REGULATION 1403

MANAGED CARE ORGANIZATIONS

Sections

1.0 Purpose and Statutory Authority

1.1 The purpose of this Regulation is to implement 18 **Del. C.** Ch. 64, as amended effective July 6, 2006, which transferred regulatory authority over Managed Care Organizations from the Department of Health and Social Services to the Department of Insurance. This Regulation is promulgated pursuant to 18 **Del. C.** §6408 and 29 **Del. C.** Ch. 101.

2.0 Definitions

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

"Chief Executive Officer" means the individual employed to manage and direct the activities of the MCO.

"Adverse determination" means a decision by an MCO to deny (in whole or in part), reduce, limit or terminate benefits under a health care contract.

"Appeal" means a request for external review of an MCO's determination resulting in a denial, termination or other limitations of covered health services based on medical necessity or appropriateness of services

"Appropriateness of services" means an appeal classification for adverse determinations that are made based on identification of treatment as cosmetic, investigational, experimental or

not an appropriate or preferred treatment method or setting for the condition for which treatment is sought.

"Balance billing" means a health care provider's demand that a patient pay a greater amount for a given service than the amount the individual's insurer, managed care organization, or health service corporation has paid or will pay for the service.

"Basic Health Services" means a range of health care services, including at least the following:

A. Physician services, including consultant and referral services, by a physician licensed by the State of Delaware;

B. At least 365 days of inpatient hospital services;

C. Medically necessary emergency health services;

D. Diagnostic laboratory services;

E. Diagnostic and therapeutic radiological services;

F. Preventive health services; and

G. Emergency out-of-area and out-of-network coverage.

"Carrier" means any entity that provides health insurance in this State. Carrier includes an insurance company, health service corporation, managed care organization and any other entity providing a plan of health insurance or health benefits subject to state insurance regulation. Carrier also includes any third-party administrator or other entity that adjusts, administers or settles claims in connection with health insurance.

"Certificate of Authority" means the authorization by the Department to operate the MCO. This certificate shall be deemed to be a license to operate such an organization.

"Covered health services" means services that are included in the enrollee's health care contract with the carrier.

"Covered Person": see "Enrollee."

"Department" means the Delaware Department of Insurance.

"Emergency care" means health care items or services furnished or required to evaluate or treat an emergency medical condition.

"Emergency medical condition" means a medical or behavioral condition, the onset of which is sudden, that manifests itself by symptoms of sufficient severity including, but not

limited to, severe pain, that a prudent layperson, possessing an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

A. Placing the health of the individual afflicted with such condition (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, or in the case of a behavioral condition, placing the health of such person or others in serious jeopardy;

B. Serious impairment to bodily functions;

C. Serious impairment or dysfunction of any bodily organ or part; or

D. Serious disfigurement of such person.

"Enrollee" means an individual and/or family who has entered into a contractual arrangement, or on whose behalf a contractual arrangement has been entered into with the MCO, under which the MCO assumes the responsibility to provide to such person(s) coverage for basic health services and such supplemental health services as are enumerated in the health care contract.

"Geographically accessible" means a location no greater than 30 miles or 40 minutes driving time from 90% of enrollees within MCO's geographic service area.

"Geographic service area" means the stated primary geographical area served by an MCO. The primary area served shall be a radius of not more than 20 miles or more than 30 minutes driving time from a primary care office operated or contracted by the MCO.

"Grievance" means a request by an enrollee that an MCO review an adverse determination by means of the MCO's internal review process.

"Health care contract" means any agreement between an MCO and an enrollee or group plan which sets forth the services to be supplied to the enrollee in exchange for payments made by the enrollee or group plan.

"Health care professional" means an individual engaged in the delivery of health care services as licensed or certified by the State of Delaware.

"Health care services" means any services included in the furnishing to any individual of medical or dental care, or hospitalization or incidental 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.

"Independent Health Care Appeals Program" means a program administered by the Department which provides for a review by an Independent Utilization Review Organization.

"Independent Utilization Review Organization (IURO)" means an entity that conducts independent external reviews of a carrier's determinations resulting in a denial, termination, or

other limitation of covered health care services based on medical necessity or appropriateness of services.

