the governing body, providers, and staff, and made available, upon request, to enrollees of the health maintenance organization.

(3) The organizational arrangements for the quality improvement program must be clearly defined and transmitted to all individuals involved in the quality improvement program and should include, but not be limited to, the following:

(a) A quality improvement committee responsible for quality improvement activities and utilization review activities;

(b) Accountability of the committee to the administrator and the governing body of the health maintenance organization including annual written and oral reports to the governing body. The written reports shall contain;

1. Studies undertaken, results, subsequent actions, and aggregate data on utilization and quality of services rendered to enrollees.

(c) Participation from an appropriate base of providers and support staff;

(d) Supervision by medical director;

(e) A minimum of quarterly meetings at appropriate location;

(f) Minutes or records of the meeting of the quality improvement committee describing the actions of the committee including problems discussed, recommendations made, and any other pertinent discussions and activities; and

(g) Information concerning quality improvement shall be treated as confidential information in accordance with Code of Alabama, 1975, '27-21A-24 and 25.

(4) The quality improvement procedures shall include defined methods for the identification and selection of clinical and administrative problems. Input for problem identification shall come from multiple sources including, but not limited to, medical chart reviews, enrollee complaints, utilization review, enrollee assessment audits, and should cover all health maintenance organization services. Methods should be established by which potential problems are selected and scheduled for further study.

(5) A health maintenance organization shall document the manner by which it examines actual and potential problems in health care administration and delivery to enrollees. While a variety of methods may be utilized, the following components shall be present:

(a) The existence of procedures for the analysis using standards certified by the State Health Officer. The procedures shall be structured to encompass;

1. The total episode of illness for which the health maintenance
organization is responsible.

2. The structure or organizational framework within which care is provided.

3. The process or method by which care is given.

4. The outcome of care including morbidity and mortality rates.

(6) The quality improvement activities shall include the development of timely and appropriate recommendations for problems in health care administration and delivery to enrollees that are identified, and the health maintenance organization shall demonstrate an operational mechanism for responding to those problems. Such a mechanism shall include:

(a) Development of appropriate recommendations for corrective action, or when no action is indicated, an appropriate response;

(b) Assignment of responsibility at the appropriate level or with the appropriate person for the implementation of the recommendation; and

(c) Implementation of action which is appropriate to the subject or problem in health care administration and delivery to enrollees.

(7) There shall be evidence of adequate follow-up on recommendations. The health maintenance organization shall be able to demonstrate that recommendations of the committee responsible for quality improvement activities are reviewed in a timely manner in order to:

(a) Assure the implementation of action relative to the recommendations;

(b) Assess the results of such action; and

(c) Provide for revision of recommendations or actions and continued monitoring when necessary.

(8) Review of the quality of care shall not be limited to technical aspects of care alone but shall also include availability, accessibility, and continuity of care provided to enrollees.

(9) A utilization review process shall be specified to assure that only those services which represent proper utilization of health care services and conform with contractual provisions are provided.

(a) "Utilization Review" means prospective, concurrent, and retrospective review and analysis of data related to utilization of health care resources in terms of cost effectiveness, efficiency, control, and quality.

(b) "Retrospective Review" means the mechanism to review medical necessity and appropriateness of medical services through the compilation and analysis of data after medical care is rendered and shall include the comparison of contracted provider practice patterns with parameters established by the utilization review committee, recommendation of changes in contracted provider practice patterns based on analysis and review, and analysis of care to enrollees to determine need for educational programs and benefit restructuring.
(c) Data on utilization of health care services shall be collected and shall be analyzed to identify for further in depth investigation of potential over-utilization, under-utilization, or misutilization of health care services by enrollees or providers. Such data shall include, but not be limited to, the following:

1. The analysis of utilization statistics;
2. The analysis of referral trends;
3. Assessment of ambulatory treatment patterns;
4. Assessment of a pre-hospitalization admission program;
5. Evaluation of a hospital inpatient monitoring program;
6. Evaluation of a retrospective review program; and
7. Monitoring of the effectiveness of a discharge planning procedure.

(d) Data on utilization shall be treated as confidential information in accordance with Code of Ala., 1975, '27-21A-24 and 25 with the exception of the aggregate utilization data required in quarterly and annual reports in 420-5-6.14(1)(d)(e), (2)(d)(e).

