DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 9110 (16 **Del.C.** §9110)

FINAL

ORDER

4408 Managed Care Organizations (MCO)--Repeal

Nature of the Proceedings:

The Department of Health and Social Services (hereinafter "Department") was established to extend general supervision of the interests of the health and lives of the people of the State of Delaware.

The Department was previously authorized by 16 **Del.C.,** Ch. 91 to promulgate regulations to effectuate those objectives by regulating managed care organizations operating within Delaware.

Pursuant to 16 **Del.C.,** Ch. 91, the Department is no longer authorized to regulate managed care organizations operating within Delaware. This authority has been transferred to the Department of Insurance. Therefore, all regulations previously promulgated by the Department are hereby **repealed.**

Pursuant to 29 **Del.C.** §10113(b)(5), no public hearing or period of public comment is required for amendments to existing regulations to make them consistent with changes in basic law.

The Department **repealed** the attached amendments on January 23, 2008.

Summary of the Evidence and Information Submitted

No period of public comment is required for Amendments to existing regulations to make them consistent with changes in basic law. 29 **Del.C.** §10113(b)(5).

Findings of Fact:

WHEREAS, the Department was previously charged with the regulation of managed care organizations operating within Delaware;

WHEREAS, 16 **Del.C.,** Ch. 91 transferred the authority for regulating these organizations to the Department of Insurance;

WHEREAS, due to this legislative change, the Department is no longer statutorily authorized to regulate these organizations;

NOW, THEREFORE, in consideration of these premises, and with the authority in 29 **Del.C.** §10113(b)(5), the Department hereby **repeals** the attached regulations.

Decision and Effective Date

The Department hereby adopts the proposed **repeal** of the regulations to be effective 10 days following final publication of this order in the Delaware *Register of Regulations*.

Text and Citation

The text of the final regulations is attached hereto as Exhibit A and is formatted to show the repeal. This order is expected to appear in the Delaware *Register of Regulations*, Volume 11, Issue 8, February 1**,** 2008.

IT IS SO ORDERED this 23rd day of January, 2008 by the Secretary of the Department of Health and Social Services.

Vincent P. Meconi, Secretary, DHSS, 1/23/2008

Part 1: Legal Authority And Definitions

1.0 Legal Authority

These regulations are adopted under 16 **Del.C.** Ch. 91, pursuant to delegation of authority from the Secretary of the Department of Health and Social Services (DHSS) to the Director of the Division of Public Health (DPH)

2.0 Definitions

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

"Appeal" means a request to reexamine or review an adverse determination made by an MCO that denies, reduces or terminates health care benefits.

"Appellant" means an enrollee or other authorized representative of the enrollee who may appeal an MCO decision.

"Authorized Representative" means an individual who the appellant willingly acknowledges to represent her/ his interests during the appeal process. An MCO may require the appellant to submit written verification of her/ his consent to be represented. If an enrollee has been determined by a physician to be incapable of assigning the right of representation, the appeal may be filed by a family member or a legal representative.

"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 services, including at least the following:

- Physician services, including consultant and referral services, by a physician licensed by the State of Delaware.
- At least three hundred sixty five (365) days of inpatient hospital services.
- Medically necessary emergency health services.
- Initial diagnosis and acute medical treatment (at least one (1) time) and responsibility for making initial behavioral health referrals.
- Diagnostic laboratory services.
- Diagnostic and therapeutic radiological services.
- Preventive health services including at least the provision of physical examinations, papanicolaou (PAP) smears, immunizations, mammograms and childrens' eye examinations (through age 17) conducted to determine the need for vision correction and performed at a frequency determined to be appropriate medical practice. Other preventive services may be provided by the MCO as contained in the Health Care Contract.
- Health education services, including education in the appropriate use of health services, and education in the contribution each enrollee can make to the maintenance of the enrollee's own health. This information shall be understandable and not misleading.
- Emergency out of area and out of network coverage.
- Pharmacy services:
- Coverage for any outpatient drug prescribed to treat a covered person for a covered chronic, disabling, or life threatening illness provided that the drug:
    - has been approved by the Food and Drug Administration (FDA) for at least one indication; and,
    - is recognized for treatment of the indication for which the drug is prescribed in an approved prescription drug reference compendium approved by the Commissioner or a substantially accepted peer reviewed medical literature.
- Coverage of a drug shall include coverage of medically necessary services associated with the administration of the drug.
- Coverage does not include:
    - experimental drugs not otherwise approved for the proposed use or indication by the Food and Drug Administration, or

- any disease, condition, service, or treatment that is excluded from coverage under the policy.

"Carrier" means any entity that provides health insurance in this State. Carrier includes an insurance company, health service corporation, health maintenance organization and any other entity providing a plan of health insurance or health benefits subject to state insurance regulation

"Certificate of Authority" means the authorization by the Department of Health and Social Services to operate the MCO. This certificate shall be deemed to be a license to operate such an Organization.

"Certified Managed Care Organization" means a managed care organization which has been issued a Certificate of Authority under 16 **Del.C.** and either a Certificate of Authority from the Department of Insurance (DOI) under the relevant provisions of Title 18 or a statement from the DOI that the DOI Certificate of Authority is not required.

"Clinical Trials" means clinical trials that are approved or funded by use of the following entities:

- One of the National Institutes of Health (NIH);
- An NIH Cooperative group or center which is a formal network of facilities that collaborate on research projects and have an established NIH approval peer review program operating within the group. This includes, but is not limited to, the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology program.;
- The federal Departments of Veterans' Affairs or Defense;
- An institutional review board of an institution in this State that has a multiple project assurance contract approval by the office of protection for the Research Risks of the NIH; and
- A qualified research entity that meets the criteria for NIH Center Support grant eligibility.

"Commissioner" means the Insurance Commissioner of Delaware.

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

"Covered Person" see "Enrollee".

"Department" means the Delaware Department of Health and Social Services.

"Department of Insurance Certificate of Authority" means the authorization by the Insurance Commissioner that the MCO has met the relevant provisions of Title 18 of the **Delaware Code**.

"Disputable Need" means an appeal classification for adverse determinations that were made based upon identification of treatment as cosmetic or experimental.

"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:

- 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;
- Serious impairment to bodily functions;
- Serious impairment or dysfunction of any bodily organ or part; or.
- 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.

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

"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 individuals engaged in the delivery of health 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.

"Health plan" shall have the same meaning as 'health benefit plan' as defined in 18 **Del.C.** §3343(a)(2).

"Independent Health Care Appeals Program" means a program within the Department of Health and Social Services which establishes a final step in the appeal process and provides for a review by an Independent Utilization Review Organization (69.126).

"Independent Practice Association" (IPA) means an arrangement in which health care professionals provide their services through the association in accordance with a mutually accepted compensation arrangement while retaining their private practices.

"Independent Utilization Review Organization (IURO)" means an entity that conducts independent external reviews of an MCO's determinations resulting in a denial, termination, or other limitation of covered health care services.

"Insurance Department" means the Delaware Department of Insurance.

"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.

"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:

- Provides or otherwise makes available to enrolled participants health care services, including at least the basic health services defined in 69.106;
- Is primarily compensated (except for co payment) for the provision of basic health care services to the enrolled participants on a predetermined periodic rate basis; and
- Provides physician services directly through physicians who are either employees or partners of such organization, or through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual practice 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:

- In accordance with generally accepted standards of medical practice;
- Consistent with the symptoms or treatment of the condition; and
- Not solely for anyone's convenience.

"Network" means the participating providers delivering services to enrollees in a managed care plan.

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

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

"Participating Provider" means a provider who, under a contract with the Organization or with its contractor or subcontractor, 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 Organization.

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

- Paid or arranged for by, or on behalf of, the enrollee before health care services are rendered by the MCO;
- Paid on a periodic basis without regard to the date on which health services are rendered; and

- 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 health care 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.

"Standing Referral" means a treatment period during which a health care specialist shall be permitted to treat an enrollee without further referral from the enrollee's primary care physician and during which this specialist may authorize further referrals, procedures, tests, and other medical services which the enrollee's primary care physician would otherwise be permitted to provide or authorize.

"Supplemental Payment" means any payment not incorporated in the premium which is required to be paid to the MCO or providers under contract to the MCO by the enrollee.

"Supplementary Health Services" means any health services other than basic health services which may be provided by a MCO to its enrollees and/or for which the enrollee may contract such as:

- Long term care;
- Vision care not included in basic health services;
- Dental services;
- Behavioral health services;
- Long term physical medicine or rehabilitative services;
- Additional pharmacy services;
- Infertility services; and
- Other services, such as occupational therapy, nutritional, home health, homemaker, hospice and family planning services.

"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.

5 DE Reg. 130 (7/1/01)
5 DE Reg. 1435 (1/1/02)

Part 2: Application And Certificate Of Authority

3.0 Application And Certificate Of Authority

3.1 No person shall establish or operate an MCO in the State of Delaware or enter this State for purposes of enrolling persons in an MCO without obtaining a "Certificate of Authority" under 16 **Del.C.** Ch. 91. A foreign corporation shall not be eligible to apply for such certificate unless it has first qualified to do business in the State of Delaware as a foreign corporation pursuant to 8 **Del.C.** §371.