"Intermediary" means a person authorized to negotiate and execute provider contracts with MCOs on behalf of health care providers or on behalf of a network.

"Internal review process" means a procedure established by an MCO for internal review of an adverse determination.

"Level 1 trauma center" means a regional resource trauma center that has the capability of providing leadership and comprehensive, definitive care for every aspect of injury from prevention through rehabilitation.

"Level 2 trauma center" means a regional trauma center with the capability to provide initial care for all trauma patients. Most patients would continue to be cared for in this center; there may be some complex cases which would require transfer for the depth of services of a regional Level 1 or specialty center.

"Managed Care Organization (MCO)" means a public or private organization, organized under the laws of any state, which:

A. Provides or otherwise makes available to enrollees health care services, including at least the basic health services defined in this section;

B. Is primarily compensated (except for co-payment) for the provision of basic health services to enrollee on a predetermined periodic rate basis; and

C. Provides physician services.

An MCO may also arrange for health care services on a prepayment or other financial basis.

"Medical necessity" means providing of covered health services or products that a prudent physician would provide to a patient for the purpose of diagnosing, or treating an illness, injury, disease or its symptoms in a manner that is:

A. In accordance with generally accepted standards of medical practice;

B. Consistent with the symptoms or treatment of the condition; and

C. Not solely for anyone's convenience.

"Network" means the participating providers delivering services to enrollees.

"Office" means any facility where enrollees receive primary care or other health care services.

"Out of area coverage" means health care services provided outside the MCO's geographic service areas with appropriate limitations and guidelines acceptable to the Department. At a minimum, such coverage must include emergency care.

"Participating provider" means a provider who, under a contract with the MCO or with its contractor or sub contractor, has agreed to provide health care services to enrollees with an expectation of receiving payment, other than coinsurance, co-payments or deductibles, directly or indirectly from the MCO.

"Premium" means payment(s) called for in the health care contract which must be:

A. Paid or arranged for by, or on behalf of, the enrollee before health care services are rendered by the MCO;

B. Paid on a periodic basis without regard to the date on which health care services are rendered; and

C. With respect to an individual enrollee, are fixed without regard to frequency, extent or cost of health services actually furnished.

"Primary care physician (PCP)" means a participating physician chosen by the enrollee and designated by the MCO to supervise, coordinate, or provide initial care or continuing care to an enrollee, and who may be required by the MCO to initiate a referral for specialty care and maintain supervision of health care services rendered to the enrollee.

"Provider" means a health care professional or facility.

"Staff Model MCO" means an MCO in which physicians are employed directly by the MCO or in which the MCO directly operates facilities which provide health care services to enrollees.

"Tertiary services" means health care services provided for the intensive treatment of critically ill patients who require extraordinary care on a concentrated basis in special diagnostic categories (e.g., burns, cardiovascular, neonatal, pediatric, oncology, transplants, etc.).

"Utilization review" means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, efficacy, and/or efficiency of, health care services, procedures or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning, or retrospective review.

3.0 Certificate of Authority

3.1 Each application for a Certificate of Authority as a Managed Care Organization shall be made on Form No. H-1 entitled "Application for Certificate of Authority as a Managed Care Organization" (Exhibit A to this regulation). The application shall be accompanied by the following:

3.1.1 The information specified in 18 **Del. C.** §6404(a);

3.1.2 Evidence of accreditation by a nationally-recognized managed care accrediting organization such as the National Committee for Quality Assurance (NCQA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or similar organization;

3.1.3 For Staff Model MCOs, evidence that the MCO satisfies the physical plant requirements of a hospital as specified by the Delaware Department of Health and Social Services;

3.1.4 Copies of management, agency or administrative contracts;

3.1.5 Equifax Reports on Officers/Directors; and/or NAIC biographical or other similar biographical forms, as directed by the Department;

3.1.6 Proof of $50,000 bond for each officer, director, partner, or other individual who receives, collects or invests money;

3.1.7 "Admittance Questionnaire for Certificate of Authority for Managed Care Organization," Form No. H-2 (Exhibit B to this regulation);

3.1.8 "Designation of official authorized to appoint and remove agents," Form No. H-3 (Exhibit C to this regulation);

3.1.9 "Designation of person to receive bulletins, regulations, etc.," Form No. H-4 (Exhibit D to this regulation);

3.1.10 "Designation of person to receive service of process," Form No. H-5 (Exhibit E to this regulation);

3.1.11 "Biographical Affidavit of Officers and Directors" (Exhibit F to this regulation); and

3.1.12 "Power of Attorney Form" (Exhibit G to this regulation).

