

DEPARTMENT OF INSURANCE

Statutory Authority: 18 Delaware Code, Sections 311 and 332 (18 **Del.C.** §§ 311 and 6401 *et seq.*)

18 **DE Admin. Code** 1403

PROPOSED

PUBLIC NOTICE

INSURANCE COMMISSIONER MATTHEW DENN hereby gives notice of proposed Department of Insurance **Regulation 1403** relating to **Managed Care Organizations**. The docket number for this proposed regulation is 357.

The Department of Insurance proposes to amend Regulation 1403 by rescinding the current regulation and substituting in lieu thereof revised provisions for the review and arbitration of health insurance claims. As a result of the enactment of Senate Bill 295 on July 6, 2005 it became necessary to re-promulgate Regulation 1301 to provide for the review of claims from managed care organizations formerly under the regulatory authority of the Department of Health and Social Services. The **Delaware Code** authority for the change is 18 **Del.C.** §§311 and 6401 *et seq.* The text can also be viewed at the Delaware Insurance Commissioner's website at www.delawareinsurance.gov and clicking on the link for "Proposed Regulations."

The Department of Insurance will hold a public hearing on the proposed changes on Monday, February 26, 2007 at 10:00 a.m. in the Consumer Services hearing room, 841 Silver Lake Blvd., Dover, DE 19904. Any person can file written comments, suggestions, briefs, and compilations of data or other materials concerning the proposed amendment. Any written submission in response to this notice and relevant to the proposed change must be received by the Department of Insurance no later than 4:30 p.m. March 6, 2007 by delivering said comments to Deputy Attorney General Michael J. Rich, c/o Delaware Department of Insurance, 841 Silver Lake Boulevard, Dover, DE 19904, or sent by fax to 302.739.5566 or emailed to michael.rich@state.de.us.

IT IS SO ORDERED this 8th day of January, 2007
Matthew Denn, Insurance Commissioner

1403 Health Maintenance Organizations [Formerly Regulation 58]

EXHIBITS:

- A. Form No. H 1 — Application for License as a Health Maintenance Organization
- B. Form No. H 2 — Admittance Questionnaire for Certificate of Authority
- C. Form No. H 3 — Designation of Official Authorized to Appoint and Remove Agents
- D. Form No. H 4 — Designation of Person to Receive Bulletins
- E. Form No. H 5 — Designation of Person to Receive Service of Process
- F. Biographical Affidavit of Officers/Directors
- G. Power of Attorney Form
- H. Rules and Regulations Governing the Application and Operation of Health Maintenance Organizations (State Board of Health)

Editorial Note: Copies of forms to be submitted by HMO's to the Delaware Insurance Department when making application for a certificate of authority follow Section 15 of Regulation No. 58.

1.0 Authority

This Regulation has been promulgated in accordance with 18 **Del.C.** Ch. 64 which provides authority for the Commissioner to regulate the insurance aspects, including financial solvency, of health maintenance organizations established or operated in this State.

2.0 Purpose

The purpose of this Regulation is to establish the criteria for licensing a health maintenance organization and to establish the procedure for obtaining and maintaining a certificate of authority.

3.0 Definitions

"Basic Health Services" means those services required by the Delaware Board of Health in their Regulation Governing the Application and operation of "Health Maintenance Organizations" hereinafter referred to as "Board of Health Regulations."

"Health Maintenance Organization" 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 the Board of Health Regulation.
- Is primarily compensated (except for co-payment) for the provision of basic health care services to enrolled participants on a predetermined periodic rate basis; and
- Provides physicians' 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).

"Health Care Provider" means a hospital, nursing home, physician, clinic or laboratory or other person which enters into an agreement with a health maintenance organization to provide health services to its subscribers or enrollees.

"Agent" means a person who is appointed or employed by a health maintenance organization and who engages in solicitation of membership in such organization. This definition does not include a person enrolling members on behalf of an employer, union, or other organization to whom a master subscriber contract has been issued.

References in Regulation No. 58 to 18 ~~Del.C.~~ Ch. 64 §§6401. to 6406 may be located from page 725 of this volume; references to 16 ~~Del.C.~~ Ch. 91 §§9101 to 9115, pages 1638.01 to 1638.09. 18 ~~Del.C.~~ Ch. 64 is entitled Insurance Regulation of Health Maintenance Organizations; 16 ~~Del.C.~~ Ch. 91 is entitled Health Maintenance Organizations.

4.0 Certificate of Authority

4.1 No person may establish, operate, or engage in the business of a health maintenance organization, or enter this State for the purpose of enrolling persons in a health maintenance organization without first obtaining a certificate of authority from the Insurance Commissioner and a certificate of authority from the Department of Health and Social Services pursuant to 16 ~~Del.C.~~ Ch. 91. For purposes of this Regulation, the phrase "establish, operate or engage in the business of a health maintenance organization, or enter this State for the purpose of enrolling persons in a health maintenance organization" shall be defined in accordance with 18 ~~Del.C.~~ §103, "Transacting Insurance."

4.2 Every health maintenance organization established or in operation in this State on the effective date of this regulation must apply for and obtain a certificate of authority from the Insurance Commissioner in order to continue such operation. If such an operation files an application within ninety (90) days of the effective date of this regulation, it may continue its operation until the application is acted upon. If the application is denied, the applicant shall be treated as a health maintenance organization which has had its certificate of authority revoked under 18 ~~Del.C.~~ §6405.

4.3 At the time of adoption of this regulation, any HMO which does not meet the minimum capital and surplus requirements within the period established for submitting an application for a certificate of authority shall be permitted to operate for a period not to exceed six months if:

- 4.3.1 the subscribers/enrollees are adequately protected; and
- 4.3.2 the HMO is seeking additional sources of capitalization; and
- 4.3.3 there is a reasonable expectation that the HMO will meet the minimum capital and surplus standards within the six month period.

5.0 Application Procedure

5.1 Each application for a certificate of authority as a health maintenance organization shall be made on Form No. H-1 entitled "Application for License as a Health Maintenance Organization," attached hereto as Exhibit A and incorporated herein. It shall be accompanied by a filing fee of \$500.00 and the following documents:

5.1.1 A copy of all documents filed under Part Two of the Board of Health Regulation;

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

5.1.3 A statement identifying the states where the health maintenance organization is authorized to operate, any states where it has pending an application for authorization to operate; any states where it has been cited for a violation of any laws or legislation and an explanation of any such alleged violation, including status or outcome;

5.1.4 Copies of management, agency or administrative contracts;

5.1.5 Proof of \$50,000 bond for each officer, director, partner, who receives, collects or invests money;

5.1.6 Designation of official authorized to appoint and remove agents Form No. H-3 (See Exhibit C);

5.1.7 Designation of person to receive bulletins, regulations, etc. Form No. H-4 (See Exhibit D);

5.1.8 Designation of person to receive service of process Form No. H5 (See Exhibit E);

5.1.9 Biographical Affidavit of Officers and Directors (See Exhibit F);

5.1.10 Power of Attorney Form (See Exhibit G);

5.1.11 Deposit of \$100,000 in accordance with 16 ~~Del.C.~~ §9105 and 18 ~~Del.C.~~ §513(f);

5.2 All of the above referenced documents must be submitted in order for the Department to review an application.

6.0 Issuance of Certificate of Authority

6.1 The Commissioner shall issue a certificate of authority to an applicant within 60 days after filing a completed application and payment of the required fee, if he is satisfied of that:

6.1.1 The applicant meets or is able to meet the requirements of Chapter 64 of Title 18 and this regulation, as set forth herein;

6.1.2 Arrangements have been made by the applicant reasonably to assure provision of the services covered by its contracts; and

6.1.3 The applicant is financially responsible and able to meet its obligations to members.

6.1.4 Certificates of authority are issued on a permanent basis but must be continued annually on or before March 1 through the payment of an annual continuation fee of \$50.00.