3.2 Each application for a Certificate of Authority shall be made in writing to the Department of Health and Social Services, shall be certified by an officer or authorized representative of the applicant, shall be in a form prescribed by the Department and shall set forth or be accompanied by the following:

3.2.1 Organizational Information

3.2.1.1 Brief history and description of current status of applicant, including an organization chart;

3.2.1.2 A copy of the basic organizational documents such as the certificate of incorporation, articles of association, or other appropriate documents and amendments thereto;

3.2.1.3 A list of the names, addresses and official positions of the persons who are to be responsible for the conduct of the affairs of the applicant. Include all members of the Board of Directors or other governing board, the principal officers in the case of a corporation, and the partners or members in the case

~~of a partnership or association; and~~

~~3.2.1.4 A list of positions and names for all management personnel.~~

~~3.2.2 Health Services Delivery~~

~~3.2.2.1 A description of the plan of operation of the MCO. Include the following items:~~

~~3.2.2.1.1 a listing of basic health services and supplemental health services with utilization projections; and~~

~~3.2.2.1.2 the arrangements for delivery of all covered health services (including details as to whether outpatient services are provided directly or through referrals/purchase agreements with outside fee for service providers); a description of service sites or facilities (specifying days and hours of operation in the case of outpatient facilities); and all special policies or provisions designed to improve accessibility of services.~~

~~3.2.2.2 A sample of the contract, agreement or arrangement between the MCO and providers, including individual physicians, IPAs, group practices, hospitals, laboratory services, nursing homes, home health agencies, and other providers. Any contract, agreement or arrangement which deviates substantially from the sample must be submitted to the OHFLC as executed. In addition, copies of executed contracts or letters of agreement between an IPA or medical group and its member or non-member physicians and other health professionals must be submitted;~~

~~3.2.2.3 A list of participating physicians by specialty and by geographic area as well as a list of other health care personnel providing services. Each physician included on the list must be identified as accepting or not accepting new patients and if there are any limitations on that physician's accepting any enrollees as patients. Staffing ratios shall be prepared for each geographic area in which the MCO proposes to operate. Staffing ratios are the number of physicians or providers by specialty per enrollee;~~

~~3.2.2.4 For staff model MCOs, a list of facilities that show the capacity, square footage, and the legal arrangements for use of the facility (leases, subleases, contract of sale, etc.). Provide copies of leases, contracts of sale, or other legal agreements relating to the facilities to be operated by the MCO;~~

~~3.2.2.5 All of the applicant's utilization review and utilization management, utilization control, quality assurance mechanisms, policies, manuals, guidelines, and materials;~~

~~3.2.2.6 The arrangements for assuring continuity of care for all services provided to enrollees. Include comments on policies related to the primary care physician's responsibilities for coordination and oversight of the enrollee's overall health care and the impact of the medical record keeping system on continuity of care;~~

~~3.2.2.7 Procedures utilized by the applicant for determining and ensuring network adequacy;~~

~~3.2.2.8 Procedures utilized by the applicant for the credentialing of providers;~~

~~3.2.2.9 Procedures for addressing enrollee grievances;~~

~~3.2.2.10 Any materials or procedures utilized by the applicant for measuring or assessing the satisfaction of enrollees; and~~

~~3.2.2.11 Procedures for monitoring enrollee access to participating providers including but not limited to:~~

~~3.2.2.11.1 appointment scheduling guidelines;~~

~~3.2.2.11.2 standards for office wait times; and~~

~~3.2.2.11.3 standards for provider response to urgent and emergent issues during and after business hours.~~

~~3.2.3 Enrollment and Marketing~~

~~3.2.3.1 A description of the geographic area to be served, with a map showing service area boundaries, locations of the MCO's participating providers, PCPs, institutional and ambulatory care facilities, and travel times from various points in the service area to the nearest ambulatory and institutional services;~~

~~3.2.3.2 Identification of all information to be released to enrollees or prospective enrollees;~~

~~3.2.3.3 A description of the proposed marketing techniques and sample copies of any advertising or promotional materials to be used within Delaware or to which Delaware citizens would be exposed;~~

3.2.3.4 Enrollee handbooks proposed for use. A finalized enrollee handbook shall also be submitted upon completion; and

3.2.3.5 Procedures for notifying enrollees of plan changes.

3.2.4 Financial

3.2.4.1 Financial information submitted to the Department of Insurance shall be deemed to meet the requirement of 16 **Del.C.** §9104(4).

3.3 Within sixty (60) days after receipt of a complete application for issuance of Certificate of Authority the Department shall determine whether the applicant, with respect to health care services to be furnished, has:

3.3.1 demonstrated the ability to provide such health services in a manner assuring availability, accessibility and continuity of services;

3.3.2 made arrangements for an ongoing health care quality assurance program;

3.3.3 the capability to comply with all applicable rules and regulations promulgated by the Department;

3.3.4 the capability to provide or arrange for the provision to its enrollees of basic health care services on a prepaid basis through insurance or otherwise, except to the extent of reasonable requirements of co-payments; and

3.3.5 for staff model MCOs, the staff and facilities to directly provide at least half of the outpatient medical care costs of its anticipated enrollees on a prepaid basis.

3.4 The Department shall issue a Certificate of Authority to any person filing an application under this section upon demonstration of compliance with these rules and regulations if:

3.4.1 The application contains all the information required under section 3.2 of this Part;

3.4.2 The Department has not made a negative determination pursuant to 69.203 of this Part; and

3.4.3 Payment of the application fees prescribed in 16 **Del.C.** Ch. 91, has been made.

3.5 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. The hearing shall be held within 60 days of receipt of 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, 29 **Del.C.** Ch. 101, and in accordance with applicable rules and regulations of the Department (63 **Del. Laws,** c.382, §1;66 **Del. Laws**, c. 124, §7).

3.6 No Certificate of Authority shall be issued without a Certificate of Authority from the DOI under the relevant provisions of Title 18 or a statement from the DOI that the DOI Certificate of Authority is not required.

3.7 If a deposit is required, it shall be continuously maintained in trust. In case of a deficiency of deposit, the Insurance Commissioner shall transmit notice thereof to both the MCO and the Department. In case the deficiency is not cured within the allowed time, the Commissioner shall give notice thereof to the Department and the Department shall revoke its Certificate of Authority to the MCO.

5 DE Reg. 130 (7/1/01)

5 DE Reg. 1435 (1/1/02)

Part 3: General Requirements

4.0 General Requirements

4.1 Every MCO operating in this State shall file with the Department every manual concerning: enrollee services rights and responsibilities; policies and procedures relating to health plan coverage; complaint and appeal criteria; and, any other manual upon request. Every filing shall indicate the effective date thereof.

4.2 Annual reports shall be filed with the Department by any MCO on or before June 1 covering the preceding fiscal year. Such reports shall include any changes in the information originally submitted or required under sections 3.0, 8.9, 9.2 and 22.0. Financial information submitted to the Department of Insurance shall be deemed to meet the requirement of 16 **Del.C.** §9104(4).

4.3 Contract Provisions

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

4.3.1.1 "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."

4.3.1.2 "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."

4.3.1.3 The contract provisions that satisfy the requirements of Subsections 4.3.1.1 and 4.3.1.2 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 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 sections 4.3.1.1 and 4.3.1.2 above.

4.3.1.4 Every contract between an MCO and a participating provider shall state that in no event shall a participating provider collect or attempt to collect from an enrollee any money owed to the provider by the MCO.

4.4 Amendments or Revisions of Contracts

4.4.1 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.

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

4.5.1 Written notification to each enrollee six (6) 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 practice; and

4.5.2 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 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.

4.6 The Medical Director and physicians designated to act on his behalf shall be Delaware licensed physicians.

4.7 Prohibited Practices

4.7.1 No MCO or representative may cause or permit the use of advertising or solicitation which is untrue or misleading.

4.7.2 No MCO may cancel or refuse to renew the enrollment of an enrollee solely on the basis of her/his health. This does not prevent the MCO from canceling the enrollment of an enrollee if misstatements of her/his health were made at the time of enrollment, or prevent the MCO from canceling or refusing to renew enrollment for reasons other than an enrollee's health including without limitation, nonpayment of premiums or fraud by the enrollee.

4.7.3 An MCO contract shall contain no provision or nondisclosure clause prohibiting physicians or other health care providers from giving patients information regarding diagnoses, prognoses and treatment options.

4.7.4 An MCO shall not deny, exclude or limit benefits for a covered individual for losses due to a preexisting condition where such were incurred more than twelve (12) months following the date of enrollment in such plan or, if earlier, the first day of the waiting period for such enrollment.

4.7.5 An MCO shall not impose any preexisting condition exclusion relating to pregnancy or in the case of a child who is adopted or placed for adoption before attaining eighteen (18) years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or

placement for adoption.

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

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

4.7.8 A contract between an MCO and a provider shall not contain definitions or other provisions that conflict with the definitions or provisions contained in these regulations.