10) A health maintenance organization shall specify in the provider manual procedures for maintenance of the provider's medical records which shall include, but not be limited to, the following:

(a) Medical records shall be maintained in a current, detailed, organized, and comprehensive manner;

1. Medical records shall be legible and should reflect all aspects of patient care, including ancillary services.
2. Records shall be available to health care practitioners at each encounter and for internal and external and Department review.
3. The health maintenance organization shall have an explicit statement of its policy for assuring confidentiality of patient records.

(b) The inpatient and outpatient care records shall demonstrate conformity with good professional medical practices and permit effective quality improvement review;

1. For a given encounter, there shall be a complete, dated, and signed progress note containing the following information.

(i) Reason for visit
(ii) Evaluation
(iii) Problem/diagnosis
Health Maintenance Organizations Chapter 420-5-6

(iv) Therapeutic plan
(v) Follow up

2. For subsequent encounters, there shall be evidence of adherence to the follow up plan.

(c) Appropriate health management and continuity of care shall be clearly reflected in the medical records.

420-5-6.08 Complaint System.

(1) A health maintenance organization shall have an enrollee complaint process, to include an informal review, a formal review, and an expedited formal review for the prompt resolution of complaints regarding such things as (a) the availability, delivery, or quality of health care service, (b) claims payment, handling or reimbursement for health care services, (c) matters pertaining to the administrative or contractual relationship, or both, between an enrollee and the health maintenance organization. Issues which can be resolved by telephone to the enrollee’s satisfaction shall not be classified as a complaint.

(a) Inquiry means normal business operations conducted verbally or in writing between the health maintenance organization and enrollees. These inquiries may include such things as requests for identification cards, clarification of benefits, and address changes. Inquiries will be resolved to the enrollee’s satisfaction and within a time frame that is acceptable to the enrollee. Inquiries shall be tracked and trended by issue involved to allow the health maintenance organization to identify systemic or commonly occurring areas.

(b) Informal Complaint means those issues that are not resolved to the members satisfaction at the inquiry level or for which the enrollee requests a written response. Informal complaints will be tracked in accordance with Chapter 420-5-6.08(4).

(c) Formal complaint means the subsequent written expression by or on behalf of an enrollee regarding the resolution of an informal complaint. Discussions between a provider and the health maintenance organization during the utilization review process do not constitute a formal complaint. Authorization from the enrollee shall not be required for the provider’s involvement in the utilization review process.

A provider may act on behalf of the enrollee in the formal complaint process if the physician certifies in writing that the enrollee is unable to act on his or her own behalf due to illness or disability. A family member, friend of the enrollee, or any other person may act on behalf of the enrollee after written notification to the health maintenance organization by the enrollee. A provider may also access the provider dispute mechanism as set forth in the provider contract without written authorization of the enrollee.

(d) Expedited Formal Complaint means a verbal or written request by the enrollee or the provider regarding an adverse medical necessity decision in the utilization review process. The request must describe the medical urgency of the situation to justify the expedited process.

16
(2) A health maintenance organization shall have a designated Alabama phone number and address for the receipt of enrollee complaints. A staff member shall be designated to oversee the complaint process.

(3) The complaint process, including the informal, formal, and expedited processes, must be fully described in enrollee contracts and enrollee handbooks.

(4) All informal, formal, and expedited complaints must be entered into a written or backed-up automated log.

   (a) The log should include the nature of the complaint, date received, date action taken by the plan and date enrollee notified.

(5) The health maintenance organization shall have an informal complaint process.

   (a) A decision regarding an informal complaint and the mailing of notice to the enrollee must take place within 45 calendar days of receipt of the informal complaint. The notification must detail the outcome of the informal complaint and in the case of an adverse outcome, advising of the right to file a formal complaint.

   (b) A formal complaint shall be filed within twelve months of the health maintenance organization’s receipt of the informal complaint. However, extenuating circumstances will be considered by the health maintenance organization.

(6) The health maintenance organization shall have a formal complaint process.

   (a) The health maintenance organization shall maintain a record which demonstrates the health maintenance organization has considered all aspects of the enrollee’s complaint.

   (b) The enrollee and any other party of interest may provide pertinent data. The enrollee will be notified in writing of this right.