7.0 Suspension or Revocation of Certificate of Authority

7.1 The certificate of authority of a health maintenance organization may be suspended by the Commissioner after a hearing, for any of the following causes:

7.1.1 If the Commissioner is satisfied, upon examination or from other evidence submitted to him, that any health maintenance organization is in an unsound financial condition, or that its business policies or methods are unsound or improper, or that its condition or management is such as to render its further transaction of business hazardous to the public or its members; or

7.1.2 The health maintenance organization has violated a provision of Chapter 64 of Title 18 or any of the chapters specified in 18 ~~Del.C.~~ §6406.

7.1.3 Upon notification by the Division of Public Health of suspension or revocation of the certificate of authority issued by the Division of Public Health.

8.0 Capital Funds Required

8.1 Each health maintenance organization that obtains a certificate of authority shall have and maintain unimpaired capital stock or unimpaired basic surplus of at least \$300,000 and free surplus of at least \$150,000 or the minimum capital and free surplus as may be required by legislative changes adopted by the General Assembly from time to time. The above capital and surplus requirements are in addition to the deposit requirements of 18 ~~Del.C.~~ §513(f).

8.2 Annually, at the time of filing the annual statement on March 1, each health maintenance organization which has a current certificate of authority shall demonstrate that it has maintained the minimum

capital established by this regulation or subsequent legislative enactment. In addition to the minimum capital, a Health Maintenance Organization must demonstrate that it has provider contracts which require that the provider agrees in the event of non payment by the HMO that the provider will not seek compensation or have any recourse against a subscriber/enrollee, as described in section 9.0.

9.0 Required Contractual Provisions

9.1 Every contract between a health maintenance organization, proposed, established or operating in this State and a health care provider (hereinafter referred to as "provider contracts"), shall include a provision substantially in the following form:

9.1.1 Provider agrees that in no event, including but not limited to non payment by the HMO, insolvency of the HMO [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 a subscriber, an enrollee or persons (other than the HMO) acting on his/their behalf for services provided pursuant to this agreement. This provision does not prohibit the provider from collecting supplemental charges or co-payments or fees for uncovered services delivered on a "fee for service" basis to HMO subscribers/enrollees.

9.1.2 Provider agrees that this provision shall survive the termination [of this agreement] for authorized services rendered prior to the termination of this agreement, regardless of the cause giving rise to termination and shall be construed to be for the benefit of the HMO subscribers/enrollees. This provision is not intended to apply to services provided [after this agreement] has been terminated.

9.1.3 Provider agrees that this provision supersedes any oral or written contrary agreement now existing or hereafter entered into between the provider and the subscriber, enrollee, or persons acting on their behalf insofar as such contrary agreement relates to liability for payment for services provided under the terms and conditions of this agreement."

9.2 Before issuing a certificate of authority authorizing an HMO to do business in Delaware, or permitting the continuation of an already authorized HMO, the Commissioner shall ascertain that the HMO has validly executed provider agreements with all providers and that the provider contracts contain the required protection for subscribers/enrollees. In the event that the HMO has not entered into such agreements with all providers, the HMO must demonstrate to the Commissioner's satisfaction that it has made a good faith effort to enter into these agreements. In lieu of these executed provider agreements, the Commissioner may, at this discretion, allow the HMO to engage in the business of a health maintenance organization if not already authorized, or continue to be engaged in the business of a health maintenance organization if previously authorized, if the HMO establishes reserves equal to 25% of the total projected annual incurred claims or benefits payments attributable to the provider which or who has not agreed to enter into a provider agreement.

10.0 Reinsurance Requirement

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

11.0 Special Requirement in the Event of Financial Impairment/insolvency

In the event of the financial impairment or insolvency of a health maintenance organization doing business in this State, as defined herein, each health maintenance organization doing business in this State shall permit a 60-day "open enrollment" period for existing subscribers of the impaired/ insolvent health maintenance organization to enroll in a solvent health maintenance organization. Each such solvent licensed health maintenance organization shall be required to accept within the "open enrollment" period any subscriber who wishes to enroll at the rates or costs and benefits which are then in effect at the chosen HMO for the class or grouping represented by the enrolling subscriber. Each such solvent licensed HMO shall accept such enrolling subscriber without any waiting periods or pre-existing conditions exclusions and such acceptance both as to premium as well as delivery of service shall be retroactive to the date on which a court of competent jurisdiction has declared the predecessor HMO financially impaired.

12.0 Required Disclosure to Subscribers/Enrollees

All forms of evidence of coverage issued by the health maintenance organization to enrolled participants, or other marketing documents purporting to describe the organization's health care services, shall contain clear and complete information indicating (1) the health care services and other benefits to which the enrolled participant is entitled, (2) any exclusions or any limitations on services or any other benefits to be provided, including any deductible or co-payment feature or any restrictions relating to preexisting conditions, and (3) the names of all hospitals and primary care or other providers normally available to the participants/enrollees.

13.0 Other Applicable Provisions

13.1 Every health maintenance organization issued a certificate of authority in this State shall be treated for the purposes of the following chapters only, as a health insurer, and its coverages shall be deemed to be medical and hospital expense incurred insurance policies for the purposes of 18 ~~Del.C.~~ Ch. 25:

- 13.1.1 Chapter 1 General Definitions and Provisions.
- 13.1.2 Chapter 3 The Insurance Commissioner.
- 13.1.3 Chapter 5 Authorization of Insurers and General Requirements.
- 13.1.4 Chapter 9 Kinds of Insurance; Limits of Risk; Reinsurance.
- 13.1.5 Chapter 11 Assets and Liabilities.
- 13.1.6 Chapter 13 Investments.
- 13.1.7 Chapter 15 Administration of Deposits.
- 13.1.8 Chapter 17 Agents, Brokers, Consultants, etc.
- 13.1.9 Chapter 21 Unauthorized Insurers.
- 13.1.10 Chapter 23 Unfair Practices in the Insurance Business.
- 13.1.11 Chapter 25 Rates and Rating Organizations.
- 13.1.12 Chapter 27 The Insurance Contract.
- 13.1.13 Chapter 33 Health Insurance Contracts.
- 13.1.14 Chapter 34 Medicare Supplement Insurance Minimum Standards.
- 13.1.15 Chapter 35 Group and Blanket Health Insurance.
- 13.1.16 Chapter 36 Individual Health Insurance Minimum Standards.
- 13.1.17 Chapter 59 Subchapter I - Rehabilitation and Liquidation.

14.0 Separability Provisions

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

15.0 Effective Date

This regulation shall become effective 30 days from the date of signing.