4.8 An MCO shall establish a mechanism by which the participating provider 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.

4.9 An MCO shall notify participating providers of the providers' responsibilities with respect to the MCO's applicable administrative policies and programs, including but not limited to payment terms, utilization review, quality assessment and improvement programs, credentialing, grievance procedures, data reporting requirements, confidentiality requirements and any applicable federal or state programs.

4.10 The rights and responsibilities under a contract between an MCO and a participating provider shall not be assigned or delegated by the provider without the prior written consent of the MCO.

4.11 An MCO is responsible for ensuring that a participating provider furnishes covered benefits to all enrollees without regard to the enrollee's enrollment in the plan as a private purchaser of the plan or as a participant in publicly financed programs of health care services. This requirement does not apply to circumstances when the provider should not render services due to limitations arising from lack of training, experience, skill or licensing restrictions.

4.12 An MCO shall notify the participating providers of their obligations, if any, to collect applicable coinsurance, co-payments or deductibles from enrollees pursuant to the evidence of coverage, or of the providers' obligations, if any, to notify enrollees of their personal financial obligations for non-covered services.

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

4.14 Notice of Changes in MCO Operations

4.14.1 The MCO shall notify the Department, in writing, on an ongoing basis, of any substantial changes in organization, bylaws, governing board, provider contracts or agreements, marketing materials, grievance procedures, enrollee handbooks, utilization management program, and any change of inpatient acute care hospitals. The Department shall be notified on at least a quarterly basis of changes in the provider network.

4.15 Changes in Ownership Interests

4.15.1 Certificates of Authority shall not be assignable or transferable in whole or in part. Accordingly, the holder of record of any Certificate of Authority to operate in Delaware, as a condition thereof, shall comply with all of the following requirements regarding changes in ownership interests. For the purposes of this section, changes in ownership interests shall refer to changes in the ownership of the holder of record of any Certificate of Authority and/or changes in ownership of any individual, corporation or other entity which, through the ownership of voting securities, by contract or by any other means, has the authority to or does in fact direct or cause the direction of the management and/ or the policies of the MCO which is the subject of the Certificate of Authority at issue.

4.16 Examinations

4.16.1 The Department may make examinations concerning the quality of health care services of any MCO. The Department may make such examination as it deems necessary for the protection of the interests of the enrollees of the MCO, but not less frequently than every three (3) years;

4.16.2 Every MCO shall submit its books and records relating to health care services to such examinations. In the course of such examinations, the Department may administer oaths to and examine the officers and agents of the MCO and of any health care providers with which it has contracts, agreements or other arrangements. The MCO shall require a provider to make health records available to the Department employees involved in assessing the quality of care or investigating the grievances or complaints of enrollees, and to comply with the applicable laws related to the confidentiality of medical or health records; and

4.16.3 The reasonable expenses of examinations under this section shall be assessed against the MCO being examined and remitted to the Department.

4.17 Violations/Penalties

4.17.1 The Department may revoke or suspend a Certificate of Authority issued to an MCO pursuant to 16 **Del.C.** Ch. 91, or may place the MCO on probation for such period as it determines, or may publicly censure an MCO if it determines, after a hearing, that:

4.17.1.1 The MCO is operating in a manner which deviates substantially, in a manner detrimental to its enrollees, from the plan of operation described by it in securing its Certificate of Authority;

4.17.1.2 The MCO does not have in effect arrangements to provide the quantity and quality of health care services required by its enrollees;

4.17.1.3 The MCO is no longer in compliance with the requirements of 16 **Del.C.** §9104(b); or

4.17.1.4 The continued operation of the MCO would be detrimental to the health or well being of its enrollees needing services.

4.17.2 The Department may issue an order directing a health carrier or a representative of a health carrier to cease and desist from engaging in any act or practice in violation of the provisions of this act. If the Secretary elects not to issue a cease and desist order, or in the event of noncompliance with a cease and desist order, the Secretary may institute a proceeding to obtain injunctive relief.

4.17.2.1 Within twenty (20) calendar days after service of the cease and desist order, the health carrier may request a hearing on the question of whether acts or practices in violation of this act have occurred. This appeal shall not stay the cease and desist order.

4.17.3 Proceedings in regard to any hearing held pursuant to this section shall be conducted in accordance with provisions for case decisions as set forth in the Administrative Procedures Act, 29 **Del.C.** §101, and any applicable rules and regulations of the Department. Any decision rendered following a hearing shall set forth the findings of fact and conclusions of the Department as to any violations of this Chapter, and shall also set forth the reasons for the Department's choice of any sanction to be imposed. The Department's choice of sanction shall not be disturbed upon appeal, except for abuse of discretion.

4.17.4 Suspension of a Certificate of Authority pursuant to this section shall not prevent the MCO from continuing to serve all its enrollees as of the date the Department issues a decision imposing suspension, nor shall it preclude thereafter adding as enrollees newborn children or other newly acquired dependents of existing enrollees. Unless otherwise determined by the Department and set forth in its decision, a suspension shall, during the period when it is in effect, preclude all other new enrollments and also all advertising or solicitation on behalf of the MCO other than communication, approved by the Department, which are intended to give information as to the effect of the suspension.

4.17.5 In the event that the Department decides to revoke the Certificate of Authority of an MCO the decision so providing shall specify the time and manner in which its business shall be concluded. If the Department determines it is appropriate, it may refer the matter of conservation or liquidation to the Insurance Commissioner, who shall then proceed in accordance with 18 **Del.C.** Ch. 59. In any case, after the Department has issued a decision revoking a Certificate of Authority, unless stayed in connection with an appeal, the MCO shall not conduct any further business except as expressly permitted in the Department's decision and it shall engage only in such activities as are directed by the Department or are required to assist its enrollees in securing continued health care coverage.

4.17.6 The Department may require a corrective action plan from an MCO when the Department determines that the MCO is not in compliance with any of the regulations contained herein.

4.17.7 Civil Monetary Penalty (CMP)

4.17.7.1 A carrier that violates any provision of this act shall be liable to a civil penalty of not less than two hundred fifty dollars ($250.00) and not greater than ten thousand dollars ($10,000.00) for each day that the carrier is in violation of the act.

4.17.7.2 The Department shall give ten (10) calendar days written notice to the health carrier of its intent to levy such a penalty.

4.17.7.3 The health carrier may, within such 10 day period, give written notice of their desire to have a hearing. Proceedings in regard to such hearing shall be conducted in accordance with provisions for case decisions as set forth in the Administrative Procedures Act, 29 **Del.C.** Ch. 101 of the Delaware Code and in accordance with applicable rules and regulations of the Department.

4.18 Fees

4.18.1 Every MCO shall pay fees in accordance with 16 **Del.C.** §9111.

4.19 Confidentiality of Health Information

4.19.1 Any data or information pertaining to the diagnosis, treatment or health of any enrollee or applicant obtained from such person or from any health care provider by any MCO shall be held in confidence and shall not be disclosed to any person except upon the express consent of the enrollee or applicant, or his physician, or pursuant to statute or court order for the production of evidence or the discovery thereof, or in the event of claim or litigation between such person and the MCO wherein such data or information is pertinent or as may be required by the Department in the course of their examinations in accordance with section 4.16. The communication of such data or information from a health care provider to a MCO shall not prevent such data or information from being deemed confidential for purposes of the Delaware Uniform Rules of Evidence.

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

4.21 Specific standards may be waived by the Department provided that each of the following conditions are met:

4.21.1 Strict enforcement of the standard would result in unreasonable hardship on the MCO.

4.21.2 A waiver must not adversely affect the health, safety, welfare, or rights of any enrollee of the MCO.

4.21.3 The request for a waiver must be made to the Department, in writing, by the MCO with substantial detail justifying the request.

4.21.4 Prior to filing a request for a waiver, the MCO shall provide written notice of the request to each enrollee. Prior to filing a request for a waiver, the MCO shall also provide written notice of the request to the Department. The notice shall state that the enrollee has the right to object to the waiver request in writing to the Department.

4.21.5 Upon filing the request for a waiver, the MCO shall submit to the Department a copy of the notice and a sworn affidavit outlining the method by which the requirement was met. The MCO shall maintain proof of the method by which the requirement was met by the MCO for the duration of the waiver and make such proof available upon the request of the Department.

4.21.6 A waiver granted by the Department is not transferable to another MCO in the event of a change of ownership.

4.21.7 A waiver shall be granted for the term of the license.

5 DE Reg. 130 (7/1/01)
5 DE Reg. 1435 (1/1/02)

Part 4: Quality Assurance And Operations

5.0 Health Care Professional Credentialing

5.1 General Responsibilities, an MCO shall:

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

5.1.2 Verify the credentials of a health care professional before entering into a contract with that health care professional. The medical director of the MCO or other designated health care professional shall have responsibility for, and shall participate in, health care professional credentialing verification;

5.1.3 Establish a credentialing verification committee consisting of licensed physicians and other health care professionals to review credentialing verification information and supporting documents and make decisions regarding credentialing verification;

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

5.1.5 Retain all records and documents relating to a health care professionals credentialing verification process for not less than four (4) years; and

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

5.2 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.