   (c) At the request of the enrollee, the health maintenance organization shall appoint a member of its staff who has no direct involvement in the case to assist the enrollee. The enrollee shall be notified in writing of this right.

   (d) The enrollee shall have the right to appear before the formal complaint committee.

   (e) The medical director for the health maintenance organization shall determine the need to consult qualified specialty consultants during the formal review process.

   (f) A review of the formal complaint shall be conducted by a committee of one or more individuals, who may be employees of the health maintenance organization. Committee members representing the health maintenance organization shall be employed by the health maintenance organization and be familiar with the policies and procedures of the Alabama health maintenance organization.

   (g) The formal complaint committee shall render a decision within 30
calendar days of receipt of the written formal complaint. The enrollee must receive written notification regarding the resolution of the formal complaint within 5 working days of the decision detailing the outcome of the formal complaint. The notification shall provide notice that the enrollee may appeal to the state complaint committee through the State Health Officer or the Commissioner of the Alabama Department of Insurance.

(h) The formal complaint committee will consider enrollee or provider requests for an expedited formal complaint review of an adverse medical necessity decision in the utilization review process. The request must support the fact that a standard response time could seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function. If justified for an expedited review, the committee shall render a decision within a time period that accommodates the clinical urgency of the situation. However, a decision must be made no later than three working days of receipt of the request. The provider’s office will be notified either electronically or in writing on the day of the decision or on the next business day if the provider’s office is closed, followed by written notification to the provider and enrollee within three working days of the decision. The notification shall provide notice that the enrollee may appeal to the state complaint committee through the State Health Officer or the Commissioner of the Alabama Department of Insurance.

(7) If the health maintenance organization delegates the receipt, investigation, decision-making, or communication piece of the complaint process to a contracted provider, the provider contract and health maintenance organization policy and procedure must adequately describe the delegated functions, required reporting to the health maintenance organization, and the health maintenance organization’s ultimate responsibility for the process.

(8) The health maintenance organization shall maintain records of all complaints and shall include in quarterly and annual reports to the Department the total number of complaints received and the number of complaints unresolved.

(9) If a complaint concerns any provider with whom a health maintenance organization contracts, the Department may make an examination concerning health care services of the health maintenance organization and provider.

420-5-6.09 Enrollee Documents.

(1) An enrollee contract is the document which is to be issued to employers, unions, trustees, or other organizations and individuals. Every health maintenance organization shall offer at least one contract to all enrollees which shall include:

(a) Definitions;

(b) Eligibility for enrollment; At a minimum

1. Enrollees must work or live in the health maintenance organization service area to be eligible for group coverage.

2. Enrollees must live in the health maintenance organization service area to be eligible for individual coverage.
(c) Health care services to be provided;

(d) Where and in what manner the health care services may be obtained including explanation of primary care physician role;

(e) Provisions for adding new family members;

(f) Benefits for newborn children;

(g) Provisions relating to termination or cancellation;

(h) Limitations, exceptions, or exclusions;

(i) Provisions relating to preexisting conditions, if applicable;

(j) Provisions relating to coordination of benefits;

(k) Provisions relating to subrogation;

(l) Any applicable arbitration provisions;

(m) Conversion privileges, if applicable;

(n) Complaint procedures;

(o) Any applicable copayments;

(p) Emergency services and out-of-area coverage;

(q) Referral services;

(r) The names of contracted specialty physicians, the names and addresses of all contracted OB/GYN providers, the names and addresses of contracted primary care providers, hospitals, and ancillary providers are to be furnished as a supplement to contracts; and

(s) Any other factors necessary for complete understanding of what is covered and what is excluded and such information required by the Alabama Department of Insurance.

**420-5-6.10 Provider Contracts.**

(1) Provider contract means a written agreement executed between a health maintenance organization and a health care provider in which the health care provider agrees to furnish specified services to enrollees of the health maintenance organization. The health maintenance organization retains the responsibility for the arrangement of the provision of those services.

(2) Health maintenance organizations shall include the following in provider contracts in addition to any requirements of the Alabama Department of Insurance. The Health Department may waive one or more of the following as appropriate for type of provider. If a contracted provider utilizes downstream contracts that the health maintenance organization must rely upon, the contracted provider must guarantee that downstream contracts contain the requirements listed below. A copy of the downstream provider contract(s) with a Department of Public Health.
Health approval stamp shall constitute such guarantee.