3.2 Each application for a Certificate of Authority as a Managed Care Organization shall be accompanied by a $750 filing fee in accordance with 18 **Del. C.** §6409.

3.3 Each application for a Certificate of Authority as a Managed Care Organization shall be accompanied by a deposit of $100,000 in accordance with 18 **Del.C.** §513(f).

3.4 All of the items and information specified in the foregoing sections 3.1 through 3.3 must be submitted in order for the Department to review an application for a Certificate of Authority.

3.5 Denial of Application for Certificate of Authority

3.5.1 If, within 60 days after a complete application for a Certificate of Authority has been filed, the Department has not issued such certificate, the Department shall immediately notify the applicant, in writing, of the reasons why such certificate has not been issued, and the applicant shall be entitled to request a hearing on the application.

3.5.2 The hearing shall be held within 60 days of the Department's receipt of the applicant's written request therefor. Proceedings in regard to such hearing shall be conducted in accordance with provisions for case decisions as set forth in the Administrative Procedures Act, Chapter 101 of Title 29, and in accordance with applicable rules and regulations of the Department.

4.0 Capital Funds Required

4.1 Each MCO that obtains a Certificate of Authority shall have and maintain unimpaired capital stock or unimpaired basic surplus of at least $300,000 and free surplus of at least $150,000 or the minimum capital and free surplus as may be required by legislative changes adopted by the General Assembly from time to time. These capital and surplus requirements are in addition to the deposit requirements of 18 **Del.C.** §513(f).

4.2 Each MCO that obtains a Certificate of Authority shall demonstrate that it has provider contracts which require that the provider agrees in the event of non-payment by the MCO that the provider will not seek compensation or have any recourse against an enrollee, as described in section 7.0 of this regulation. In the event that the MCO has not entered into such agreements with all providers, the MCO must demonstrate to the Department's satisfaction that it has made a good faith effort to enter into these agreements. In lieu of these executed provider agreements, the Department, at its discretion, may allow the MCO to engage in the business of a managed care organization if the MCO establishes reserves equal to 25% of the total projected annual incurred claims or benefits payments attributable to the provider which or who has not agreed to enter into a provider agreement.

4.3 Annually, at the time of filing the annual report on June 1, each MCO which has a current Certificate of Authority shall demonstrate that it is in compliance with the requirements of Sections 4.1 and 4.2 of this regulation.

5.0 Reinsurance Requirement

5.1 Each MCO shall secure insurance reinsurance protection to provide to the MCO in the event of catastrophic or unusual losses which would be in excess of the levels of loss which the MCO assumes in the basis of its calculation of premium charges.

6.0 Special Requirement in the Event of Financial Impairment/Insolvency

6.1 In the event of the financial impairment or insolvency of an MCO doing business in this State, each MCO doing business in this State shall permit a 60-day "open enrollment" period for existing enrollees of the impaired/insolvent MCO to enroll in a solvent MCO.

6.2 Each such solvent licensed MCO shall be required to accept within the "open enrollment" period any enrollee who wishes to enroll at the rates or costs and benefits which are then in effect at the chosen MCO for the class or grouping represented by the enrollee.

6.3 Each such solvent licensed MCO shall accept such enrollee without any waiting periods or pre-existing conditions exclusions and such acceptance both as to premium as well as delivery of service shall be retroactive to the date on which a court of competent jurisdiction has declared the predecessor MCO financially impaired.