5.3 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. The standards shall meet the requirements of sections 5.1 and 5.4. Selection criteria shall not be established in a manner:

5.3.1 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

5.3.2 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.

5.4 Qualifications of primary care providers

5.4.1 Physicians qualified to function as primary care providers include: licensed physicians who have successfully completed a residency program accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association in family practice, internal medicine, general practice, pediatrics, obstetrics gynecology or who are diplomats of one of the above certifying boards approved by the American Board of Medical Specialties or one of the certifying boards of the American Osteopathic Association.

5.5 Verification Responsibilities, an MCO shall:

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

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

5.5.1.2 Current level of professional liability coverage, if applicable;

5.5.1.3 Status of hospital privileges, if applicable;

5.5.1.4 Specialty board certification status, if applicable; and

5.5.1.5 Current Drug Enforcement Agency (DEA) registration certificate, if applicable.

5.5.2 Obtain, subject to either primary or secondary verification:

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

5.5.2.2 The health care professional's malpractice history.

5.5.3 Not less than every three (3) years obtain primary verification of a participating health care professional's:

5.5.3.1 Current license or certification to render health care in Delaware;

5.5.3.2 Current level of professional liability coverage, if applicable;

5.5.3.3 Status of hospital privileges, if applicable;

5.5.3.4 Current DEA registration certificate, if applicable; and

5.5.3.5 Specialty board certification status, if applicable.

5.5.4 Require all participating providers to notify the MCO of changes in the status of any of the items listed in this section 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.

5.6 Health Care Professionals Right to Review Credentialing Verification Information

5.6.1 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 as set forth below.

5.6.1.1 Each health care professional who is subject to the credentialing verification process shall have the right to review all information, including the source of that information, obtained by the MCO to satisfy the requirements of this section during the MCO's credentialing process.

5.6.1.2 An MCO shall notify a health care professional of any information obtained during the MCO's credentialing verification process that does not meet the MCO's credentialing verification standards or that varies substantially from the information provided to the MCO by the health care professional, except that the MCO shall not be required to reveal the source of information if the information is not obtained to meet this requirement, or if disclosure is prohibited by law.

5.6.1.3 A health care professional shall have the right to correct any erroneous information. The MCO shall have a formal process by which a health care professional may submit supplemental

or corrected information to the MCO's credentialing verification committee and request a reconsideration of the health professional's credentialing verification application if the health care professional feels that the MCO's credentialing verification committee has received information that is incorrect or misleading. Supplemental information shall be subject to confirmation by the MCO.

6.0 Provider Network Adequacy

6.1 Primary, Specialty and Ancillary Providers

6.1.1 The MCO shall maintain an adequate network of primary care providers, specialists, and other ancillary health care resources to serve the enrolled population at all times. The MCO shall develop and submit annually to the Department policies and procedures for measuring and assessing the adequacy of the network. At a minimum, the network of providers shall include:

6.1.1.1 A sufficient number of licensed primary care providers under contract with the MCO to provide basic health care services. All enrollees must have immediate telephone access seven (7) days a week, twenty four (24) hours a day, to their primary care provider or his/her authorized on call back up provider;

6.1.1.2 A sufficient number of licensed medical specialists available to MCO enrollees to provide medically necessary specialty care. The MCO must have a policy assuring reasonable access to frequently used specialists within each service area; and

6.1.1.3 sufficient number of other health professional staff including but not limited to licensed nurses and other professionals available to MCO enrollees to provide basic health care services. If a plan has an insufficient number of providers within reasonable geographic distances and appointment times to meet the medical needs of the enrollee, the MCO shall cover nonparticipating providers, and shall prohibit balance billing.

6.1.2 The MCO shall allow referral to a non network provider, upon the request of a network provider, when medically necessary covered 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.

6.2 Facility and Ancillary Health Care Services

6.2.1 The MCO shall maintain contracts or other arrangements acceptable to the Department with institutional providers which have the capability to meet the medical needs of enrollees and are geographically accessible. The network of providers shall include:

6.2.1.1 At least one licensed acute care hospital including at least licensed medical surgical, pediatric, obstetrical, and critical care services in any service area no greater than thirty (30) miles or forty (40) minutes driving time from ninety percent (90%) of enrollees within the service area.

6.2.1.2 Surgical facilities including hospitals licensed ambulatory surgical facilities, and/or physicians surgical practices. Such services shall be available in each service area no greater than thirty (30) miles or forty (40) minutes driving time from ninety percent (90%) of enrollees within the service area.

6.2.1.3 The MCO shall have a policy assuring access to the following specialized services, as determined to be medically necessary:

6.2.1.3.1 At least one hospital providing regional perinatal services;

6.2.1.3.2 A hospital offering pediatric intensive care services;

6.2.1.3.3 A hospital offering neonatal intensive care services;

6.2.1.3.4 Therapeutic radiation provider;

6.2.1.3.5 Magnetic resonance imaging center;

6.2.1.3.6 Diagnostic radiology provider, including X-ray, ultrasound, and CAT scan;

6.2.1.3.7 Emergency mental health service;

6.2.1.3.8 Diagnostic cardiac catheterization services in a hospital;

6.2.1.3.9 Specialty pediatric outpatient centers for conditions including sickle cell, hemophilia, cleft lip and palate, and congenital anomalies;

6.2.1.3.10 Clinical Laboratory certified under CLIA; and

6.2.1.3.11 Certified renal dialysis provider.

6.2.1.4 Such services shall be reasonably accessible. Evidence indicating such

services shall include contracts or other agreements acceptable to the Department.

6.2.2 If offered by the plan, the MCO shall have a policy assuring access to the following specialized services, as determined to be medically necessary:

6.2.2.1 A licensed long term care facility with skilled nursing beds;

6.2.2.2 Residential substance abuse treatment center;

6.2.2.3 Inpatient psychiatric services for adults and children;

6.2.2.4 Short term care facility for involuntary psychiatric admissions;

6.2.2.5 Outpatient therapy providers for mental health and substance abuse conditions;

6.2.2.6 Home health agency licensed by the Department;

6.2.2.7 Hospice program licensed by the Department; and

6.2.2.8) Pharmacy services.

6.2.2.9 Such services shall be reasonably accessible. Evidence indicating such services shall include contracts or other agreements acceptable to the Department.

6.2.3 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 available within the geographical service area. 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.

6.3 Emergency and Urgent Care Services

6.3.1 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.

6.3.2 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 appeal to the Commissioner for arbitration.

6.3.3 Enrollees shall have access to emergency care twenty four (24) hours per day, seven (7) 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.

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

6.3.4.1 Medical and psychiatric care, which shall be available twenty four (24) hours a day, seven (7) days a week;

6.3.4.2 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;

6.3.4.3 Out of area health care for urgent or emergency conditions where the enrollee cannot reasonably access in network services;

6.3.4.4 Hospital services for emergency care; and

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

6.3.5 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.

6.4 All enrollees shall be provided with an up to date and comprehensive list of the provider network upon enrollment and upon request. Updates due to provider changes must be provided at least quarterly.

7.0 Utilization Management

7.1 Utilization Management Functions

7.1.1 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. The plan shall identify at least:

7.1.1.1 Scope of utilization management activities;

7.1.1.2 Procedures to evaluate clinical necessity, access, appropriateness, and efficiency of services;

7.1.1.3 Mechanisms to detect under utilization;

7.1.1.4 Clinical review criteria and protocols used in decision making;

7.1.1.5 Mechanisms to ensure consistent application of review criteria and uniform decisions;

7.1.1.6 System for providers and enrollees to appeal utilization management determinations in accordance with the procedures set forth; and

7.1.1.7 A mechanism to evaluate enrollee and provider satisfaction with the complaint and appeals systems set forth. Such evaluation shall be coordinated with the performance monitoring activities conducted pursuant to the continuous quality improvement program set forth.

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

7.1.3 Compensation to persons providing utilization review services for a 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.

7.2 Utilization Management Staff Availability

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

7.2.2 The MCO shall provide enrollees with a toll free telephone number by which to contact customer service staff on at least a five (5) day, forty (40) hours a week basis.

7.2.3 The MCO shall supply providers with a toll free telephone number by which to contact utilization management staff on at least a five (5) day, forty (40) hours a week basis.

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

7.3 Utilization Management Determinations

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

7.3.2 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 is requested.

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

7.3.4 An MCO may not retroactively deny reimbursement for a covered 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.

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

8.0 Appeal Procedure

8.1 Scope of Appeal

8.1.1 The following appeal procedure shall be utilized when the subject of the appeal is based upon medical necessity or disputable need. For all other appeals, the carrier shall develop and implement written

policies and procedures that require a review process and a written response to the appellant.

8.2 Appeal Procedure

8.2.1 Information Disclosure. An MCO shall provide enrollees with a written explanation of the appeal process upon enrollment, annually, upon request and each time the appeal process is substantially changed. An carrier shall also provide participating providers with a written explanation of the appeal process, upon initial participation with the carrier network, upon request and each time the appeal process is substantially changed.