(a) Full identification of the parties of the contract including name, address, and phone number of the provider;

(b) Effective date of the contract and date of execution;

(c) Term, termination, and renewal mechanisms;

(d) Obligation of the health maintenance organization to the provider;

1. Payment/reimbursement methodologies must be described in terms a reasonably prudent layperson could be expected to understand.

2. If utilized, withhold or other incentives or reimbursement arrangements incentives must be clearly defined. The factors that will be measured and the amount of time required by the health maintenance organization to analyze the data and report the outcome to the provider will be clearly described in the contract. Providers will receive a report consistent with the terms of the contract and showing the resulting funds or lack of funds, due to be paid within six (6) months of the conclusion of the withhold period. Full payment of any funds due to the provider will be made at the time of the report.

3. Reimbursements or deductions based on circumstances outside the provider’s control, such as plan performance, must be defined as an additional discount or a bonus and may not be defined as a withhold.

4. Organizations applying for health maintenance organization certification must file contracts and attachments that fully and clearly describe payment methodologies, reimbursement, and incentives in terms a reasonably prudent layperson could be expected to understand.

(e) Services to be provided by the provider including location of services, site phone number, times of availability of services, and provisions for coverage in provider’s absence;

(f) Minimum standards of care as established by the health maintenance organization and required of the provider;

(g) Provisions for emergency services;

(h) Provisions for referral services;

(i) A description of the utilization review program and provisions for provider participation in utilization review;

(j) Provisions requiring provider to participate in enrollee grievance procedure;

(k) Provisions requiring sharing of medical records and confidentiality of medical records;

(l) Provisions relating to credentials of provider;

(m) Education requirements relating to the knowledge of operation of the
health maintenance organization's provider's role in the health maintenance organization;

(n) Provisions for adequate medical malpractice coverage;

(o) Provisions for dispute mechanism;

(p) A description of quality improvement procedures and provisions for provider participation in quality improvement; and

(q) A provider shall not deny an enrollee's access to quality care by billing the enrollee directly. Therefore, the contract shall contain a clause that the provider will look solely to the health maintenance organization for compensation for services provided to health maintenance organization enrollees. The clause shall not extend to copayments. The clause shall read;

1. (Provider) hereby agrees that in no event, including but not limited to, non-payment, health maintenance organization insolvency, or breach of this agreement, shall (provider) bill, charge, collect a deposit from seek compensation, remuneration or reimbursement from or have any recourse against enrollee, or persons other than the health maintenance organization acting on behalf of the enrollee for services provided pursuant to this agreement. This provision shall not prohibit collection of copayments, deductibles, and coinsurances on the health maintenance organization's behalf made in accordance with the terms of the (applicable agreement) between the health maintenance organization and enrollee.

(Provider) further agrees that (a) this provision shall survive the termination of this agreement regardless of the cause giving rise to termination and shall be construed to be for the benefit of the health maintenance organization subscriber, and that (b) this provision supersedes any oral or written contrary agreement now existing or hereafter entered into between (Provider) and enrollee, or persons on their behalf.

Provider may not change, amend, or waive any provision of this contract without prior written consent of the health maintenance organization. Any attempts to change, amend, or waive this contract are void.

(r) Provisions requiring that the provider cooperate with the health maintenance organization in complying with applicable laws relating to health maintenance organizations and provider complies with applicable laws regulating provider.

(3) Network providers whose contract with the health maintenance organization state the network has an attorney in fact relationship to bind its providers, do not require review of downstream contracts.

(4) All provider contract documents must be clear and understandable.

420-5-6.11 Professional Staffing of Health Maintenance Organizations.

(1) Professional staff standards.

(a) A health maintenance organization shall have a sufficient number of physicians to adequately cover the health care needs of enrollees.
1. The health maintenance organization shall conduct an annual affirmative capacity analysis of availability of providers required to render covered services.

(b) For purposes of these Rules, the following definitions apply:

1. "Credentials" means certificates, diplomas, licenses and other written documentation that establishes proof of training, education and experience in a field of expertise based on national and state standards.