Editorial Note: ~~Forms to be submitted and certain instructional material begin on the next following page.~~

EXHIBIT A
STATE OF DELAWARE
DEPARTMENT OF INSURANCE
APPLICATION FOR
HEALTH MAINTENANCE ORGANIZATION
CERTIFICATE OF AUTHORITY

Application is hereby made by

Corporate Title

Corporate Address

Administrative/Mailing Address

Incorporated or Organized on _____, in _____

Date Domicile

as a _____ (stock, mutual, reciprocal, fraternal, mutual benefit, etc.) insurer for a Certificate of Authority to transact the business of insurance within the State of Delaware for the line of Accident and Health, as set forth in Title 18, ~~Del.C.~~

Federal Employer's Identification Number (EIN) _____

Corporate Title

By:-

Title:-

Date:-

FORM NO. H-1

EXHIBIT B

STATE OF DELAWARE

DEPARTMENT OF INSURANCE

ADMITTANCE QUESTIONNAIRE FOR

CERTIFICATE OF AUTHORITY

OF HEALTH MAINTENANCE ORGANIZATION

The following data is being submitted to the Delaware Department of Insurance:

1. Company Name:

Home Office:

Contact Person:

Telephone No.

2. Proposed location of principal place of business within State:

Address at which all books, accounts and documents relating to business in this State will be kept:

If applicant is a foreign proprietorship, partnership, or corporation, address of principal place of

business:

3. Applicant is: () Individual Proprietor

() Partnership

() Corporation

() Other (Specify)

4. If applicant is a corporation (Attached Certificate of Incorporation)

(a) State of Incorporation-

(b) Date of Incorporation-

(c) If a foreign corporation, name and address of Agent for Service of Process in Delaware:

5. If applicant has engaged previously in the same or a similar business; provide details, including name(s), address(es), and date(s) first commenced:

6. State whether applicant is, directly or indirectly, under common ownership, control, or management or is otherwise affiliated or associated with any insurer, or any person, firm or corporation having or exercising control of an insurer.

() Yes, supply complete details () No

7. If applicant is a partnership

(a) State whether general partnership or limited partnership:

(b) Give names and addresses of all partners specifically identifying limited partners, if any:

8. If applicant is a corporation, trust or other entity, other than a partnership, of which ownership is manifested by shares, identify each type of shares and state:

(a) Number of shares authorized:

(b) Number of shares outstanding:

(c) Par Value:

(d) Give name, residence address, title and number and percent of shares directly or beneficially owned by every officer and director and every person, firm or corporation owning or controlling 10% or more of the shares of each type:

Name and

Number

Residence Address	Title	of Shares (%)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

9. Attach current, certified financial statement, which is as of the following date:

10. If applicant, or any subsidiary, affiliated, or associated health maintenance organization, has more than one place of business, give the name and address of each:

11. If the appropriate answer is "Yes" to any of the following questions concerning the applicant, manager, any officer, director, owner or beneficial owner of 10% or more of the shares, complete details must be given, including name, address, disposition of charges, etc.

Have any of the above:

(a) Applied previously in this State for a license to engage in the business of a health maintenance organization?

Yes No

(b) Received a rejection, revocation or suspension of license under laws of this State governing a health maintenance organization?

Yes No

(c) Received a rejection, revocation or suspension of license under a health maintenance organization law or regulation, or similar law or regulation in any other State?

Yes No

Exhibit B concluded

(d) Received a revocation or suspension of any license, been convicted or entered a plea of guilty, or nolo contendere, with respect to any law of regulation relating to the business of insurance?

Yes No

(e) Been arrested, indicted, convicted, entered a plea of guilty or nolo contendere with respect to a State or Federal offense in this or any other State?

Yes No

(f) Been placed in voluntary or involuntary bankruptcy, receivership, trusteeship, or conservatorship?

Yes No

(g) Do any of the above now hold a license to engage in the business of a health maintenance organization or a similar or related business in any State, District or Territory of the United States?

Yes No

AFFIDAVIT

County _____

State _____

I, _____, the undersigned being the _____

(Title, if a corporation)

of the _____

(Name of Health Maintenance Organization)

swear, (or affirm), that to the best of my knowledge and belief, the statements contained in this application, including the accompanying statements (if any), are true and complete.

By: _____

Title: _____

Subscribed and sworn to before me this _____ day of _____, 19____.

Notary Public

DEPARTMENT OF INSURANCE
STATE OF DELAWARE
LICENSE DIVISION
NOTICE OF POWER OF APPOINTMENT
AND
REMOVAL OF AGENTS LICENSED

To the INSURANCE COMMISSIONER of the State of Delaware:

(Name of Health Maintenance Organization)

of _____, in the State of _____, hereby constitutes and appoints

(Name of Appointee)

(Address)

whose signature appears below, with full power to appoint and remove agents for said Company within the State of Delaware and such appointment of said agents shall be as valid and binding as if made directly by the officers of said Company. This designation may be changed by a subsequent filing.

(Signature of Appointee)

WITNESS our hands and seal of the Company hereto attached this _____ day of _____, 19____.

(Signature)

(Title)

(SEAL)

EXHIBIT D
DEPARTMENT OF INSURANCE
STATE OF DELAWARE
DESIGNATION OF PERSON(S) TO RECEIVE
DELAWARE REGULATIONS, BULLETINS,
CIRCULAR LETTERS, AND NOTICE OF
REGULATORY PROCEEDINGS

To the Insurance Commissioner, State of Delaware:

(Name of Health Maintenance Organization)

hereby designates:

(Telephone) (_____) _____

(Name of Designee)

to receive, from the Delaware Insurance Department, copies of Regulations, Bulletins, circular Letters and Notice of Regulatory Proceedings when issued by the Department, at the following address:

WITNESS my hand and seal of the Company affixed hereto this _____ day of _____, 19____.

(Signature)

(Officer's Title)

(SEAL)

EXHIBIT E
DEPARTMENT OF INSURANCE
STATE OF DELAWARE
DESIGNATION OF PERSON FOR
RECEIPT OF SERVICE OF PROCESS

To the Insurance Commissioner of the State of Delaware, pursuant to 18 Del.C. §524(e)

(Name of Health Maintenance Organization)

of _____ hereby

(Administrative/Mailing Address)

designates _____ Telephone: () _____

(Name of Designee)

as the person to whom process served upon the Commissioner against the above cited company is to be forwarded. (If the address of the designee is other than reflected above, please provide the mailing address.)

WITNESS my hand and seal of the company this _____ day of _____,
19_____.

(Title of Officer)
(SEAL)

FORM NO. H-5

EXHIBIT F

BIOGRAPHICAL AFFIDAVIT

(Print or Type)

Full Name and Address of Company (Do Not Use Group Names):

In connection with the above named company, I herewith make representation and supply information about myself as hereinafter set forth. (Attach addendum or separate sheet if space hereon is insufficient to answer any question fully.) IF ANSWER IS "NO" OR "NONE", SO STATE.