8.2.2 Stages of Appeal Process

8.2.2.1) An carrier shall establish an appeal process for appellants for review of coverage determinations based on medical necessity or disputable need. The appeal process shall consist of the following stages: an internal review by the carrier ("Stage 1 Appeal"), a second subsequent internal review by the carrier ("Stage 2 Appeal") and an external review ("Stage 3 Appeal").

8.2.2.2 Each stage of the appeal process shall provide for expedited review that shall not exceed seventy two (72) hours

8.2.2.2.1 In the event that the subject of the appeal concerns an imminent, emergent, or serious threat to the appellant each stage (1,2 and 3) of the appeal process may take seventy two (72) hours each.

8.2.2.2.2 In the event that the subject of the appeal concerns an emergency medical condition (69.115), both stages of internal review (stage 1 and 2) must be concluded within a total of seventy two (72) hours. Stage 3 must be completed within an additional seventy two (72) hours.

8.2.3 Petition for External Review form. All carriers shall complete a DHSS approved form and forward it to the Department to initiate the Independent Health Care Appeals Program.

8.2.4 Waiver of Internal Review Process. In the event that the carrier fails to comply with any of the deadlines for completion of the Stage 1 or 2 appeals, or in the event that the carrier for any reason waives its rights to an internal review of any appeal, then the appellant shall be relieved of his or her obligation to complete the carrier internal review process, and at the appellant's option, may proceed directly to the Stage 3 appeal process.

8.2.5 Appellant Rights.

8.2.5.1 An carrier shall not disenroll, terminate or in any way penalize an enrollee who exercises the right to appeal solely on the basis of filing the appeal.

8.2.5.2 Carrier Assistance

8.2.5.2.1 Upon the initiation of an appeal, an MCO shall notify an appellant of the right to have a staff member appointed to assist her/him with understanding the appeal process. Such assistance shall be available during the appeal process.

8.2.5.2.2 An appellant may request such assistance at any stage of the appeal process.

8.2.5.2.3 Upon such request, an MCO shall appoint a member of its staff who has had no prior direct involvement in the case to assist the appellant.

8.2.5.3 After an adverse determination, an appellant shall have the right to discuss a coverage determination with the medical director, or physician designee, of the carrier who made the coverage determination.

8.2.6 Carrier Records. An carrier shall maintain written or electronic records to document all appeals received. For each appeal an MCO shall maintain, at a minimum, the following information:

8.2.6.1 A general description of the reason for the appeal;

8.2.6.2 Date received;

8.2.6.3 Date of each review;

8.2.6.4 Resolution at each stage of appeal;

8.2.6.5 Date of resolution at each stage; and

8.2.6.6 Name and plan identification number of the appellant for whom the appeal was filed.

8.2.7 Reporting. An carrier shall submit the following information to the Department within thirty (30) days after the close of each calendar quarter:

8.2.7.1 The total number appeals filed.

8.2.7.2 The number of Stage 1 appeals. This shall include only those appeals

based upon medical necessity and/or disputable need.

8.2.7.3 The number of Stage 1 appeals upheld.

8.2.7.4 The number of Stage 1 appeals overturned.

8.2.7.5 The number of Stage 2 appeals. This shall include only those appeals based upon medical necessity and/or disputable need.

8.2.7.6 The number of Stage 2 appeals upheld.

8.2.7.7 The number of Stage 2 appeals overturned.

8.2.7.8 The number of petitions made to the Independent Health Care Appeals Program.

8.3 Stage 1 Appeal Procedure

8.3.1 Procedure. An carrier shall establish and maintain an internal appeal procedure in which an appellant, who is dissatisfied with a coverage determination by the carrier, that is based on medical necessity or disputable need, shall have the opportunity to appeal the determination. This appeal is made to the carrier, who will then assign the medical director and/or a physician designee, who has had no prior direct involvement with the appellant's case, to conduct the review.

8.3.2 Timeframes. A Stage 1 appeal shall be concluded as soon as possible in accordance with the medical exigencies of the case but no more than five (5) business days after receipt of the appeal. In no event shall appeals that involve an imminent, emergent, or serious threat to the health of the appellant exceed seventy-two (72) hours.

8.3.3 Notice of Determination. A carrier shall provide notice of the Stage 1 appeal determination to the appellant within five business days of receipt of the appeal. If such notice is provided verbally to the appellant, the carrier shall provide written notice of the determination to the appellant within five (5) business days of the verbal notice. In the event that the adverse determination is upheld, the written notice shall include the reason for the determination, an explanation of the appellant's right to proceed to a Stage 2 appeal and a review of the entire appeals process. This information shall include specific contact information (address and phone number) that is appropriate for each appeal stage.

8.4. Stage 2 Appeal Procedure

8.4.1 A carrier shall establish and maintain an internal appeal procedure in which an appellant who is dissatisfied with a Stage 1 appeal determination by an carrier shall have the opportunity to appeal the determination to the carrier. A panel, selected by the carrier, shall consist of at least two (2) physicians and/or other health care professionals having no direct involvement with the appellant's case prior to this review, one of who should be in the same or similar specialty that typically manages the care under review. If the same or similar physician/health care professional is not a member of the panel, such physician/health care professional must consult on the health care service at issue and report such consultation in writing to the panel for consideration.

8.4.2 Written Notice of Meeting. A carrier shall acknowledge receipt of all Stage 2 appeals in writing to the appellant. This acknowledgement shall include the place, date and time of the Stage 2 appeal meeting and shall give the appellant at least fifteen (15) calendar days notice of the appeal meeting. The appellant may request a change in the meeting schedule to facilitate attendance.

8.4.3 Appeal Meeting. The carrier shall hold the Stage 2 appeal meeting during regular business hours at a location reasonably accessible to the appellant. If a face-to-face meeting is not practical for geographic reasons, the carrier shall offer the appellant the opportunity to communicate with the review panel, at the carrier's expense, by conference call, video conferencing, or other appropriate technology. The carrier shall not unreasonably deny a request for postponement of the meeting made by an appellant. The appellant's right to a fair review shall not be conditional on the appellant's appearance at the Stage 2 appeal meeting.

8.4.4 Appellant Rights

8.4.4.1 An appellant has the right to:

8.4.4.1.1 Attend the Stage 2 appeal,

8.4.4.1.2 Present his or her case to the review panel,

8.4.4.1.3 Submit supporting material both before and at the appeal meeting,

8.4.4.1.4 Ask questions of any representative of the carrier participating on the panel,

8.4.4.1.5 Be accompanied and supported by a person of her/his choice in addition to her/his representative, and

8.4.4.1.6 Review all relevant information that is not confidential, proprietary or privileged.

8.4.5 Timeframes. A Stage 2 appeal shall be concluded as soon as possible in accordance with the medical exigencies of the case but no more than thirty (30) calendar days after receipt of the request for the Stage 2 appeal. In no event shall a Stage 2 appeal involving an imminent, emergent or serious threat to the health of the appellant exceed seventy two (72) hours.

8.4.6 Extensions. The carrier may extend the Stage 2 appeal for up to an additional thirty (30) calendar days for reasonable cause by submitting a written explanation for the delay to the Department within the original thirty (30) calendar day review period. An carrier honoring an appellant's request for extension for necessity or convenience shall be deemed a reasonable cause. In no event may an carrier extend the review period for an expedited appeal.

8.4.7 Written Notice of Determination

8.4.7.1 A carrier shall provide written notice of the Stage 2 appeal determination to the appellant within five (5) business days of such determination. In the event of an adverse determination, such notice shall include:

8.4.7.1.1 The qualifications of the members of the Stage 2 appeal panel;

8.4.7.1.2 A statement of the panel's understanding of the nature of the appeal and all pertinent facts;

8.4.7.1.3 The rationale for the review panel's determination;

8.4.7.1.4 Reference to evidence or documentation considered by the panel in making that determination;

8.4.7.1.5 Instructions for requesting a written statement of the clinical rationale, including the clinical review criteria used to make the determination; and

8.4.7.1.6 The appellant's right to proceed to a Stage 3 appeal.

8.5 External Utilization Appeal Process (Stage 3) Independent Health Care Appeals Program (External Appeal Process/Stage 3)

8.5.1 Upon receipt of an adverse determination at Stage 2, any who is dissatisfied with the results, shall have the opportunity to pursue her/his appeal before an independent utilization review organization.

8.5.2 The appellant must file the request for appeal with the carrier within sixty (60) calendar days of receipt of the adverse determination from the internal review process.

8.5.3 Upon receipt of a request for external review, the carrier shall fax the Petition for External Review form as soon as possible but within no more than three (3) business days to the Department and shall send a hard copy of the request to the Department by mail.

8.5.4 The Department shall assign an approved IURO to conduct the external review and shall notify the carrier.

8.5.5 The assigned IURO shall, within five (5) calendar days of assignment, notify the appellant in writing by certified or registered mail, that the appeal has been accepted for external review. The notice shall include a provision stating that the appellant may submit additional written information and supporting documentation that the IURO shall consider when conducting the external review. Appellant shall submit such written documentation to the IURO within seven (7) calendar days following the date of receipt of the notice.