2. A Credentialing@ means the process by which the health maintenance organization reviews and evaluates the qualifications of licensed independent practitioners and other providers of health care services to its enrollees. Eligibility is determined by the extent to which applicants meet defined requirements for education, licensure, professional standing, service availability, and accessibility, as well as for conformity to a health maintenance organization or applicant organization’s quality and utilization management requirements.

3. A Credential Verification Organization@ means an organization that has demonstrated the capability to perform primary source verification for any physician/provider on behalf of a health maintenance organization or applicant organization.

4. A Delegated Credentialing Organization@ means a hospital, health care delivery network (for example, vision care, mental health, chiropractic), or independent practice association (IPA) of physicians that has demonstrated the capability to perform credentialing as defined above for a limited network of providers.

(c) There shall be established a credentials committee charged with the responsibility of reviewing each provider prior to contracting with the provider to determine that each provider is properly credentialed in Alabama. The credentials committee shall conduct annual reviews of each contracted provider for state licensure/controlled substance certificate; and, conduct a complete credentialing review every two years. All providers shall be recredentialed every two years.

1. The credentials committee shall assure appropriate licensure and certification of providers.

2. The health maintenance organization may delegate primary source verification to Alabama Department of Public Health approved credentialing verification organizations, delegated credentialing organizations, or both.

3. The health maintenance organization may rely upon the credentialing of approved delegates, with oversight, which must also be approved by the Alabama Department of Public Health.

4. Expired drug enforcement agency certificates and malpractice insurance should be updated between cycles as necessary.

(2) Medical director standards.
Health Maintenance Organizations

Chapter 420-5-6

(a) A health maintenance organization shall identify a physician who shall serve as medical director of the Alabama health maintenance organization. A medical director must have a current license to practice medicine granted by the Medical Licensure Commission of Alabama. Alternatively, an HMO may employ, for no longer than 12 months, an individual as medical director provided that the individual is eligible to be licensed as an Alabama physician, and the individual has submitted an application for licensure with the Medical Licensure Commission of Alabama.

(b) The medical director shall be responsible for, at a minimum, the following:

1. General coordination of the medical care of the health maintenance organization on behalf of the health maintenance organization;
2. Implementation and oversight of protocols for quality improvement;
3. Implementation and oversight of quality improvement programs and continuing education requirements; and
4. Implementation and oversight of protocols for the credentials committee.
5. Oversight of medical necessity determinations.

(c) The time spent by the medical director in performing medical director functions shall not be counted in the physician-enrollee ratio required in (1)(a) above.

(3) The health maintenance organization shall define procedures for taking corrective action against any provider whose conduct is detrimental to public safety or the delivery of care, or disruptive to the operation of the health maintenance organization.

420-5-6.12 Enrollee Rights.

(1) A health maintenance organization shall develop and adhere to written procedures for informing enrollees of at least the following rights:

(a) An enrollee has the right to timely and effective redress of grievances through a system established under 420-5-6.08;
(b) An enrollee has the right to obtain current information concerning a diagnosis, treatment, and prognosis from a physician or other provider in terms the enrollee can be reasonably expected to understand. When it is not advisable to give such information to the enrollee, the information shall be made available to an appropriate person on the enrollee's behalf;
(c) An enrollee has the right to be given the name, professional status, and function of any personnel providing health services to him;
(d) An enrollee has the right to give his informed consent before the start of any surgical procedure or treatment;
(e) An enrollee has the right to refuse any drugs, treatment, or other procedure offered to him by the health maintenance organization or its providers to the extent provided by law and to be informed by a physician of the medical consequences of the subscriber's refusal of any drugs, treatment, or procedure;
(f) When emergency services are necessary, an enrollee has the right to obtain such services without unnecessary delay;

(g) An enrollee has the right to have all records pertaining to his medical care treated as confidential unless disclosure is otherwise permitted by law;

(h) An enrollee has the right to all information in his medical records unless access is specifically restricted by the attending physician for medical reasons;

(i) An enrollee has the right to be advised if a health care facility or any of the providers participating in his care propose to engage in or perform human experimentation or research affecting his care or treatment. An enrollee or legally responsible party on his behalf may, at any time, refuse to participate in or continue in any experimental or research program to which he has previously given informed consent; and

(j) An enrollee has the right to be informed of these rights listed in this subsection.

(2) No health maintenance organization may, in any event, cancel or refuse to renew an enrollee solely on the basis of the health of an enrollee.