1. Affiant's Full Name (Initials Not Acceptable.)
2. a. Have you ever had your name changed? _____ If yes, give the reason for the change
- b. Other names used at any time.
3. Affiant's Social Security Number.
4. Date and Place of Birth.
5. Affiant's Business Address.
Business Telephone:
6. List your residences for the last ten (10) years starting with your current address, giving:
DATE ADDRESS CITY AND STATE
7. Education: Dates, Names, Locations and Degrees.
College
Graduate Studies
Others
8. List memberships in Professional Societies and Associations.
9. Present or Proposed Position with the Applicant Company.
10. List complete employment record (up to and including present jobs, positions, directorates or officerships) for the past twenty (20) years, giving:
DATES EMPLOYER AND ADDRESS TITLE
11. Present employer may be contacted. Yes No (Circle One)
Former employers may be contacted. Yes No (Circle One)
12. a. Have you ever been in a position which required a fidelity bond?
If any claims were made on the bond, give details.
- b. Have you ever been denied an individual or position schedule fidelity bond, or had a bond cancelled or revoked?

If yes, give details.

13. List any professional, occupational, and vocational licenses issued by any public or governmental licensing agency or regulatory authority which you presently hold or have held in the past (state date license issued, issuer of license, date terminated, reasons for termination).

14. During h last ten (10) years, have you ever been refused a professional, occupational, or vocational license by any public or governmental licensing agency or regulatory authority, or has any such license held by you ever been suspended or revoked?

If yes, give details.

15. List any insurers in which you control directly or indirectly or own legally or beneficially 10% or more of the outstanding stock (in voting power).

If any of the stock is pledged or hypothecated in any way, give details.

16. Will you or members of your immediate family subscribe to or own, beneficially or of record, shares of stock of the applicant insurance company or its affiliate?

If any of the shares or stock are pledged or hypothecated in any way, give details.

17. Have you ever been adjudged a bankrupt?

18. a. Have you ever been convicted or had a sentence imposed on suspended or had pronouncement of a sentence suspended or been pardoned for conviction of or pleaded guilty or nolo contendere to an information or indictment charging any felony, or charging a misdemeanor involving embezzlement, theft, larceny, or mail fraud, or charging a violation of any corporate securities statute or any insurance law, or have you been subject to any disciplinary proceedings of any federal or state regulatory agency?

If yes, give details.

Exhibit F Concluded

b. Has any company been so charged, allegedly as a result of any action or conduct on your part? If yes, give details.—

19. Have you ever been an officer, director, trustee, investment committee member, key employee, or controlling stockholder of any insurer which, while you occupied any such position or capacity with respect to it, became insolvent or was placed under supervision or in receivership, rehabilitation, liquidation or conservatorship?—

20. Has the certificate of authority or license to do business of any insurance company of which you were an officer or director or key management person ever been suspended or revoked while you occupied such position?—

If yes, give details.

Dated and signed this _____ day of _____ at _____.

I hereby certify under penalty of perjury that I am acting on my own behalf, and that the foregoing statements are true and correct to the best of my knowledge and belief.

(Signature of Affiant)

County _____

State _____

Personally appeared before me the above named _____ personally known to me, who, being duly sworn, deposes and says that he executed the above instrument and that the statements and answers contained therein are true and correct to the best of his knowledge and belief.

Subscribed and sworn to before me this _____ day of _____, 19____.

Notary Public

My Commission Expires _____

(SEAL)

EXHIBIT G

EXHIBIT H

Rules and Regulations Governing the Application and Operation of Health Maintenance Organizations Adopted by the State Board of Health on January 27, 1983, effective March 15, 1983 Revised July 1, 1989

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Exhibit A

PART ONE

Legal Authority and Definitions

A. ~~Legal Authority.~~ These regulations are adopted under Part VIII, Title 16, ~~Del.C.~~, Chapter 91, pursuant to delegation of authority from the Secretary of the Department of Health and Social Services to the Director of the Division of Public Health on December 22, 1982.

B. ~~Definitions.~~

1. ~~"Basic health services" means a range of services, including at least the following: usual physician services, hospitalization, laboratory, x-ray, emergency and preventive services and out-of-area coverage.~~

~~Included under basic health services are the following:~~

a. ~~"Administrator/Director" means the individual employed to manage and direct the activities of the Health Maintenance Organization.~~

b. ~~Physician services, including consultant and referral services by a physician or other health care providers licensed by the State of Delaware.~~

c. ~~At least three hundred sixty (360) days of inpatient hospital services.~~

d. ~~Medically necessary emergency health services.~~

e. ~~Initial diagnosis and acute medical treatment (one (1) time only) and responsibility for making referrals (but not assuming financial responsibility) to appropriate ancillary facilities for the abuse of or addiction to alcohol and drugs.~~

f. ~~Diagnostic laboratory and diagnostic and therapeutic radiological services.~~

g. ~~Preventive health services include the provision of physical examinations, Papanicolaou smears, immunizations, infertility services and children's eye examinations (through age 17), conducted to determine the need for vision correction performed at a frequency determined to be appropriate medical practice. Other preventive services may be provided by the Organization as contained in the Health Care Contract. The~~

minimum level, scope and range of such services shall be determined by the Organization, subject to the approval of the State Board of Health.

h. The Organization should encourage, and actively provide, or arrange for, its members health education services, education in the appropriate use of health services and education in the contribution each member can make to the maintenance of his own health. This information, in whatever form it may take, must be in the opinion of the State Board of Health, understandable and not misleading.

i. Emergency out-of-area coverage.

2. "Supplementary health services" means any health services other than basic health services which may be provided by an Organization to its members and/or for which the member may contract such as:

a. ICF or long term care,

b. vision care not included in basic health services,

c. dental services,

d. mental health services,

e. long term physical medicine or rehabilitative services,

f. prescription health services, and

g. other services, such as occupational therapy, nutritional, home health, homemaker and family planning services.

3. "Certified Health Maintenance Organization" means a Health Maintenance Organization which has been issued a Certificate of Authority under 16 ~~Del.C. §~~, or which is operating pending action as provided in 16 ~~Del.C. §~~(b).

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

5. "Health Maintenance Organization" (HMO) means a public or private organization organized under the laws of any state, which:

(i) provides or otherwise makes available to enrolled participants health care services, including at least the basic health services defined in 1. above;

(ii) is compensated (except for co-payment) for the provision of basic health services to the enrolled participants on a predetermined periodic rate basis; and

(iii) provides physician services primarily 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).

6. "Insurance Department" means the Delaware Insurance Department.

7. "Member" 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 Organization, under which the Organization assumes the responsibility to provide to such person(s) basic health services and such supplemental health services as are enumerated in the Health Care Contract.

8. "Health care professional" means individuals engaged in the delivery of health services as licensed by the State of Delaware.

9. "Office" means any facility where members receive primary care and/or other health services.

10. "Certificate of Authority" means the authorization by the department of Health and Social Services to operate an HMO and this certificate shall be deemed to be a license to operate such an Organization.

11. "Commissioner" means the Insurance Commissioner of Delaware.

12. "Health care contract" refers to any agreement between an Organization and a member or group which sets forth the services to be supplied to the member in exchange for payments made by the member.

13. "Premium" refers to payment(s) called for in the Health Care Contract which must be:

a. paid or arranged for by, or on behalf of, the member before health care services are rendered by the Organization;

b. paid on a periodic basis without regard to the date on which health services are rendered; and

c. with respect to an individual member are fixed without regard to frequency, extent or cost of health services actually furnished.

14. "Supplemental payment" refers to any payment not incorporated in premium which is required to be paid to the Organization or providers under contract to the Organization by the member.

