6401 Legislative intent.

It is the intent of the General Assembly in enacting this chapter to provide that the Insurance Commissioner regulate managed care organizations, including financial solvency, established or operated in this State. It is the intent of the General Assembly that such organizations be subject only to the provisions of this chapter, including those other chapters of this title expressly included in § 6411 of this title, and no insurance law hereinafter enacted shall be deemed to apply to managed care organizations unless they are specifically referred to therein.


§ 6402 Short title.

This chapter shall be known and may be cited as the "Delaware Managed Care Organization Act" or the "Delaware MCO Act."


§ 6403 Definitions.

As used in this chapter, unless the context clearly indicates a different meaning, the following words and phrases shall have the meaning ascribed to them in this section:

(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.

(2) "Certified managed care organization" means a managed care organization which has been issued a certificate of authority under this title.

(3) "Department" means the Delaware Department of Insurance.

(4) "Health-care services" means any service 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.
(5) "Managed care organization" means a public or private organization, organized under the laws of any state, which:

a. Makes health-care services, including at least the basic health services defined in paragraph (1) of this section above, available to enrolled participants;

b. Is primarily compensated (except for copayment) for the provision of basic health-care services to enrolled participants on a predetermined periodic rate basis; and

c. Provides physicians' services.

The organization may also arrange for health-care services on a prepayment or other financial basis.

§ 6404 Certificate of authority; when required; application and issuance.

(a) No person shall establish, operate or engage in the business of a managed care organization or enter this State for the purpose of enrolling persons in a managed care organization without first obtaining a certificate of authority from the Insurance Commissioner. A foreign corporation shall not be eligible to apply for such certificate of authority unless it has first qualified to do business in this State as a foreign corporation pursuant to § 371 of Title 8.

(b) Application for a certificate of authority as a managed care organization shall be made on forms promulgated by the Insurance Commissioner and shall contain such information as the Commissioner shall by regulation require. The application shall be accompanied by copies of any documents which the Insurance Commissioner shall by regulation require and copies of the following documents:

(1) Certificate of incorporation;

(2) Bylaws;

(3) A list of the names and addresses of the members of the board of directors or other governing body of the corporation and its principal officers;

(4) A statement of the geographic areas in which the managed care organization proposes to operate;

(5) A statement describing how the managed care organization shall operate, including its anticipated enrollment, its basic health services, its personnel, the proposed method of marketing and a financial plan which includes a projection of operating results for the first 3 years of operation;

(6) A statement identifying the states where the managed care organization is authorized to operate, any states where it has pending an application for authorization to operate; and States where it has been cited for a violation of any laws or legislation and an explanation of any such alleged violation, including the status or outcome;
(7) Forms of proposed contracts to be offered for members who enroll on a direct payment or standard
group basis;

(8) Tables of rates to be charged for such contracts or statement of the rating formulas to be used in lieu of fixed rates; and

(9) Financial statements showing the applicant's assets, liabilities and sources of financial support; provided that if the applicant's financial affairs are audited by an independent certified public accountant, a copy of the applicant's most recent certified financial statement shall be deemed to satisfy this requirement.

(c) Within 60 days of receipt of an application for issuance of a certificate of authority, the Department shall determine whether the applicant, with respect to health-care services to be furnished:

(1) Has demonstrated the ability to provide such health-care services in a manner assuring availability, accessibility and continuity of services;

(2) Has arrangements for an ongoing health-care quality assurance program concerning health-care processes;

(3) Has the capability to comply with all applicable rules and regulations promulgated by the Department;

(4) Has 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) Has the staff and facilities to directly provide at least half of the outpatient medical care costs of its anticipated enrollees on a prepaid basis.

(d) The Commissioner shall issue a certificate of authority to the applicant when the applicant has shown to the Commissioner's satisfaction that:

(1) The applicant meets or is able to meet the requirements of this title as set forth herein;

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

(3) The applicant is financially responsible and able to meet its obligations to members.

§ 6405 Suspension or revocation of certificate of authority.