420-5-6.13 External Quality Improvement Assessment.

(1) When the Department may direct for cause, each health maintenance organization shall have an external quality improvement assessment performed.

(2) The assessment shall study the quality of care being provided to plan enrollees and the effectiveness of the quality improvement program established according to 420-5-6.07.

(3) The assessment shall be conducted by an expert experienced in health maintenance organization review activities.

(a) The expert shall be hired by the health maintenance organization and not involved in the operation or direction of the health maintenance organization or in the delivery of health care services to its enrollees.

(b) The expert must be an individual or organization with recognized experience in the appraisal of medical practice and quality improvement in a health maintenance organization setting.

(c) The expert shall be approved by the Department.

(d) The expert shall review, at least, a statistically significant sample of medical records.

(e) The expert shall issue a written report of his findings to the health maintenance organization's governing body.

(4) A copy of the expert's report shall be submitted to the Department within 10 business days of its receipt by the health maintenance organization.

420-5-6.14 Annual and Quarterly Reports.
(1) Any person which has received a Certificate of Authority to operate a health maintenance organization shall submit before March 1 of each year a detailed report of its activities during the preceding calendar year. The report shall include, at least, the following:

(a) A copy of the annual financial report submitted to the Commissioner;

(b) Copies of the quality improvement and utilization review reports submitted to the governing body according to 420-5-6.07;

(c) A copy of the complaint resolution system established according to 420-5-6.08, including a summary of total number of complaints handled, a compilation of causes underlying the complaints, and the resolution of complaints;

(d) A statement of number of providers leaving the health maintenance organization and the number of providers replacing them and total number of providers; and

(e) A summary of enrollment and disenrollment rates during the year.

(2) Any health maintenance organization shall submit to the Department quarterly reports which shall contain, at least, the following:

(a) A copy of any quarterly financial report required by the Commissioner;

(b) A summary of total number of grievances handled, a compilation of causes underlying the grievances, and the resolution of grievances;

(c) A statement of number of providers leaving the health maintenance organization and the number of providers replacing them and total number of providers;

(d) A summary of enrollment and disenrollment rates during the quarter; and

(e) Utilization statistics containing the following minimum data:

1. The hospitalization experience in terms of the number of days of inpatient hospitalization experienced per 1,000 enrollees on a quarterly basis, year-to-date basis, and annualized basis; and

2. The average number of physician inpatient and outpatient visits per enrollee on a quarterly basis, year-to-date basis, and annualized basis.

(f) Quarterly reports shall be submitted according to the following schedule:

1. The report for the first quarter, January 1 to March 31, shall be submitted no later than May 15;

2. The report for the second quarter, April 1 to June 30, shall be
submitted no later than August 15.

3. The report for the third quarter, July 1 to September 30, shall be submitted no later than November 15; and

4. The report for the last quarter, October 1 to December 31, shall be submitted concurrently with the annual report required in Subsection 1.

(3) The Department may add or delete information required on an annual and quarterly basis upon written notification to each health maintenance organization.

(4) Federally qualified health maintenance organizations may submit copies of reports submitted to federal authorities which contain substantially the same information required in (2) and (3).

420-5-6.15 **Exceptions.**

(1) The Department may, at its discretion, for justifiable reasons and only in cases where the health, safety, and welfare of any citizens would not be impaired, grant exceptions to and departures from this Chapter when the policy objectives and intentions of this Chapter are otherwise substantially met.

(2) A request for exceptions to this Chapter shall be made in writing to the Department. A request, whether approved or not, will be retained on file by the Department. An approved request shall be retained on file by the health maintenance organization during the period the exception remains in effect.

(3) An exception granted under this Chapter may be revoked by the Department at its discretion for good cause whenever the policy objectives and intentions for granting the exception will no longer be furthered.

(4) The Department will give written notice revoking an exception and will state the reason for its action and a specific date upon which the exception will be terminated.

(a) The Department will provide a reasonable time between the date of written notice of revocation and the date of termination of an exception from compliance with the applicable regulations.

(b) Failure of the health maintenance organization to comply by the specified date may result in action to revoke the previously approved Certificate of Authority.

(c) The Department's denial or revocation of an exception is a final agency action and shall be appealable in accordance with Code of Ala., 1975, '27-21A-1, et seq.