7.0 Required Contractual Provisions

7.1 Every contract between an MCO and a participating provider shall contain the following language:

7.1.1 “Provider agrees that in no event, including but not limited to nonpayment by the MCO or intermediary, insolvency of the MCO or intermediary, or breach of this agreement, shall the provider bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against an enrollee or a person (other than the MCO or intermediary) acting on behalf of the enrollee for services provided pursuant to this agreement. This agreement does not prohibit the provider from collecting coinsurance, deductibles or co-payments, as specifically provided in the evidence of coverage, or fees for uncovered services delivered on a fee-for-service basis to enrollees.”

7.1.2 “In the event of an MCO or intermediary insolvency or other cessation of operations, covered services to enrollees will continue through the period for which a premium has been paid to the MCO on behalf of the enrollee or until the enrollee’s discharge from an inpatient facility, whichever time is greater. Covered benefits to enrollees confined in an inpatient facility on the date of insolvency or other cessation of operations will continue until their continued confinement in an inpatient facility is no longer medically necessary.”

7.2 The contract provisions that satisfy the requirements of Section 7.1 above shall be construed in favor of the enrollee, shall survive the termination of the contract regardless of the reason for termination, including the insolvency of the MCO, and shall supersede any oral or written contrary agreement between a participating provider and an enrollee or the representative of an enrollee if the contrary agreement is inconsistent with the hold harmless and continuation of covered services provisions required by Section 7.1 above.

7.3 A contract between an MCO and a participating provider shall not contain definitions or other provisions that conflict with the definitions or provisions contained in this regulation.

8.0 Enrollee Rights and Responsibilities

8.1 The MCO shall establish and implement written policies and procedures regarding the rights of enrollees and the implementation of these rights.

8.2 The MCO shall disclose to each new enrollee, and any enrollee upon request, in a format and language understandable to a layperson, the following minimum information:

8.2.1 Benefits covered and exclusions or limitations, including restrictions related to preexisting conditions;

8.2.2 Out-of-pocket costs to the enrollee;

8.2.3 Lists of participating providers;

8.2.4 Policies on the use of primary care physicians, referrals, use of out of network providers, and out of area services;

8.2.5 Policies governing the provision of emergency and urgent care;

8.2.6 Written explanation of the internal and external review processes;

8.2.7 For staff model MCOs, the location and hours of its inpatient and outpatient health services;

8.2.8 A statement of enrollee's rights that includes at least the right:

8.2.8.1 To available and accessible services when medically necessary, including availability of care 24 hours a day, seven days a week for urgent or emergency conditions;

8.2.8.2 To be treated with courtesy and consideration, and with respect for the enrollee's dignity and need for privacy;

8.2.8.3 To be provided with information concerning the MCO's policies and procedures regarding products, services, providers, grievance procedures and other information about the organization and the care provided;

8.2.8.4 To choose a primary care provider within the limits of the covered benefits and plan network, including the right to refuse care of specific practitioners;

8.2.8.5 To receive from the enrollee's physician(s) or provider, in terms that the enrollee understands, an explanation of his complete medical condition, recommended treatment, risk(s) of the treatment, expected results and reasonable medical alternatives. If the enrollee is not capable of understanding the information, the explanation shall be provided to his next of kin or guardian and documented in the enrollee's medical record;

8.2.8.6 To formulate advance directives;

8.2.8.7 To all the rights afforded by law or regulation as a patient in a licensed health care facility, including the right to refuse medication and treatment after possible consequences of this decision have been explained in language the enrollee understands;

8.2.8.8 To prompt notification of termination or changes in benefits, services or provider network;

8.2.8.9 To file a grievance with the MCO and to receive a response to the grievance within a reasonable period of time; and

8.2.8.10 To file a petition for arbitration or appeal for review by an Independent Utilization Review Organization, as appropriate.

8.2.9 A complete statement of responsibilities of enrollees.

8.3 In the case of nonpayment by the MCO to a participating provider for a covered service in accordance with the enrollee's health care contract, the provider may not bill the enrollee. This does not prohibit the provider from collecting coinsurance, deductibles or co-payments as determined by the MCO. This does not prohibit the provider and enrollee from agreeing to continue services solely at the expense of the enrollee, as long as the provider clearly informs the enrollee that the MCO will not cover these services.