(a) The Commissioner may, after a hearing, suspend or revoke the certificate of authority of a managed care organization for any of the following causes:
(1) If the managed care organization is no longer qualified therefor under this chapter;

(2) For a violation by the managed care organization of any provision of this chapter;

(3) Upon any applicable ground under this chapter or any of the chapters specified in § 6411 of this title for which the certificate of authority of an insurer may be suspended or revoked;

(4) If the managed care organization is operating in a manner which deviates substantially, in a manner detrimental to its enrollees, from the plan of operation described by it in securing its certificate of authority;

(5) If the managed care organization does not have in effect arrangements to provide the quantity and quality of health-care services required by its enrollees; or

(6) If the continued operation of the managed care organization would be detrimental to the health or well-being of its enrollees needing services.

(b) 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, Chapter 101 of Title 29, 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.

(c) Suspension of a certificate of authority pursuant to this section shall not prevent a managed care organization 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 managed care organization other than communication, approved by the Department, which are intended to give information as to the effect of the suspension.

(d) In the event that the Department decides to revoke the certificate of authority of a managed care organization, the decision so providing shall specify the time and manner in which its business shall be concluded. In any case, after the Department has issued a decision revoking a certificate of authority, unless stayed in connection with an appeal, the managed care organization shall not conduct any further business except as expressly permitted in the Department's decision and it shall engage only in such activities as are directed by the Department are required to assist its enrollees in securing continued health care coverage.

63 Del. Laws, c. 382, § 1; 66 Del. Laws, c. 124, §§ 1, 7-9; 71 Del. Laws, c. 229, §§ 1, 6; 75 Del. Laws, c. 362, § 2;

§ 6406 Annual report.
(a) Every managed care organization shall annually, on or before June 1, file with the Department a report covering the preceding fiscal year.

(b) Such report shall include:

(1) A financial statement of the organization, including its balance sheet and receipts and disbursements for the preceding fiscal year; and

(2) A statement explaining any material change in the information originally submitted pursuant to this title.

§ 6407 Prohibited practices.

(a) No managed care organization or representative thereof may cause or knowingly permit the use of advertising or solicitation which is untrue or misleading.

(b) No managed care organization may cancel or refuse to renew the enrollment of an enrollee solely on the basis of the enrollee's health. This subsection shall not prevent a managed care organization from canceling the enrollment of an enrollee if the enrollee misrepresented the state of the enrollee's health at the time of enrollment. This subsection shall not prevent a managed care organization from canceling or refusing to renew an enrollment for reasons other than an enrollee's health, including without limitation nonpayment of premiums or fraud by the enrollee.

(c) The Department shall have exclusive authority to investigate violations of this section.

§ 6408 Rules and regulations.

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

§ 6409 Fees.

Every managed care organization subject to this chapter shall pay $750 for filing an application for a certificate of authority and $500 for filing an annual report.

§ 6410 Provision of professional services.
(a) A managed care organization shall have a medical director. The medical director shall be licensed to practice medicine in Delaware in accordance with § 1702 of Title 24. The medical director's duties shall include, at a minimum, those specified in regulations promulgated by the Department pursuant to the authority granted. The medical director may assign duties to other physicians and nonphysician personnel employed by, or under contract to, the managed care organization, provided, however, that the medical director shall retain responsibility for assigned duties. Any decision to deny a covered service shall be rendered by a physician.

(b) A certified managed care organization may contract with, or employ, any licensed health-care professional to provide health-care services, notwithstanding any statute, rule or regulation to the contrary. No managed care organization 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.


§ 6411 Relationship to other laws.

(a) Managed care organizations shall be subject to this chapter and to the following chapters of this title, as amended from time to time, to the extent applicable and not in conflict with the express provisions of this chapter. For purposes of the following chapters only, a managed care organization shall be treated as a health insurer, and its coverages shall be deemed to be "medical and hospital expense-incurred insurance policies" for purposes of Chapter 25 of this title:

(1) Chapter 1 of this title (General Definitions and Provisions).

(2) Chapter 3 of this title (The Insurance Commissioner).

(3) Chapter 5 of this title (Authorization of Insurers and General Requirements).

(4) Chapter 9 of this title (Kinds of Insurance; Limits of Risk; Reinsurance).

(5) Chapter 11 of this title (Assets and Liabilities).

(6) Chapter 13 of this title (Investments).

(7) Chapter 15 of this title (Administration of Deposits).

(8) Chapter 17 of this title (Licensing of Professional Insurance Personnel).

(9) Chapter 21 of this title (Unauthorized Insurers — Prohibitions, Process and Advertising).