8.5.5.1 Upon receipt of any information submitted by the appellant, the assigned IURO shall as soon as possible but within no greater than two (2) business days, forward the information to the carrier.

8.5.5.2 The IURO must accept additional documentation submitted by the carrier in response to additional written information and supporting documentation from the appellant.

8.5.6 Within seven (7) business days after the receipt of the notification required in section 8.5, the carrier shall provide to the assigned IURO, the documents and any information considered in making the internal appeal determination.

8.5.6.1 If the carrier fails to submit documentation and information or fails to participate within the time specified, the assigned IURO may terminate the external review and make a decision, with the approval of the Department, to reverse the internal appeal determination.

8.5.7 The external review may be terminated if the carrier decides to reverse its adverse determination and provide coverage or payment for the health care service that is the subject of the appeal.

8.5.7.1 Immediately upon making the decision to reverse its adverse

~~determination, the carrier shall notify the appellant, the assigned IURO, and the Department in writing of its decision.~~

~~8.5.7.2 The assigned IURO shall terminate the external review upon receipt of the written notice from the carrier.~~

~~8.5.8 Within forty five (45) calendar days after the receipt of the request for external review, the assigned IURO shall provide written notice of its decision to uphold or reverse the adverse determination to:~~

~~8.5.8.1 The appellant;~~

~~8.5.8.2 The carrier; and~~

~~8.5.8.3 The Department.~~

~~8.5.9 The IURO shall include the following information in the notice sent pursuant to section 8.5.8:~~

~~8.5.9.1 The qualifications of the members of the review panel;~~

~~8.5.9.2 A general description of the reason for the request for external review;~~

~~8.5.9.3 The date the IURO received the assignment from the Department to conduct the external review;~~

~~8.5.9.4 The date(s) the external review was conducted;~~

~~8.5.9.5 The date of its decision;~~

~~8.5.9.6 The principal reason(s) for its decision;~~

~~8.5.9.7 References to the evidence or documentation, including practice guidelines and clinical review criteria, considered in reaching its decision.~~

~~8.5.10 The decision of the IURO is binding upon the carrier.~~

~~8.6 Expedited External Utilization Appeal Process~~

~~8.6.1 An appellant may request an expedited external review with the carrier at the time the enrollee receives a final adverse determination if the enrollee suffers from a condition that poses an imminent, emergent or serious threat or has an emergency medical condition.~~

~~8.6.2 At the time the carrier receives a request for an expedited external review, the MCO shall immediately fax the Petition for External Review form to the Department and shall send a hard copy to the Department by mail.~~

~~8.6.3 If the Department determines that the review meets the criteria for expedited review, the Department shall assign an approved IURO to conduct the external review and shall notify the carrier.~~

~~8.6.4 At the time the carrier receives the notification of the assigned IURO, the carrier shall provide or transmit all necessary documents and information considered in making the final adverse determination to the assigned IURO electronically, by telephone, by facsimile or any other available expeditious method.~~

~~8.6.5 As expeditiously as the enrollee's medical condition permits or circumstances require, but in no event more than seventy two (72) hours after the date of the receipt of the request for an expedited external review, the IURO shall:~~

~~8.6.5.1 Make a decision to uphold or reverse the final adverse determination; and~~

~~8.6.5.2 Immediately notify the appellant, the carrier, and the Department of the decision.~~

~~8.6.6 Within two (2) calendar days of the immediate notification, the assigned IURO shall provide written confirmation of the decision to the appellant, the carrier, and the Department~~

~~8.6.7 The decision of the IURO is binding upon the carrier.~~

~~8.7 Petition to DHSS~~

~~8.7.1 If an carrier receives an appellant's request for access to the IHCAP whose subject is a benefit that is a written exclusion from the enrollee's benefit package, the carrier may make a written request to have the appeal reviewed for appropriate inclusion in the IHCAP by the Department. The request must be made in writing at the time the Petition for External Review Form is faxed to the Department and include any necessary supporting documentation.~~

~~8.7.2 The Department shall review the petition and may, in its discretion:~~

~~8.7.2.1 dismiss the appeal and notify the appellant in writing that the appeal is inappropriate for the IHCAP; or,~~

~~8.7.2.2 appoint an IURO to conduct a preliminary review; or,~~

~~8.7.2.3 appoint an IURO to conduct a full external review.~~

~~8.8 Preliminary External Review~~

8.8.1 If an carrier receives an appellant's request for access to the IHCAP for an appeal that it believes is not appropriate for inclusion in the IHCAP, the carrier may file a motion to dismiss. The motion must be made in writing at the time the Petition for External Review Form is faxed to the Department and include any necessary supporting documentation.

8.8.2 Upon the written request of an carrier, the Department shall

8.8.2.1 Appoint an IURO to review the details of the motion to determine if the appeal is appropriate for inclusion in the IHCAP.

8.8.2.1.1 Appeals that are inappropriate for inclusion are dismissed.

8.8.2.1.2 Appeals that are appropriate for inclusion are subject to a full external review.

8.8.2.2 Appoint an IURO to conduct a full external review.

8.9 All costs for external IURO review shall be borne by the carrier. The carrier shall reimburse the Department for the cost of the review within ninety (90) calendar days of the receipt of the decision by the IURO.

8.10 The Department shall approve IUROs eligible to be assigned to conduct external reviews.

8.10.1 Any IURO wishing to be approved to conduct external reviews shall submit an application form (as developed by the Department) and include with the form, all documentation and information necessary for the Department to determine if the IURO satisfies minimum qualifications.

8.10.2 The Department shall maintain a current list of approved IUROs.

9.0 Quality Assessment and Improvement

9.1 Continuous Quality Improvement

9.1.1 Under the direction of the Medical Director or her/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. The plan shall describe at least:

9.1.1.1 The scope and purpose of the program;

9.1.1.2 The organizational structure of quality improvement activities;

9.1.1.3 Duties and responsibilities of the medical director and/or designated physician responsible for continuous quality improvement activities;

9.1.1.4 Contractual arrangements, where appropriate, for delegation of quality improvement activities;

9.1.1.5 Confidentiality policies and procedures;

9.1.1.6 Specification of standards of care, criteria and procedures for the assessment of the quality of services provided and the adequacy and appropriateness of health care resources utilized;

9.1.1.7 A system of ongoing evaluation activities, including individual case reviews as well as pattern analysis;

9.1.1.8 A system of focused evaluation activities, particularly for frequently performed and/or highly specialized procedures;

9.1.1.9 A system of monitoring enrollee satisfaction and network provider's response and feedback on MCO operations;

9.1.1.10 A system for verification of provider's credentials, recertification, performance reviews and obtaining information about any disciplinary action against the provider available from the Delaware Board of Medical Practice or any other state licensing board applicable to the provider;

9.1.1.11 The procedures for conducting peer review activities which shall include providers within the same discipline and area of clinical practice; and

9.1.1.12 A system for evaluation of the effectiveness of the continuous quality improvement program.

9.1.2 There shall be a multidisciplinary continuous quality improvement committee responsible for the implementation and operations of the program. The structure of the committee shall include representation from the medical, nursing and administrative staff, with substantial involvement of the medical director of the MCO.

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

9.1.4 The MCO shall provide enrollees the opportunity to comment on the quality improvement

process.

9.1.5 The program shall monitor the availability, accessibility, continuity and quality of care on an ongoing basis. Indicators of quality care for evaluating the health care services provided by all participating providers shall be identified and established and shall include at least:

9.1.5.1 A mechanism for monitoring enrollee appointment and triage procedures including wait times to get an appointment and wait times in the office;

9.1.5.2 A mechanism for monitoring enrollee continuity of care and discharge planning for both inpatient and outpatient services;

9.1.5.3 A mechanism for monitoring the appropriateness of specific diagnostic and therapeutic procedures as selected by the continuous quality improvement program;

9.1.5.4 A mechanism for evaluating all providers of care that is supplemental to each provider's quality improvement system;

9.1.5.5 A mechanism for monitoring network adequacy and accessibility to assure the network services the needs of their diverse enrolled population; and

9.1.5.6 A system to monitor provider and enrollee access to utilization management services including at least waiting times to respond to telephone requests for service authorization, enrollee urgent care inquiries, and other services required.

9.1.6 The MCO shall develop a performance and outcome measurement system for monitoring and evaluating the quality of care provided to MCO enrollees. The performance and outcome measures shall include population based and patient centered indicators of quality of care, appropriateness, access, utilization, and satisfaction. Data for these performance measures shall include but not be limited to the following:

9.1.6.1 Indicator data collected by MCOs from chart reviews and administrative databases;

9.1.6.2 Enrollee satisfaction surveys;

9.1.6.3 Provider surveys;

9.1.6.4 Annual reports submitted by MCOs to the Department; and

9.1.6.5 Computerized health care encounter data.

9.1.7 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.