9.0 Provider Relations

9.1 An MCO shall establish a mechanism by which participating providers will be notified on an ongoing basis of the specific covered health services for which the provider will be responsible, including any limitations or conditions on services.

9.2 An MCO shall establish procedures for resolution of administrative, payment or other disputes between providers and the MCO.

9.3 The MCO shall establish a policy governing termination of providers. The policy shall include at least:

9.3.1 Written notification to each enrollee six weeks prior to the termination or withdrawal from the MCO's provider network of an enrollee's primary care physician except in cases where termination was due to unsafe health care practices; and

9.3.2 Except in cases where termination was due to unsafe health care practices that compromise the health or safety of enrollees, assurance of continued coverage of services at the contract price by a terminated provider for up to 120 calendar days after notification of termination in cases where it is medically necessary for the enrollee to continue treatment with the terminated provider. In cases of the pregnancy of an enrollee, medical necessity shall be deemed to have been demonstrated and coverage shall continue to completion of postpartum care.

10.0 Prohibited Practices

10.1 An MCO shall not offer incentives to a participating provider to provide less than medically necessary services to an enrollee.

10.2 An MCO shall not penalize a participating provider because the provider, in good faith, reports to State authorities any act or practice by the MCO that jeopardizes patient health or welfare.

10.3 An MCO shall not engage in any other practices prohibited by applicable provisions of Title 18 of the Delaware Code and regulations promulgated thereunder.

11.0 Quality Assurance and Operations

11.1 Medical Director's Duties. The medical director shall be responsible for the direction, provision and quality of health care services provided to enrollees, including but not limited to the following:

11.1.1 Establishing policies and procedures covering all health care services provided to enrollees;

11.1.2 Coordinating, supervising and overseeing the functioning of professional services;

11.1.3 Providing clinical direction and leadership to the continuous quality improvement and utilization management programs;

11.1.4 Providing clinical direction to physicians responsible for utilization management determinations;

11.1.5 Establishing a committee responsible for delineating qualifications of participating providers and reviewing and verifying credentials of participating providers;

11.1.6 Evaluating the medical aspects of provider contracts; and

11.1.7 Overseeing the continuing in-service education of professional staff.

11.2 Health Care Professional Credentialing

11.2.1 General Responsibilities. An MCO shall:

11.2.1.1 Establish written policies and procedures for credentialing verification of all health care professionals with whom the MCO contracts and apply these standards consistently;

11.2.1.2 Verify the credentials of a health care professional before entering into a contract with that health care professional;

11.2.1.3 Make available for review by the applying health care professional upon written request all application and credentialing verification policies and procedures;

11.2.1.4 Retain all records and documents relating to a health care professional's credentialing verification process for not less than four years; and

11.2.1.5 Keep confidential all information obtained in the credentialing verification process, except as otherwise provided by law.

11.2.2 Selection standards for participating providers shall be developed for primary care professionals and each health care professional discipline. The standards shall be used in determining the selection of health care professionals by the MCO, its intermediaries and any provider networks with which it contracts. Selection criteria shall not be established in a manner:

11.2.2.1 That would allow an MCO to avoid high-risk populations by excluding providers because they are located in geographic areas that contain populations or providers presenting a risk of higher than average claims, losses or health services utilization; or

11.2.2.2 That would exclude providers because they treat or specialize in treating populations presenting a risk of higher than average claims, losses or health services utilization.

11.2.3 Nothing in these regulations shall be construed to require an MCO to select a provider as a participating provider solely because the provider meets the MCO's credentialing verification standards, or to prevent the MCO from utilizing separate or additional criteria in selecting the health care professionals with whom it contracts.

11.2.4 Verification Responsibilities. An MCO shall:

11.2.4.1 Obtain primary verification of at least the following information about the applicant:

11.2.4.1.1 current license, certification, or registration to render health care in Delaware and history of same;

11.2.4.1.2 current level of professional liability coverage, if applicable;

11.2.4.1.3 status of hospital privileges, if applicable;

11.2.4.1.4 specialty board certification status, if applicable; and

11.2.4.1.5 current Drug Enforcement Agency (DEA) registration certificate, if applicable.