(11) Chapter 25 of this title (Rates and Rating Organizations).
(12) Chapter 27 of this title (The Insurance Contract).

(13) Chapter 33 of this title (Health Insurance Contracts).

(14) Chapter 34 of this title (Medicare Supplement Insurance Minimum Standards).

(15) Chapter 35 of this title (Group and Blanket Health Insurance).

(16) Chapter 36 of this title (Individual Health Insurance Minimum Standards).

(17) Chapter 50 of this title (Insurance Holding Company System Registration).

(18) Subchapter II of Chapter 58 of this title (Risk-Based Capital (RBC) for Health Organizations).

(19) Chapter 59 of this title (Rehabilitation and Liquidation).

(b) A certified managed care organization shall not be deemed to be practicing medicine and the managed care organization shall be exempt from statutes, rules and regulations relating to the practice of medicine. A certified managed care organization shall not be deemed to be practicing any other licensed health-care profession, and the managed care organization shall be exempt from statutes, rules and regulations relating to such professions.

(c) Except as provided in § 6407 of this title, solicitation of enrollees by a certified managed care organization or its employees shall not be construed as a violation of any statute, rule or regulation relating to solicitation or advertising by health professionals.

§ 6412 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 managed care organization shall be held in confidence and shall not be disclosed to any person except upon the express consent of the enrollee or applicant, or the enrollee's or applicant's 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 managed care organization wherein such data or information is pertinent. The communication of such data or information from a health care provider to a managed care organization shall not prevent such data or information from being deemed confidential for purposes of the Delaware Uniform Rules of Evidence.

§ 6413 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 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 managed care organization, 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 Department shall have authority to enforce this section.


§ 6414 Nondisclosure clause.

A managed care organization contract shall contain no provision or nondisclosure clause prohibiting physicians or other health-care providers from giving patients information regarding diagnoses, prognoses and treatment options.


§ 6415 Refusal to contract.

A managed care organization shall not refuse to contract with or compensate for covered services an otherwise eligible health-care provider solely because that provider has in good faith communicated with 1 or more of the provider's current, former or prospective patients regarding the provisions, terms or requirements of the health maintenance organization's products or services as they relate to the needs of that provider's patients.


§ 6416 Independent health care appeals program.

(a) There is established the Independent Health Care Appeals Program in the Department of Insurance. The program will include, at a minimum, a final step in the grievance process which provides for a review by an Independent Utilization Review Organization, hereafter referred to as "IURO," as specified in regulations promulgated by the Department pursuant to the authority granted in § 6408 of this title. The purpose of the program is to provide an independent medical necessity or appropriateness of services review of final decisions of carriers to deny, reduce or terminate benefits in the event the final decision is contested by the covered person. For the purpose of this chapter "medical necessity" means the providing of covered health-care services or products that a prudent physician would provide to a patient for the purpose of diagnosing or treating an illness, injury, or disease or its symptoms, in a manner that is:
(1) In accordance with generally accepted standards of medical practice;

(2) Consistent with the symptoms or treatment of the condition; and

(3) Not solely for anyone's convenience.

(b) The appeal review shall include any decisions regarding covered benefits by the covered person's health benefits plan, and any determination by the IURO shall be binding on the health carriers. If the IURO makes a determination in favor of the carrier, it will give rise to a rebuttable presumption to that effect in any subsequent action brought by or on behalf of the covered person with respect to the decision. Should the determination favor the covered person, the health carrier shall have the ability to appeal the issue to Superior Court. In any such instance in which an appeal is taken to the Superior Court, that Court shall, upon receiving notice of the appeal, appoint an independent attorney to defend the determination from which the appeal is taken. The expenses of the appeal to the Superior Court, including the assessment of attorney fees for the attorney appointed by the Court, shall be assessed by the Court against the health carrier. This act will affect "health carriers," defined as any entity subject to insurance laws and regulations of the State.

(c) A covered person may apply to the Independent Health Appeals Program for a review of any decision to deny, reduce or terminate covered benefits if the person has already completed the carrier's internal appeals process and the person contests the final decision by a carrier. Within 4 months of the date the final decision was issued by the carrier, a covered person or the covered person's authorized representative may file a request for an external review with the health carrier. Upon receipt of a request for an external review, the health carrier shall send an electronic copy of the request to the Department.