9.1.8 Continuous quality improvement activities shall be coordinated with other performance monitoring activities including utilization management and monitoring of enrollee and provider complaints.

9.1.9 The MCO shall maintain documentation of the quality improvement program in a confidential manner. This documentation shall be available to the Department and shall include:

9.1.9.1 Minutes of quality improvement committee meetings; and

9.1.9.2 Records of evaluation activities, performance measures, quality indicators and corrective plans and their results or outcomes.

9.2 External Quality Audit

9.2.1 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. External quality audits must be completed no less frequently than once every three (3) years. Such audit shall be performed by a nationally known accreditation organization or an independent quality review organization acceptable to the Department.

9.2.1.1 MCOs must submit the following information to the Department in order to receive approval for the nationally known accreditation organization or independent quality review organization that will conduct the triennial reviews or perform accreditation for the MCO:

9.2.1.1.1 evidence that the nationally known accreditation organization or independent quality review organization has experience performing external quality audits or accreditation of MCOs, and

9.2.1.1.2 the current standards for independent quality reviews or accreditations of MCOs as established and maintained by the accrediting entity.

9.2.2 The report must describe in detail the MCO's conformance to performance standards and the rules within these regulations. The report shall also describe in detail any corrective actions proposed and/or undertaken by the MCO.

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

9.3 Reporting and Disclosure Requirements

9.3.1 The Board of Directors of the MCO shall be kept apprised of continuous quality improvement activities and be provided at least annually with regular written reports from the program delineating quality improvements, performance measures used and their results, and demonstrated improvements in clinical and service quality.

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

9.3.2.1 Include a summary of its quality assessment and quality improvement programs in marketing materials;

9.3.2.2 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

9.3.2.3 Make available annually to 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.

9.3.3 MCOs shall submit such performance and outcome data as the Department may request.

2 DE Reg. 962 (12/1/98)
5 DE Reg. 130 (7/1/01)
5 DE Reg. 1435 (1/1/02)

Part 5: Enrollee Rights And Responsibilities

10.0 Enrollee Rights And Responsibilities

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

10.2 In the case of nonpayment by the MCO to a 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.

10.3 The MCO shall permit enrollees to choose their own primary care physician from the MCO network. This choice may be more flexible, depending on the type of health plan purchased by the enrollee. When MCOs maintain from a list of health care professionals within the plan, this list shall be updated as health care professionals are added or removed and shall include:

10.3.1 a sufficient number of primary care physicians who are accepting new enrollees; and

10.3.2 a sufficient number of primary care physicians that reflects a diversity that is adequate to meet the diverse needs of the enrolled populations' varied characteristics including age, gender, language, race and health status.

10.4 The MCO shall establish and implement a procedure, for those plans which do not allow direct access to a health care specialist, by which enrollees can obtain a standing referral to a health care specialist. This procedure:

10.4.1 Shall provide for a standing referral to a specialist if the enrollee's network provider determines that the enrollee needs continuing care from a specialist;

10.4.2 May require the MCO's approval of an initial treatment plan designed by the specialist which may limit the number of visits to the specialist, limit the duration of the standing referral, or require updates on the enrollee's condition[. Such approval shall not be withheld absent a decision by a qualified physician that the treatment sought in the treatment plan is not reasonably related to the appropriate treatment of the insured's condition];

10.4.3 May require that referrals, procedures, tests, and other medical services be

~~provided by network providers unless such services are not available through network providers or are not available within a reasonable period of time. The MCO shall make acceptable service arrangements with non-network providers and the enrollee, and shall prohibit balance billing.~~

~~10.5 The MCO shall provide coverage of routine patient care costs (those normally covered under an enrollee's health plan) for enrollees engaging in clinical trials for treatment of life-threatening diseases.~~

~~10.5.1 Clinical trials must meet the following requirements:~~

~~10.5.1.1 The subject or purpose of the trial must be the evaluation of an item or service that falls within the covered benefits of the enrollee health plan and is not specifically excluded from coverage;~~

~~10.5.1.2 The trial must not be designed exclusively to test toxicity or disease pathophysiology;~~

~~10.5.1.3 The trial must have therapeutic intent;~~

~~10.5.1.4 Trials of therapeutic interventions must enroll patients with diagnosed disease;~~

~~10.5.1.5 The principal purpose of the trial is to test whether the intervention potentially improves the participant's health outcomes;~~

~~10.5.1.6 The trial is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;~~

~~10.5.1.7 The trial does not unjustifiably duplicate existing studies; and,~~

~~10.5.1.8 The trial is in compliance with Federal regulations relating to the protection of human subjects.~~

~~10.5.2 Routine patient care costs include all items and services that are otherwise generally available to a qualified individual that are provided in the clinical trial with the exception of:~~

~~10.5.2.1 The investigational items or service itself;~~

~~10.5.2.2 Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the enrollees; and,~~

~~10.5.2.3 Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.~~

~~10.6 The MCO shall provide each enrollee with an enrollee's benefit handbook which includes a complete statement of the enrollee's rights, a description of all complaint and appeal procedures, a clear and complete summary of the evidence of coverage, and notification of their personal financial obligations for non-covered services. The statement of the enrollee's rights shall include at least the right:~~

~~10.6.1 To available and accessible services when medically necessary, including availability of care twenty four (24) hours a day, seven (7) days a week for urgent or emergency conditions;~~

~~10.6.2 To be treated with courtesy and consideration, and with respect for the enrollee's dignity and need for privacy;~~

~~10.6.3 To be provided with information concerning the MCO's policies and procedures regarding products, services, providers, appeal procedures and other information about the organization and the care provided;~~

~~10.6.4 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;~~

~~10.6.5 To receive from the enrollee's physician(s) or provider, in terms that the enrollee understands, an explanation of her/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 her/his next of kin or guardian and documented in the enrollee's medical record;~~

~~10.6.6 To formulate advance directives;~~

~~10.6.7 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;~~

~~10.6.8 To prompt notification, as required in these rules, of termination or changes in benefits, services or provider network;~~

~~10.6.9 To file a complaint or appeal with the MCO and to receive an answer to those complaints within a reasonable period of time; and~~

10.6.10 To file a complaint with the Department or the Commissioner.

10.7 The MCO shall establish and implement written policies and procedures regarding the responsibilities of enrollees. A complete statement of these responsibilities shall be included in the enrollee's benefit handbook.

10.8 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:

10.8.1 Benefits covered and limitations;

10.8.2 Out of pocket costs to the enrollee;

10.8.3 Lists of participating providers;

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

10.8.5 Written explanation of the appeals process;

10.8.6 A description of and findings from the quality assurance and improvement programs;

10.8.7 The patterns of utilization of services; and

10.8.8 For staff model MCOs, the location and hours of its inpatient and outpatient health services.

10.9 The MCO shall provide culturally competent services to the greatest extent possible.

5 DE Reg. 130 (7/1/01)

5 DE Reg. 1435 (1/1/02)

Part 6: Requirements For Staff Model Mcos

In Addition To All Other Requirements Of These Regulations, Staff Model MCOs Shall Meet The Requirements Of This Section.

11.0 Environmental Health and Safety

11.1 Office premises and other structures operated by the MCO must have appropriate safeguards for patients.

11.2 All buildings shall conform to all State and medical codes and all regulations applicable to services being offered. These codes shall include but are not limited to:

11.2.1 State Plumbing Code.

11.2.2 Waste Disposal Regulations.

11.2.3 Public Water Supply Regulations.

11.2.4 Food Service Requirements.

11.2.5 Radiation Control Regulations.

11.2.6 Hazardous Waste Regulations.

11.2.7 Air and Water Pollution Regulations.

11.2.8 Hand washing facilities shall be installed in accordance with applicable State and local regulations and conveniently located.

11.2.9 Toilet facilities shall meet appropriate State and local regulations.

11.2.10 State Fire Code requirements.

11.3 The buildings must be architecturally accessible to handicapped individuals and comply with the Americans with Disabilities Act.

11.4 Measures must be taken to insure that facilities are guarded against insects and rodents.

11.5 Housekeeping

11.5.1 A housekeeping procedures manual shall be written and followed. Special emphasis shall be given to procedures applying to infectious diseases or suspect areas.

11.5.2 All premises shall be kept neat, clean, and free of litter and rubbish.

11.5.3 Walls and ceilings shall be maintained free of cracks and falling plaster and shall be cleaned and painted regularly.

11.5.4 Floors shall be cleaned regularly and in such a manner that it will minimize the spread of pathogenic organisms in the atmosphere; dry dusting and sweeping shall be prohibited.

11.5.5 Suitable equipment and supplies shall be provided for cleaning all surfaces.

11.5.6 Solutions, cleaning compounds and hazardous substances shall be properly labeled and stored in safe places.

12.0 Emergency Utilities or Facilities

12.1 The MCO shall be equipped to handle emergencies due to equipment failures. Emergency electrical service for lighting and power for equipment essential to life safety shall be provided in accordance with hospital regulations where appropriate. (Minimum Requirements for Construction of Hospital and Health Care Facilities, Section 7.32H.)