15. "Geographical area" refers to the stated primary geographical area served by an Organization. The primary area served shall be a radius of not more than thirty (30) miles or more than forty (40) minutes driving time from each office operated or contracted by the Organization. Members recruited outside the primary service area

must receive special arrangements to be approved by the Director. In non-metropolitan areas, i.e., not containing a city of over fifty thousand (50,000) persons, the limits of the primary service areas may be larger, but will be subject to approval of the Director.

16. "Out of area coverage" refers to health care services, as specified in the Health Care Contract, provided outside the Organization's geographic service area with appropriate limitations and guidelines acceptable to the Director and the Commissioner. As a minimum, such coverage must include emergency care.

17. "Comprehensive health planning agencies" refers to those agencies which have the responsibility for the planning and review of health facilities, resources and services under the State or Federal authority.

18. "Special services" refers, but is not limited to, the following services:

a. Pharmacy services. Pharmaceutical services, when provided by the Organization or its provider's staff, 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. Organizations with a licensed pharmacy shall have a Pharmacy and Therapeutics Committee. Pharmaceutical services may be provided on the premises of the Organization or by contract with an independent licensed provider. The contract shall be available for inspection by the Director at all times.

b. Clinical laboratory services. All clinical laboratories operated by the Organization must have a director who is a physician or a person formally trained in a clinical laboratory field (i.e., biochemistry), as approved by the Director and who is qualified by training and experience to supervise and conduct the work of the clinical laboratory. If the laboratory director is not a qualified pathologist, the services of a pathologist so qualified shall be retained on a consultative basis to confer with the laboratory director and/or members of the medical staff on a periodic basis acceptable to the Director. If an Organization uses or controls a laboratory which performs limited services as defined by the Director, the Director shall have the authority to determine whether the laboratory is subject to this provision.

c. Radiology services. The Organization'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 Organization shall provide for regular consultation by a qualified radiologist, who is under contract with the Organization and is responsible for reviewing all x rays and procedures. The number of qualified radiological technologists employed shall be sufficient to meet the Organization's requirements. If the Organization operates a radiology service and provides emergency services, at least one qualified technologist shall be on duty or on call at all times. The Director may exempt an Organization where the method and personnel used to deliver radiology and/or emergency services warrant it.

PART TWO

Application and Certificate of Authority

A. No person shall establish or operate an HMO in the State of Delaware or enter this State for purposes of enrolling persons in an HMO without obtaining a "Certificate of Authority." 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~~.

B. Every HMO which is established or operating in this State on the effective date of these regulations must apply for and obtain a Certificate of Authority in order to continue such operation.

C. Each application for a Certificate of Authority shall be made in writing to the Department of Health and Social Services, Division of Public Health, shall be verified by an officer or authorized representative of the applicant, shall be in a form prescribed by the Department (Exhibit A attached) and shall set forth or be accompanied by the following:

1. Organizational Information

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

b. A copy of the basic organizational document of the applicant and all amendments thereto;

c. 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

d. A list of positions, names and brief resume for all management personnel.

2. Health Services Delivery

a. A description of the plan of operation of the HMO. Include the following items: a listing of basic and supplemental health services with utilization projections; a discussion of the arrangements for delivery of all covered health services (including indications as to whether outpatient services are provided directly or through referrals/purchase agreements with outside fee for service providers); a general description of service sites or facilities (specifying days and hours of operation in the case of outpatient facilities); a discussion of special policies or provisions designed to improve accessibility of services;

b. Copies of executed contracts or letters of agreement between the HMO and providers, including individual physicians, IPAs, group practices, hospitals, laboratory services, nursing homes, home health agencies, and so on. 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;

c. A list of participating (plan) physicians by specialty as well as a list of other health care personnel providing services. Provide staffing ratios for each category of personnel:

d. 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 HMO;

e. A description of the applicant's utilization control and quality assurance mechanisms, including information on committee structures, criteria, and procedures for corrective action; and

f. A discussion of the arrangements for assuring continuity of care for all services provided to enrollees. Include comments on the primary care physician's responsibilities for coordination and oversight of the patient's overall health care and the impact of the medical record keeping system on continuity of care.

3. Enrollment and Marketing

a. A brief description of the target population, including projections of enrollment levels for at least the first three (3) years of operation and the key assumptions (such as, assumed penetration rate) underlying these projections;

b. A description of the geographic area to be served, with a map showing service area boundaries, locations of the HMO's institutional and ambulatory care facilities, and travel times from various points in the service area to the nearest ambulatory and institutional services; and

c. A description of the proposed marketing techniques and sample copies of any advertising or promotional material.

4. Financial

a. A financial statement for the most recent fiscal year (certified by C.P.A. when possible).

b. Financial projections for a minimum of three (3) years. If deficits are anticipated, the projections should cover the period up to and including the year in which break-even is expected. Include projections of revenue and expenses; a projected balance sheet; a pro forma cash flow statement; and a pro forma statement of changes in financial position. Indicate the assumptions on which statements are based, including inflation and utilization assumptions;

c. Sources of financing (private and governmental) and, where appropriate, written assurances of the availability of financing;

d. A description of reinsurance arrangements or risk sharing arrangements with providers; and

e. The proposed premiums for all classes of enrollee, co-payments, and the rating plan or rating rules used by the applicant.

D. Within sixty (60) days of receipt of application for issuance of Certificate of Authority the Department, acting through the Division of Public Health, shall determine whether the applicant, with respect to health care services to be furnished, has:

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

2. arrangements for an ongoing health care quality assurance program;

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

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~~

5. ~~the staff and facilities to directly provide at least half of the outpatient medical care costs of its anticipated enrollees on a prepaid basis.~~

E. ~~The Department shall issue a Certificate of Authority to any person filing an application under this section within sixty (60) days of receipt of such application if:~~

1. ~~The application contains all the information required under C. of this Part;~~

2. ~~The Department has not made a negative determination pursuant to D. of this Part; and~~

3. ~~Payment of the application fees prescribed in 16 Del.C. 9114 has been made.~~

F. ~~If within sixty (60) days after an 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. Such requests for hearing must be filed with the Division of Public Health within sixty (60) days of the notification of nonapproval of the application. The hearing shall be held within sixty (60) days of the receipt of written request. Hearings shall be conducted in accordance with applicable laws and regulations.~~

G. ~~No Certificate of Authority shall be issued until there is first filed with the Department a certification by the Insurance Commissioner of Delaware that a deposit has been made, and is being maintained, in accordance with the terms and conditions of 18 Del.C. 513(f).~~

~~The required deposit shall be continuously maintained in trust. In case of a deficiency of deposit, the Insurance Commissioner shall transmit notice thereof to both the HMO 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 HMO.~~

H. ~~Every HMO operating in this State shall file with the Department every manual, minimum, class rate, rating schedule, or rating plan and every other rating rule and every modification of any of the foregoing which it proposes to use. Every filing shall indicate the effective date thereof.~~

I. ~~Annual reports shall be filed with the Department by any HMO on or before July 1 covering the preceding fiscal year. Such reports shall include a financial statement of the Organization, its balance sheet and receipts and disbursements for the preceding fiscal year, and a statement explaining any material changes in the information originally submitted.~~