(d) The Department shall, at the time of the receipt of the request for an external review, assign an IURO from the list of certified IUROs pursuant to this section and shall so inform the health carrier. The IURO shall notify the covered person or the covered person's authorized representative in writing that they have been assigned to conduct an external review. Included in the notice shall be a statement that the covered person or the covered person's authorized representative may submit additional information and supporting documentation that the IURO shall consider when conducting the external review. Such additional information must be submitted within 7 days of receipt of the notification.

(e) Within 7 calendar days after the date on which the health carrier receives notice of the IURO assigned, the health carrier shall provide to the assigned IURO all documents and information utilized in making the final decision to deny, reduce or terminate benefits, as well as the final written decision from internal appeal.

(f) For cases in which the denial, reduction or termination of benefits by the health carrier is based on grounds other than medical necessity or the appropriateness of services, as defined in this section, review from the final decision of the health carrier, following completion of the health carrier's internal review process, shall be through the Department of Insurance in accordance with the provisions of § 332 of this title.
(g) For cases in which a denial, reduction or termination of benefits should be reviewed by both an IURO and by the Department of Insurance, or where there is ambiguity as to where the review should be conducted, the review shall be conducted by an IURO pursuant to this section.

§ 6417 Appeal reviews; independent utilization review organizations.

(a) The Insurance Commissioner or designee shall certify such organizations that meet the requirements of this section or regulations to be promulgated pursuant to it or shall deem certified any independent review entity meeting standards developed for this purpose by an independent, national accrediting organization. The Department will contract these IUROs.

(b) The Insurance Commissioner or designee shall appoint an IURO on a rotating basis to hear each appeal. The carrier shall be responsible for all costs associated with the appeal regardless of the final ruling, and shall reimburse the Department within 90 days of a final decision for the expenses related to the appeal process. In addition, upon the written request of an MCO, the Insurance Commissioner or designee shall have the discretion to appoint an IURO to conduct a preliminary review to determine if an appeal is clearly without merit. The cost of the preliminary review shall be borne by the MCO.

(c) Regulations promulgated under this section shall include the following requirements:

(1) Expert reviewers assigned by independent review organizations must be physicians or other appropriate health-care practitioners who meet the following minimum requirements:

a. Expert in the treatment of the covered person's medical condition, and knowledgeable about the recommended service or treatment through recent or current actual clinical experience treating patients with the same or similar medical conditions of the covered person.

b. Hold a nonrestricted license in a State of the United States, and for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of review.

c. Have no history of disciplinary action or sanctions (including but not limited to loss of staff privileges or participation restrictions) taken or pending by any hospital, government or regulatory body.

(2) The independent review organization shall submit to the Department the following information:

a. The names of all stockholders and owners of more than 5% of any stock or options, if a publicly held organization.

b. The names of all entities the independent review organization controls or is affiliated with, including the nature and extent of any ownership or control, including the affiliated organization's type of business.
c. The names of all directors, officers and executives of the independent review organization, as well as a statement regarding any relationships the directors, officers and executives may have with any health-care service plan, disability insurer, managed care organization, provider group or board or committee.

(3) Neither the expert reviewer, nor the independent review organization, has any material professional, familial or financial conflict of interest with any of the following:

a. The plan.

b. Any officer, director or management of the plan.

c. The physician, the physician's medical group or the independent practice association proposing the service or treatment.

d. The institution at which the service or treatment would be provided.

e. The development or manufacture of the principal drug, device, procedure or other therapy proposed for the covered person whose treatment is under review.

f. The covered person.

g. National, state or local trade association of health benefit plans or health-care providers.

(4) The independent review organization shall have a quality assurance mechanism in place that ensures the timeliness and quality of the reviews, the qualifications and independence of the experts, and the confidentiality of the medical records and review materials.

a. The Insurance Commissioner or designee shall establish procedures for transmitting the completed application for an appeal review to the independent review entity.