12.2 In facilities which provide hospital services, the emergency electrical system shall be so controlled that the auxiliary power is brought to full voltage and frequency and can be connected within ten (10) seconds.

12.3 Emergency utilities for MCOs and contract providers must be supplied according to procedures performed on the premises.

13.0 Construction

13.1 New construction or substantial modifications on an existing facility shall conform to applicable State, county and local codes, including the National Fire Protection Association Publication No. 101 - Life Safety Code, latest edition adopted by the State Fire Prevention Board.

13.2 Radiation requirements of the Authority on Radiation Protection shall be met.

13.3 Facility plans or modifications shall be submitted to the Department for review and approval prior to any work being begun.

14.0 Personnel

14.1 The office shall be staffed by appropriately trained personnel. Appropriate manuals shall be developed to serve as guidelines and set standards for patient care provided by nonprofessional personnel.

14.2 Offices with five (5) or more physicians shall have at least one (1) full time registered nurse (RN).

14.3 Ponprofessional personnel shall have appropriate in-service education on clinical operations and procedures. The in-service training program must be conducted at least annually.

14.4 Primary physician. There shall be at least one (1) full time or full time equivalent (F.T.E.) physician available on contract. There shall be at least one (1) F.T.E. primary physician for every 1,000 enrollees.

14.5 Medical Specialties. There shall be either full time or part-time physicians, other appropriate professional specialists, or written agreements adequate to ensure access to all needed services for enrollees.

15.0 Equipment

Each office operated by the MCO must have the necessary equipment and instruments to provide the required services. Equipment and instruments for services, when covered by written contract with medical specialists or other providers outside of the office, need not be present in the MCO's office. Where emergency services are provided in the office, equipment such as a defibrillator, laryngoscope and other similar equipment must be present.

16.0 Specialized Services

16.1 The MCO shall provide special services necessary for diagnosis and treatment such as ultra sound. Where it is not feasible to provide these services in the office, there shall be a written agreement for these services in a nearby location except for isolated rural areas where arrangements for these services shall be subject to review and approval by the Department.

16.1.1 The MCO's radiology services shall be supervised and conducted by a qualified radiologist, either full time or part-time; or, when radiology services are supervised and conducted by a physician who is not a qualified radiologist, the MCO shall provide for regular consultation by a qualified radiologist, who is under contract with the MCO and is responsible for reviewing all X-rays and procedures. The number of qualified radiological technologists employed shall be sufficient to meet the MCO's requirements. If the MCO operates a radiology service and provides emergency services, at least one (1) qualified technologist shall be on duty or on call at all times.

16.1.2 Pharmaceutical services must be under the direct supervision of a registered

pharmacist who is responsible to the administrative staff for developing, coordinating and supervising all pharmaceutical services; or, in the case of dispensing of pharmaceuticals by a physician, such dispensing shall not violate the requirements of State law. MCOs with a licensed pharmacy shall have a Pharmacy and Therapeutics Committee. Pharmaceutical services may be provided on the premises of the MCO or by contract with an independent licensed provider. The contract shall be available for inspection by the Department at all times.

16.1.3 When the MCO provides its own emergency services, facilities must be provided to ensure prompt diagnosis and emergency treatment including adequate Emergency Room space, separate from major surgical suites. In Emergency Room facilities provided for or arranged for by the MCO there shall be as a minimum: adequate oxygen, suction, CPR, diagnostic equipment, as well as standard emergency drugs, parenteral fluids, blood or plasma substitutes and surgical supplies. Radiology facilities, clinical laboratory facilities and current toxicology including antidotes shall be available at all times.

16.1.4 Personnel shall be trained and approved by an appropriate professional organization in the operation and procedures of emergency equipment.

17.0 Central Sterilizing and Supply

Autoclaves or other acceptable sterilization equipment shall be provided of a type capable of meeting the needs of the MCO and of a recognized type with approved controls and safety features. Bacteriological culture tests shall be conducted at least monthly. The maintenance program of the sterilization system shall be under the supervision of competent trained personnel.

2 DE Reg. 962 (12/1/98)
5 DE Reg. 130 (7/1/01)
5 DE Reg. 1435 (1/1/02)

Part 7: Administrative Requirements

18.0 Administration

The MCO shall designate an appropriate person or persons to handle the administrative functions of the MCO. These functions shall include the following responsibilities: interpretation, implementation and application of policies and programs established by the MCO's governing authority; establishment of safe, effective and efficient administrative management; control and operation of the services provided; authority to monitor or supervise the operation and in accordance with acceptable medical standards; and such other duties, responsibilities and tasks as the governing body or other designated authority may empower such individual(s).

19.0 Qualifications

Persons appointed to administrative positions in the MCO shall have the necessary current training and experience in the field of health care as appropriate to carry out the functions of their job descriptions.

20.0 Medical Privileges

Participating physicians shall have hospital privileges commensurate with their contractual obligations. Physicians must be licensed in Delaware.

21.0 Medical Records

21.1 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 the regulations of the Department.

21.2 These records shall include the following information: name, identification number, age, sex, residence, employment, patient history, physical examination, laboratory data, diagnosis, treatment prescribed and drugs administered.

21.3 The medical record should also contain an abstract summary of any inpatient hospital care or referred treatment.

21.4 Regulatory agencies shall have access to medical records for purposes of monitoring and review of MCO practices.

21.5 Enrollees' records shall be filed for five (5) years following active status before being destroyed.

22.0 Reporting Requirements and Statistics

22.1 The MCO shall submit reports as required by these regulations.

22.1.1 The MCO shall disclose to its enrollees the following information:

22.1.1.1 the patterns of utilization of its services based on the information in 9.1.6; and

22.1.1.2 the location and hours of its inpatient and outpatient health services.

22.1.2 The following information is required to be submitted to the Department on an annual basis:

22.1.2.1 Physician visits per enrollee per year.

22.1.2.2 Hospital admissions per year and per 1,000 enrollees per year.

22.1.2.3 Hospital days per year and per 1,000 enrollees per year.

22.1.2.4 Average length of stay per hospital confinement.

22.1.2.5 Outside consultations per year and per 1,000 enrollees per year.

22.1.2.6 Emergency Room visits per year and per 1,000 enrollees per year.

22.1.2.7 Laboratory procedures per year and per 1,000 enrollees per year.

22.1.2.8 X-ray procedures per year and per 1,000 enrollees per year.

22.1.2.9 Total number of enrollees at the end of the year.

22.1.2.10 Total number of enrollees enrolled during the year.

22.1.2.11 Total number of enrollees terminated during the year.

22.1.2.12 Cost of operation.

22.1.2.13 Current provider directory including PCPs, specialists, facilities and ancillary health care services.

22.1.2.14 A statistical summary evaluating the network adequacy and accessibility to the enrolled population.

22.1.2.15 Annual appeal report of medical necessity and disputable need to include:

22.1.2.15.1 Number of appeals at each level of appeal;

22.1.2.15.2 A compilation of causes underlying the appeals;

22.1.2.15.3 Resolution of the appeals; and,

22.1.2.15.4 Number of appeals terminated during the external review as described by 69.404E7.

22.1.2.16 Annual appeal report of all other appeals (not medical necessity or disputable need) to include:

22.1.2.16.1 Number of appeals at each level of appeal;

22.1.2.16.2 A compilation of causes underlying the appeals; and,

22.1.2.16.3 Resolution of the appeals.

22.1.3 The following administrative reports are required by the Department whenever there is a change:

22.1.3.1 Full name of the Chief Executive Officer.

22.1.3.2 Full name of the Medical Director.

22.1.3.3 Address(es) of the office(s) in operation.

22.1.3.4 Name(s) of the hospital(s) used by the MCO

5 DE Reg. 130 (7/1/01)

APPENDIX A

DEPARTMENT OF HEALTH AND SOCIAL SERVICES OFFICE OF HEALTH FACILITIES LICENSING & CERTIFICATION 302-995-8521

Managed Care Organization APPLICATION FOR A CERTIFICATE OF AUTHOIRTY AND ANNUAL REPORT

A. IDENTIFYING INFORMATION

1. Name of applicant:_____

Address:_____

_____

_____

_____

Telephone:_____

2. Chief Executive Officer: _____
3. Type of MCO: (Check one)
Staff Group Practice Individual Practice Association Other
_____
4. Anticipated date of operation:_____
5. Area of operation, i.e., county or statewide:_____

B. Statement of Certification and Acknowledgment:

I certify that the statements made in this application are accurate, complete, and current to the best of my knowledge and belief. I understand that this application does not relieve me of any responsibility under Part VIII, Title 16, Chapter 93 of the **Delaware Code** (Certificate of Public Review).

_____ _____
Signature of Chief Executive Officer Title Date

C. Fee Schedule (NOTE: Checks should be made payable to the State of Delaware)

Application Fee:	$375.00
Filing of Annual Report:	$250.00

D. Please return this application to:
Health Facilities Licensing and Certification
2055 Limestone Road, Suite 200
Wilmington, DE 19808

5 DE Reg. 130 (7/1/01)

11 DE Reg 1059 (02/01/08)