J. ~~Prohibited Practices:~~

1. ~~No HMO or representative may cause or knowingly permit the use of advertising or solicitation which is untrue or misleading; and~~

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

K. ~~A certified HMO may solicit enrollees and sell its services by its own employees, persons licensed to sell health insurance, or licensed or permitted to sell the benefit program of a health service corporation.~~

L. ~~Relationships with Insurance Companies and Health Service Corporations:~~

~~Any person or corporation authorized to transact insurance or to engage in the business of a health service corporation in this State, may either directly or through a subsidiary or affiliate, operate an HMO subject to the provisions of 16 Del.C. § 91. In addition, no provision of the Insurance Code shall bar such person or corporation from contracting with an HMO to provide insurance, reinsurance or similar protection for such HMO against the cost of care provided through the HMO and to provide coverage in the event of the failure of the HMO to meet its obligations.~~

M. ~~Examinations:~~

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

2. ~~Every HMO 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 HMO and of any health care providers with which it has contracts, agreements or other arrangements;

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

4. In lieu of such examination of an out of state HMO the Department may accept the report of a similar examination made by the appropriate agency of another state; provided that if the HMO delivers health care services in this State, such report from another state shall not relieve the Department of its responsibility to make its own examination.

N. Suspension or Revocation of Certificate of Authority.

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

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

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

c. The HMO is no longer in compliance with the requirements of ~~16 Del.C. § 9104(b)~~; or

d. The continued operation of the HMO would be detrimental to the health or well-being of its enrollees needing services.

2. 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;

3. Suspension of a Certificate of Authority pursuant to this section shall not prevent an HMO 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 HMO other than communication, approved by the Department, which are intended to give information as to the effect of the suspension.

4. In the event that the Department decides to revoke the Certificate of Authority of an HMO 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, and he 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 HMO shall not conduct any further business except as expressly permitted in the Department's decision and its 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.

O. Regulation and Administrative Procedures.

The Department shall have authority to promulgate such reasonable rules and regulations as are necessary to carry out the provisions of this Chapter. Such rules and regulations shall conform to and be promulgated pursuant to the Administrative Procedures Act, ~~29 Del.C., Ch. 101~~.

P. Fees.

Every HMO subject to this Chapter shall pay the following fees.

1. For filing an application for a Certificate of Authority—\$375.00.

2. For filing an annual report—\$250.00.

Q. Relationship to Other Laws.

1. Except as provided in 5. below, a certified HMO shall not be deemed to be practicing medicine and the HMO shall be exempt from the provisions of statutes, rules and regulations relating to the practice of medicine;

~~2. No HMO delivering health care services in this State shall engage in a contract with or employ, for the delivery of such services, any person who does not hold a Delaware license to practice the profession for which such person is engaged or employed, if such practice requires a license; and~~

~~3. Except as provided in 16 Del.C., 9108 or 9109, solicitation of enrollees by a certified HMO or its employees shall not be construed as a violation of any statute, rule or regulation relating to solicitation or advertising by health professionals.~~

~~4. The provisions of Title 18 and other laws of this State relating to insurance, insurance contracts, insurance policies, insurers or health service corporations shall not be applicable to any certified HMO. If an insurer or health service corporation operates a certified HMO only the activities related to the operation of the certified HMO shall be exempt from the provisions of such laws relating to insurers or health service corporations.~~

~~5. Notwithstanding 1. and 4. of this section, every HMO shall be a health care provider within the meaning of the Health Care Malpractice Insurance and Litigation Act, 18 Del.C., Ch. 68.~~

~~6. Issuance of a Certificate of Authority pursuant to 9104 shall be deemed licensure by the State Board of Health for purposes of the Delaware Health Facilities Act, 16 Del.C., 9703(5).~~

~~R. Confidentiality of Health Information.~~

~~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 HMO 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 HMO wherein such data or information is pertinent. The communication of such data or information from a health care provider to an HMO shall not prevent such data or information from being deemed confidential for purposes of the Delaware Uniform Rules of Evidence.~~

~~S. Freedom of Choice.~~

~~In order to promote freedom of choice by employers and others in Delaware who purchase group health care coverage, it shall be unlawful, from and after thirty (30) days following the effective date of this enactment, for any insurer, health service corporation, or other person in the business of providing or insuring health care services or coverage, to offer any insurance or health care coverage to any person in this State on a basis which would preclude such person from allowing some members of a group to elect to enroll in a certified HMO either by means of an express prohibition or by requiring the same payment regardless of such election; provided, however, that it shall not be unlawful for such persons to offer insurance or coverage on a basis where the rates or cost thereof are calculated according to the number of persons in the group for which such coverage is provided. The Insurance Department shall have authority to enforce the provisions of this section.~~

PART THREE

Quality Assurance and Operation of Health Maintenance Organizations

The guidelines contained in this Part shall be enforced by the State Board of Health in a manner which facilitates an Organization's compliance thereto. Variations in the requirements of this Part may be approved at the discretion of the State Board of Health.

A. Hours of Service

1. The Organization must provide clinical services six (6) days a week for a total of forty (40) hours with no less than three (3) hours on any given day, unless otherwise approved by the State Board of Health.

2. Emergency services must be available twenty four (24) hours per day and seven (7) days per week.

a. The Organization shall have a well defined, written plan for the availability of twenty four (24) hour emergency care, which as a minimum makes provision for the assessment and treatment or referral to an appropriate facility.

b. These plans must be reviewed annually. When changes are made, a plan acceptable to the Board must be on file.

c. The Board may waive the radius for emergency services if the services are adequate.

d. When the Organization provides its own emergency services, facilities must be provided to ensure prompt diagnosis and emergency treatment: this includes adequate Emergency Room space, separate from major surgical suites. In Emergency Room facilities provided for or arranged for by the Organization 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 information shall be available at all times.

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

B. Environmental Health and Safety

1. Office premises and other structures operated by the Organization must have appropriate safeguards for patients.

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:

a. State Plumbing Code.

b. Waste Disposal Regulations.

c. Public Water Supply Regulations.

d. Food Service Requirements.

e. Radiation Control Regulations.

f. Hazardous Waste Regulations.

g. Air and Water Pollution Regulations.

h. Handwashing facilities shall be installed in accordance with applicable State and local regulations and conveniently located.

i. Toilet facilities shall meet appropriate State and local regulations.

j. Must meet the requirements of the State Fire Code.

3. The buildings must be architecturally accessible to handicapped individuals.

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

C. Housekeeping

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

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

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

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.

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

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

D. Emergency Utilities or Facilities

1. The Organization 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 and Equipment for Hospitals and Medical Facilities, Section 7.32H. (4)(b).)

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 be connected within ten (10) seconds.

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

E. Construction

1. New construction or substantial modifications on an existing organization 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.

2. Radiation requirements of the Authority on Radiation Protection must be met.

3. Facility plans or modifications must be submitted in the required manner.

F. Personnel

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 non-professional personnel.