b. The independent review entity shall promptly review the pertinent medical records of the covered person to determine whether the carrier's denial, reduction or termination of benefits deprived the covered person of medically necessary services covered by the person's health benefits plan, based on applicable, generally accepted practice guidelines developed by the federal government, national or professional medical practice societies, boards or associations and any applicable clinical protocols or practice guidelines developed by the carrier. The organization shall complete its review and make its written determination within 45 days of receipt of a completed application for an appeal review. In no event shall appeals involving an imminent, emergent or serious threat to the health of the enrollee, as determined by the treating health-care practitioner, exceed 72 hours. Upon completion of the review, the entity shall state its findings in writing and make a determination of whether the carrier's denial, reduction or termination of benefits deprived the covered person of medically necessary services covered by the person's health benefits plan. If the organization determines that the denial, reduction or termination of benefits deprived the person of medically necessary covered services, it shall send a determination to the covered person and the carrier. The determination shall be binding on the carrier
and the carrier shall promptly notify the person what action it intends to take to implement the determination.

c. Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to benefits under coverage under the plan. Nothing in this section shall be construed to require the plan to pay for services of a nonparticipating physician that are not otherwise covered pursuant to the evidence of coverage under the plan.

d. The Insurance Commissioner or designee shall require the independent review organization to establish procedures to provide for an expedited review of a carrier's denial, reduction or termination of a benefit decision when a delay in receipt of the services could seriously jeopardize the health or well-being of the covered person.

e. The covered person's medical records provided to the program and the independent utilization review organization and the findings and recommendations of the organization made pursuant to this chapter are confidential and shall be used only by the Department, the organization and the affected carrier for the purposes of this chapter. The medical records and findings and determinations shall not otherwise be divulged or made public so as to disclose the identity of any person to whom they relate and shall not be included under any materials available to public inspection pursuant to Chapter 100 of Title 29.

f. A carrier may at any time determine to provide the requested medical services by so notifying the organization or the Insurance Commissioner or designee, as well as the covered person which notification shall terminate the review process. The cost of a partial review by an IURO shall be borne by the carrier.

72 Del. Laws, c. 441, § 1; 75 Del. Laws, c. 362, § 2;

§ 6418 Indemnification and immunity of employees.

(a) An employee of the Department who participates in the program shall not be liable in any action for damages to any person for any action taken within the scope of that employee's function in the program. The Attorney General shall defend the person in any civil suit and the State shall provide indemnification for any damages awarded.

(b) The carrier that is the subject of the review shall not be liable in any action for damages to any person for any action taken to implement a determination of the independent review organization pursuant to this chapter.

(c) Any physician serving on the IURO chosen by the Insurance Commissioner or designee to hear an appeal shall not be liable in any action for damages to any person for any action taken within the scope of that physician's function in the program.

72 Del. Laws, c. 441, § 1; 70 Del. Laws, c. 186, § 1; 75 Del. Laws, c. 362, § 2;
§ 6419 Violations; penalties.

(a) A carrier that violates any provision of this chapter shall be liable to a civil penalty of not less than $250 and not greater than $10,000 for each day that the carrier is in violation of the chapter if 10-days notice in writing is given of the intent to levy the penalty and, at the discretion of the Insurance Commissioner or designee, the carrier has 30 days, or such additional time as the Insurance Commissioner or designee shall determine to be reasonable, to remedy the condition which gave rise to the violation and fails to do so within the time allowed.

(b) The Insurance Commissioner or designee may issue an order directing a carrier or a representative of a carrier to cease and desist from engaging in any act or practice in violation of the provisions of this chapter.

(c) Within 20 days after service of the order of cease and desist, the respondent may request a hearing on the question of whether acts or practices in violation of this section have occurred. The hearing shall be conducted pursuant to the Administrative Procedure Act (Chapter 101 of Title 29), and judicial review shall be available as provided therein. This appeal shall not stay the cease and desist order.

(d) In the case of any violation of the provisions of this chapter, if the Insurance Commissioner or designee elects not to issue a cease and desist order, or in the event of noncompliance with a cease and desist order issued pursuant to subsection (b) of this section, the Insurance Commissioner or designee may institute a proceeding to obtain injunctive relief in accordance with the applicable court rules.

72 Del. Laws, c. 441, § 1; 75 Del. Laws, c. 362, § 2.

§ 6420 Enforcement; adoption of rules and regulations.

The Insurance Commissioner shall enforce the provisions of this chapter. The Insurance Commissioner shall adopt rules and regulations, pursuant to the Administrative Procedure Act (Chapter 101 of Title 29), necessary to carry out the purposes of this chapter. The regulations shall establish procedures for protections defined in this chapter.