11.2.4.2 Obtain, subject to either primary or secondary verification:

11.2.4.2.1 the health care professional's record from the National Practitioner Data Bank; and

11.2.4.2.2 the health care professional's malpractice history.

11.2.4.3 Not less than every three years obtain primary verification of a participating health care professional's:

11.2.4.3.1 current license or certification to render health care in Delaware;

11.2.4.3.2 current level of professional liability coverage, if applicable;

11.2.4.3.3 status of hospital privileges, if applicable;

11.2.4.3.4 current DEA registration certificate, if applicable; and

11.2.4.3.5 specialty board certification status, if applicable.

11.2.4.4 Require all participating providers to notify the MCO of changes in the status of any of the items listed in this section 11.2.4 at any time and identify for participating providers the individual to whom they should report changes in the status of an item listed in this section 11.2.4.

11.2.5 Health Care Professional's Right to Review Credentialing Verification Information. An MCO shall provide a health care professional the opportunity to review and correct information submitted in support of that health care professional's credentialing verification application.

11.3 Provider Network Adequacy

11.3.1 Primary, Specialty and Ancillary Providers

11.3.1.1 The MCO shall maintain an adequate network of primary care providers, specialists, and other ancillary health care resources to serve enrollees at all times.

11.3.1.2 If a plan has an insufficient number of providers that are geographically accessible and available within a reasonable period of time to provide covered

health services to enrollees, the MCO shall cover non-network providers, and shall prohibit balance billing.

11.3.1.3 The MCO shall allow referral to a non-network provider, upon the request of a network provider, when medically necessary covered health services are not available through network providers, or the network providers are not available within a reasonable period of time. The MCO shall make acceptable service arrangements with the provider and enrollee, and shall prohibit balance billing.

11.3.2 Facility and Ancillary Health Care Services

11.3.2.1 The MCO shall maintain contracts or other arrangements acceptable to the Department with institutional providers which have the capability to provide covered health services to enrollees and are geographically accessible.

11.3.2.2 The MCO shall make acceptable service arrangements with the provider and enrollee, and shall prohibit balance billing, if the appropriate level of service is not geographically accessible. These services will not be limited to the State of Delaware. These services could include but are not limited to tertiary services, burn units and transplant services.

11.3.3 Emergency and Urgent Care Services

11.3.3.1 The MCO shall establish written policies and procedures governing the provision of emergency and urgent care which shall be distributed to each enrollee at the time of initial enrollment and after any revisions are made. These policies shall be easily understood by a layperson.

11.3.3.2 When emergency care services are performed by non-network providers, the MCO shall make acceptable service arrangements with the provider and enrollee, and shall prohibit balance billing. In those cases where the MCO and the provider cannot agree upon the appropriate charge, the provider may petition the Department for arbitration.

11.3.3.3 Enrollees shall have access to emergency care 24 hours per day, seven days per week. The MCO shall cover emergency care necessary to screen and stabilize an enrollee and shall not require prior authorization of such services if a prudent lay person acting reasonably would have believed that an emergency medical condition existed.

11.3.3.4 Emergency and urgent care services shall include but are not limited to:

11.3.3.4.1 medical and psychiatric care, which shall be available 24 hours a day, seven days a week;

11.3.3.4.2 trauma services at any designated Level I or II trauma center as medically necessary. Such coverage shall continue at least until the enrollee is medically stable, no longer requires critical care, and can be safely transferred to another facility,

in the judgment of the treating physician. If the MCO requests transfer to a hospital participating in the MCO network, the patient must be stabilized and the transfer effected in accordance with federal regulations at 42 CFR 489.20 and 42 CFR 489.24;

11.3.3.4.3 out of area health care for urgent or emergency conditions where the enrollee cannot reasonably access in-network services;

11.3.3.4.4 hospital services for emergency care; and

11.3.3.4.5 upon arrival in a hospital, a medical screening examination, as required under federal law, as necessary to determine whether an emergency medical condition exists.