~~2. Offices with five (5) or more physicians shall have at least one (1) full-time registered nurse (R.N.). The HMO may as an alternative, subject to the approval of the Director of the Division of Public Health, employ a licensed practical nurse (L.P.N.) and retain a licensed R.N. as a consultant.~~

~~3. Non-professional personnel shall have appropriate in-service education on clinical operations and procedures. The in-service training program must be conducted at least annually and be approved by the State Board of Health.~~

~~4. Primary physicians. There shall be at least one (1) full-time or full-time equivalent physician available on contract. There shall be at least 0.5 full-time equivalent primary physician for every 1,000 members enrolled.~~

~~5. Medical specialties. There shall be either full-time or part-time physicians, other appropriate professional specialists, or written agreements acceptable to the State Board of Health for consultation in internal medicine, pediatrics, general surgery, oral surgery, ENT, obstetrics and gynecology, orthopedic surgery, ophthalmology, pharmacy, radiology, physical therapy, psychiatry, nutrition and other reasonable services.~~

~~G. Health Services Information~~

~~Health services information shall be available to members and staff before and during enrollment periods. This should be understandable and not misleading.~~

~~H. Equipment~~

~~Each office operated by the Organization 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 Organization's office. Where emergency services are provided in the office, equipment such as a defibrillator, laryngoscope and other similar equipment must be present.~~

~~I. Specialized Services~~

~~The Organization shall provide special services necessary for diagnosis and treatment such as electrocardiography. 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 Board.~~

~~J. Central Sterilizing and Supply~~

~~Autoclaves or other acceptable sterilization equipment shall be provided of a type capable of meeting the needs of the Organization 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.~~

PART FOUR

Administrative Requirements

A. Administration

~~The Organization shall designate or assure the designation of appropriate person(s) to handle the administrative functions of the Organization. These functions shall include the following responsibilities: interpretation, implementation and application of policies and programs established by the Organization'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 of the office(s) in a manner acceptable to the Organization 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).~~

B. Qualifications

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

C. Medical Group Privileges

~~The physicians who are under contract, either full-time or part-time, shall have hospital privileges commensurate with their contractual obligations. Physicians must be licensed in Delaware in Medicine and Surgery and in all their branches. All offered medical specialty services must be covered either by the privileges of the full-time or part-time physicians or qualified medical specialists under written contract to the Organization.~~

D. Peer Review

The Organization shall show written evidence of continuing internal peer review which compares with generally accepted standards in the field of utilization review. This entails an ongoing quality assurance program for its health services and provides review by physicians and other health professionals of the process followed in the provision of health services.

1. The review program shall include the following:
 - a. a description of the method of review;
 - b. the goals of the review;
 - c. the standards used for comparative purposes; and
 - d. the results of the application of the above process.

2. In lieu of the internal peer review, the Organization may elect to satisfy this requirement by contracting with an outside peer review organization approved by the State Board of Health. The organizational methodology and results of this contractual program must be on file.

E. Medical Records

The Organization must maintain or provide for the maintenance of a medical records system which meets the accepted standards of the health care industry and necessary regulations of the State Board of Health.

1. 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.

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

3. Regulatory agencies shall have access to medical records for purposes of monitoring and review of HMO practices with appropriate safeguards for individual confidentiality.

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

F. Reporting Requirements and Statistics

The Organization shall submit reports, applicable to the State Board of Health, as required by these regulations and such generally applicable reports as requested. Reports on the individual operation of an Organization shall be submitted as reasonably required by the Department.

1. The Organization shall also provide in accordance with these regulations (including safeguards concerning the confidentiality of the doctor-patient relationship), an effective procedure for developing, compiling and evaluating statistics as well as other information.

2. The Organization shall disclose to its members the following information:

- a. the cost of its operation;
- b. the patterns of utilization of its services based on the information in 3. below; and
- c. the location and hours of its inpatient and outpatient health services.

3. The following statistics are required to be submitted to the Department on an annual basis:

- a. Physician visits per member per year.
- b. Hospital admissions per year and per 1,000 members per year.
- c. Hospital days per year and per 1,000 members per year.
- d. Average length of stay per hospital confinement.
- e. Outside consultations per year and per 1,000 members per year.
- f. Emergency Room visits per year and per 1,000 members per year.
- g. Laboratory procedures per year and per 1,000 members per year.
- h. X-ray procedures per year and per 1,000 members per year.

4. The following will also be submitted to the Department annually:

- a. Total number of members at the end of the year.
- b. Total number of members enrolled during the year.
- c. Total number of members terminated during the year.

5. The following administrative reports are required by the Department whenever there is a

change:

- a. Full name of the Administrator.
- b. Full name of the Medical Director.
- c. Address(es) of the office(s) in operation.
- d. Name(s) of the hospital(s) used by the Organization.

G. Departmental Reviews

~~1. External Medical Audit~~

~~The Organization shall be subject to annual audits for the quality of the medical assurance system. The Organization shall provide the necessary data for the external audit as outlined by the Department. Where a Professional Standards Review Organization (PSRO) exists in the area, the Organization may contract with PSRO to provide periodic audits as to the quality of the medical assurance system.~~

~~2. Fiscal Examinations~~

~~The Commissioner may make an examination of the operation of any Organization as often as he deems it necessary for the protection of the interests of the people of the State of Delaware, but such examinations shall not be less frequently than once every three (3) years. Fiscal examinations shall be limited to the Organization's records of its operation unless the Commissioner deems it necessary to examine the records of providers pursuant to their services to the Organization.~~

~~The expenses of examinations shall be assessed against the Organization being examined and such Organization shall remit the expenses to the Commissioner.~~

~~H. Grievance Procedure~~

~~The Organization shall have an approved written grievance program which shall be available to its members as well as to any medical group or groups and other health delivery entities providing health services for the Organization. Copies of the procedures and a method of initiating a grievance shall be posted in a conspicuous place in all offices and sent to each member or member family unit when they are enrolled and each time the methods and procedures are substantially changed. The Organization shall designate to whom the grievance should be directed with an alternate person if the grievance involves the designated person.~~

~~1. Each grievance shall be answered in writing within thirty (30) days of submittal with the reply directed to the member(s) with the grievance.~~

~~2. Every Organization shall provide a reasonable procedure for handling grievances initiated by members and the recording of information related thereto in a form which may be readily reviewed by the Board of the Organization.~~

~~3. All grievance files shall be retained by the Organization for the Commissioner's and/or Department's examinations.~~

~~4. The Organization must notify the member whose grievance they cannot resolve that he may take his grievance to the Board of Directors.~~

~~I. Variances~~

~~A variance from the requirements of these regulations may be granted by the State Board of Health as the Board deems appropriate; provided, however, that such variance shall be within the spirit of these regulations and not contrary to law.~~

Exhibit A

STATE OF DELAWARE

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

HMO APPLICATION FOR A CERTIFICATE OF AUTHORITY

A. Identifying Information:

(1) Name of Applicant:

(1.1) Address:

(1.2) Telephone

(1.3) Zip Code:

(2) Chief Executive Officer:

(3) Type of Organization: (Check One)

() Staff

() Group Practice

() Individual Practice Association

() Other (Please describe)

(4) Anticipated date of operation:

B. Statement of Certification and Acknowledgement:

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 ~~Del.C.~~ (Certificate of Need).

Signature of Chief Executive Officer Date

A filing fee of \$375.00, payable to the Division of Public Health, must accompany this application. An original and two (2) copies of the application shall be submitted to:

Division of Public Health
Department of Health and Social Services
Jesse S. Cooper Memorial Building
Federal and Water Streets
Dover, Delaware 19904

1.0 Purpose and Statutory Authority

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

2.0 Definitions

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

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

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

"Appropriateness of services" means an appeal classification for adverse determinations that are made based on identification of treatment as cosmetic, investigational, experimental or not an appropriate or preferred treatment method or setting for the condition for which treatment is sought.

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

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

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

B. At least 365 days of inpatient hospital services;

C. Medically necessary emergency health services;

D. Diagnostic laboratory services;

E. Diagnostic and therapeutic radiological services;

F. Preventive health services; and

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

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

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

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

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

"Covered Person": see "Enrollee."

"Department" means the Delaware Department of Insurance.

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

"Emergency medical condition" means a medical or behavioral condition, the onset of which is sudden, that manifests itself by symptoms of sufficient severity including, but not limited to, severe pain, that a prudent layperson, possessing an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

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

B. Serious impairment to bodily functions;

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

D. Serious disfigurement of such person.

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

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

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

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

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

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

"Health care services" means any services included in the furnishing to any individual of medical or dental care, or hospitalization or incidental to the furnishing of such care or hospitalization, as well as the furnishing to any person of any and all other services for the purpose of preventing, alleviating, curing or healing human illness, injury or physical disability.

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

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

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

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

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

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

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

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

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

C. Provides physician services.

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

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

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

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

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

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

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

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

- A. Paid or arranged for by, or on behalf of, the enrollee before health care services are rendered by the MCO;
- B. Paid on a periodic basis without regard to the date on which health care services are rendered; and
- C. With respect to an individual enrollee, are fixed without regard to frequency, extent or cost of health services actually furnished.

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

"Provider" means a health care professional or facility.

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

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

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

3.0 Certificate of Authority

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

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

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

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

3.1.4 Copies of management, agency or administrative contracts;

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

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

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

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

to this regulation);

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

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

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

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

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

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

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

3.5 Denial of Application for Certificate of Authority

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

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

4.0 Capital Funds Required

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

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

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

5.0 Reinsurance Requirement

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

6.0 Special Requirement in the Event of Financial Impairment/Insolvency

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

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

6.3 Each such solvent licensed MCO shall accept such enrollee without any waiting periods or pre-

existing conditions exclusions and such acceptance both as to premium as well as delivery of service shall be retroactive to the date on which a court of competent jurisdiction has declared the predecessor MCO financially impaired.

7.0 Required Contractual Provisions

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

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

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

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

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

8.0 Enrollee Rights and Responsibilities

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

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

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

8.2.2 Out-of-pocket costs to the enrollee;

8.2.3 Lists of participating providers;

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

8.2.5 Policies governing the provision of emergency and urgent care;

8.2.6 Written explanation of the internal and external review processes;

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

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

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

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

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

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

8.2.8.5 To receive from the enrollee's physician(s) or provider, in terms that the enrollee understands, an explanation of his complete medical condition, recommended treatment, risk(s) of the treatment, expected results and reasonable medical alternatives. If the enrollee is not capable of understanding the

information, the explanation shall be provided to his next of kin or guardian and documented in the enrollee's medical record;

8.2.8.6 To formulate advance directives;

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

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

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

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

8.2.9 A complete statement of responsibilities of enrollees.

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

9.0 Provider Relations

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

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

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

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

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

10.0 Prohibited Practices

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

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

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

11.0 Quality Assurance and Operations

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

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

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

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

11.1.4 Providing clinical direction to physicians responsible for utilization management

determinations:

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

11.1.6 Evaluating the medical aspects of provider contracts; and

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

11.2 Health Care Professional Credentialing

11.2.1 General Responsibilities. An MCO shall:

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

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

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

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

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

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

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

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

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

11.2.4 Verification Responsibilities. An MCO shall:

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

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

11.2.4.1.2 current level of professional liability coverage, if applicable;

11.2.4.1.3 status of hospital privileges, if applicable;

11.2.4.1.4 specialty board certification status, if applicable; and

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

11.2.4.2 Obtain, subject to either primary or secondary verification:

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

11.2.4.2.2 the health care professional's malpractice history.

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

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

11.2.4.3.2 current level of professional liability coverage, if applicable;

11.2.4.3.3 status of hospital privileges, if applicable;

11.2.4.3.4 current DEA registration certificate, if applicable; and

11.2.4.3.5 specialty board certification status, if applicable.

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

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

11.3 Provider Network Adequacy

11.3.1 Primary, Specialty and Ancillary Providers

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

11.3.1.2 If a plan has an insufficient number of providers that are geographically accessible and available within a reasonable period of time to provide covered health services to enrollees, the MCO shall cover non-network providers, and shall prohibit balance billing.

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

11.3.2 Facility and Ancillary Health Care Services

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

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

11.3.3 Emergency and Urgent Care Services

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

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

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

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

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

11.3.3.4.2 trauma services at any designated Level I or II trauma center as medically necessary. Such coverage shall continue at least until the enrollee is medically stable, no longer requires critical care, and can be safely transferred to another facility, in the judgment of the treating physician. If the MCO requests transfer to a hospital participating in the MCO network, the patient must be stabilized and the transfer effected in accordance with federal regulations at 42 CFR 489.20 and 42 CFR 489.24;

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

11.3.3.4.4 hospital services for emergency care; and

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

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

11.3.4 The MCO shall submit evidence of network adequacy to the Department upon request. If

the Department receives a complaint regarding an MCO's network adequacy, the burden shall be on the MCO to prove network adequacy to the satisfaction of the Department.

11.4 Utilization Management

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

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

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

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

11.4.5 Utilization Management Staff Availability

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

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

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

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

11.4.6 Utilization Management Determinations

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

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

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

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

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

11.5 Quality Assessment and Improvement

11.5.1 Continuous Quality Improvement

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

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

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

11.5.1.4 The MCO shall follow up on findings from the program to assure that

effective corrective actions have been taken, including at least policy revisions, procedural changes and implementation of educational activities for enrollees and providers.

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

11.5.2 External Quality Audit

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

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

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

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

11.5.3 Reporting and Disclosure Requirements

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

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

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

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

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

12.0 Recordkeeping and Reporting Requirements

12.1 Medical Records Retention

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

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

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

12.1.2 Retention and Destruction

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

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

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

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

12.2 Reporting Requirements and Statistics

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

- 12.2.1.1 A statistical summary evaluating the network adequacy and accessibility to the enrolled population;
- 12.2.1.2 Annual appeal report of all grievances, petitions for arbitration and appeals under the Independent Health Care Appeals Program as required under Department Regulation 1301.
- 12.2.1.3 Evidence of compliance with the capital funds requirements of section 4.0 of this regulation.
- 12.2.2 An MCO shall submit the following information to the Department whenever there is a change:
- 12.2.2.1 Substantial changes in organization, bylaws, or governing board
- 12.2.2.2 Full name of the Chief Executive Officer
- 12.2.2.3 Full name of the Medical Director
- 12.2.2.4 Substantial changes in marketing materials, grievance procedures or the utilization management program
- 12.2.2.5 Any significant amendment to or revision relating to the text or subtext of an approved provider contract shall be submitted to and approved by the Department prior to the execution of an amended or revised contract with the providers of an MCO.

13.0 Compliance with Regulation

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

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

14.0 Separability Provisions

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

10 DE Reg. 1249 (02/01/07) (Prop.)