11.3.3.5 When an enrollee has received emergency care from a non-network provider and is stabilized, the enrollee or the provider must request approval from the MCO for continued post-stabilization care by a non-network provider. The MCO is required to approve or disapprove coverage of post-stabilization care as requested by a treating physician or provider within the time appropriate to the circumstances relating to the delivery of services and the condition of the enrollee, but in no case to exceed one hour from the time of the request.

11.3.4 The MCO shall submit evidence of network adequacy to the Department upon request. If the Department receives a complaint regarding an MCO's network adequacy, the burden shall be on the MCO to prove network adequacy to the satisfaction of the Department.

11.4 Utilization Management

11.4.1 The MCO shall establish and implement a comprehensive utilization management program to monitor access to and appropriate utilization of health care and services. The program shall be under the direction of a designated physician and shall be based on a written plan that is reviewed at least annually.

11.4.2 Utilization management determinations shall be based on written clinical criteria and protocols reviewed and approved by practicing physicians and other licensed health care providers within the network. These criteria and protocols shall be periodically reviewed and updated, and shall, with the exception of internal or proprietary quantitative thresholds for utilization management, be readily available, upon request, to affected providers and enrollees.

11.4.3 All materials including internal or proprietary materials for utilization management shall be available to the Department upon request.

11.4.4 Compensation to persons providing utilization review services for an MCO shall not contain incentives, direct or indirect, for these persons to make inappropriate review decisions. Compensation to any such persons may not be based, directly or indirectly, on the quantity or type of adverse determinations rendered.

11.4.5 Utilization Management Staff Availability

11.4.5.1 At a minimum, appropriately qualified staff shall be immediately available by telephone, during routine provider work hours, to render utilization management determinations for providers.

11.4.5.2 The MCO shall provide enrollees with a toll free telephone number by which to contact customer service staff on at least a five day, 40 hours a week basis.

11.4.5.3 The MCO shall supply providers with a toll free telephone number by which to contact utilization management staff on at least a five day, 40 hours a week basis.

11.4.5.4 The MCO must have policies and procedures addressing response to inquiries concerning emergency or urgent care when a PCP or his authorized on call back up provider is unavailable.

11.4.6 Utilization Management Determinations

11.4.6.1 All determinations to authorize services shall be rendered by appropriately qualified staff.

11.4.6.2 All determinations to deny or limit an admission, service, procedure or extension of stay shall be rendered by a physician. The physician shall be under the clinical direction of the medical director responsible for medical services provided to the MCO's Delaware enrollees. Such determinations shall be made in accordance with clinical and medical criteria and standards and shall take into account the individualized needs of the enrollee for whom the service, admission, procedure or extension is requested.

11.4.6.3 All determinations shall be made on a timely basis as required by the exigencies of the situation.

11.4.6.4 An MCO may not retroactively deny reimbursement for a covered health service provided to an enrollee by a provider who relied upon the written or verbal authorization of the MCO or its agents prior to providing the service to the enrollee, except in cases where the MCO can show that there was material misrepresentation, fraud or the patient was found not to have coverage.

11.4.6.5 An enrollee must receive written notice of all determinations to deny coverage or authorization for services required and the basis for the denial.

11.5 Quality Assessment and Improvement

11.5.1 Continuous Quality Improvement

11.5.1.1 Under the direction of the Medical Director or his designated physician, the MCO shall have a system-wide continuous quality improvement program to monitor the quality and appropriateness of care and services provided to enrollees. This program shall be based on a written plan which is reviewed at least semi-annually and revised as necessary.

11.5.1.2 The MCO shall assure that participating providers have the opportunity to participate in developing, implementing and evaluating the quality improvement system.

11.5.1.3 The MCO shall provide enrollees the opportunity to comment on the quality improvement process.

11.5.1.4 The MCO shall follow up on findings from the program to assure that effective corrective actions have been taken, including at least policy revisions, procedural changes and implementation of educational activities for enrollees and providers.

11.5.1.5 The MCO shall make documentation regarding the quality improvement program available to the Department upon request.

11.5.2 External Quality Audit

11.5.2.1 Each MCO shall submit, as a part of its annual report due June 1, evidence of its most recent external quality audit that has been conducted or of acceptable accreditation status.

11.5.2.2 The report of the external quality audit must describe in detail the MCO's conformance to performance standards and the rules within this regulation. The report shall also describe in detail any corrective actions proposed and/or undertaken by the MCO.

11.5.2.3 External quality audits must be completed no less frequently than once every three years. Such audit shall be performed by a nationally known accreditation organization or an independent quality review organization acceptable to the Department.

11.5.2.4 In lieu of the external quality audit, the Department may accept evidence that an MCO has received and has maintained the appropriate accreditation from a nationally known accreditation organization or independent quality review organization.

11.5.3 Reporting and Disclosure Requirements

11.5.3.1 An MCO shall document and communicate information about its quality assessment program and its quality improvement program, and shall:

11.5.3.1.1 include a summary of its quality assessment and quality improvement programs in marketing materials;

11.5.3.1.2 include a description of its quality assessment and quality improvement programs and a statement of enrollee rights and responsibilities with respect to those programs in the materials or handbook provided to enrollees; and

11.5.3.1.3 make available annually to participating providers and enrollees findings from its quality assessment and quality improvement programs and information about its progress in meeting internal goals and external standards, where available. The reports shall include a description of the methods used to assess each specific area and an explanation of how any assumptions affect the findings.

11.5.3.2 An MCO shall submit to the Department such performance and outcome data as the Department may request.

12.0 Recordkeeping and Reporting Requirements

12.1 Medical Records Retention

12.1.1 The MCO must maintain or provide for the maintenance of a medical records system which meets the accepted standards of the health care industry and State and federal regulations.

12.1.1.1 The MCO shall provide sufficient space and equipment for the processing and the safe storage of records.

12.1.1.2 Medical records shall be protected from loss, damage and unauthorized use.

12.1.2 Retention and Destruction

12.1.2.1 With the exception of medical records of minors (individuals under the age of 18 years), medical records shall be preserved as original records, on microfilm or electronically stored for no less than five years after the most recent patient care usage, after which time records may be destroyed at the discretion of the MCO.

12.1.2.2 Medical records of minors shall be preserved for the period of minority plus five years (i.e., 23 years) or as otherwise required by State law.

12.1.2.3 An MCO shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.

12.1.3 The Department shall have access to medical records for purposes of monitoring and review of MCO practices.

12.2 Reporting Requirements and Statistics

12.2.1 Annual reports. In addition to the information required to be included in an MCO's annual report as specified in 18 **Del. C.** §6406 or elsewhere in this regulation, an MCO shall submit the following information to the Department on an annual basis:

12.2.1.1 A statistical summary evaluating the network adequacy and accessibility to the enrolled population;

12.2.1.2 Annual appeal report of all grievances, petitions for arbitration and appeals under the Independent Health Care Appeals Program as required under Department Regulation 1301.

12.2.1.3 Evidence of compliance with the capital funds requirements of section 4.0 of this regulation.

12.2.2 An MCO shall submit the following information to the Department whenever there is a change:

12.2.2.1 Substantial changes in organization, bylaws, or governing board

12.2.2.2 Full name of the Chief Executive Officer

12.2.2.3 Full name of the Medical Director

12.2.2.4 Substantial changes in marketing materials, grievance procedures or the utilization management program

12.2.2.5 Any significant amendment to or revision relating to the text or subtext of an approved provider contract shall be submitted to and approved by the Department prior to the execution of an amended or revised contract with the providers of an MCO.

13.0 Compliance with Regulation

13.1 The MCO is responsible for meeting each requirement of this regulation. If the MCO chooses to utilize contract support or to contract functions under this regulation, the MCO retains responsibility for ensuring that the requirements of this regulation are met.

13.2 The Department may require a corrective action plan from an MCO when the Department determines that the MCO is not in compliance with applicable provisions of Title 18 of the Delaware Code or regulations promulgated thereunder.

14.0 Separability Provisions

14.1 If any provision of this regulation shall be held invalid, the remainder of the regulation shall not be affected thereby.