CHAPTER 4685 DEPARTMENT OF HEALTH HEALTH MAINTENANCE ORGANIZATIONS

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4685,0100 DEFINITIONS.

Subpart 1. **Scope.** For the purposes of parts 4685.0100 to 4685 3400 the terms used have the meanings given to them in this part and in Minnesota Statutes, chapter 62D

[For text of subps 2 to 4a, see M R]

Subp 5 Comprehensive health maintenance service. "Comprehensive health maintenance service" means a group of services which includes at least all of the types of services defined below

[For text of items A to C, see M.R.]

D "Outpatient health services" means ambulatory care including health supervision, preventive, diagnostic and therapeutic services, including diagnostic radiologic service, therapeutic services for congenital, developmental, or medical conditions that have delayed speech or motor development, treatment of alcohol and other chemical dependency, treatment of mental and emotional conditions, provision of prescription drugs, and other supportive treatment.

[For text of item E, see MR]

Subp 5a **Cosmetic services.** "Cosmetic services" means surgery and other services performed primarily to enhance or otherwise alter an enrollee's physical appearance without correcting or improving a physiological function.

Subp 5b **Custodial care.** "Custodial care" means assistance with meeting personal needs or the activities of daily living that does not require the services of a physician, registered nurse, licensed practical nurse, chiropractor, physical therapist, occupational therapist, speech therapist, or other health care professional, and includes bathing, dressing, getting m and out of bed, feeding, walking, elimination, and taking medications

[For text of subp 6, see M.R.]

Subp 6a Experimental, investigative, or unproven. "Experimental, investigative, or unproven" means a drug, device, medical treatment, diagnostic procedure, technology, or procedure for which reliable evidence does not permit conclusions concerning its safety, effectiveness, or effect on health outcomes

Subp 7 **Formal procedural requirements.** "Formal procedural requirements" means those rules governing the conduct of administrative hearings applicable to and affecting the rights, duties, and privileges of each party of a contested case, as the term is defined and as the rules are set forth in Mmnesota Statutes, chapter 14.

Subp 7a **Formulary.** "Formulary" means a current list of covered outpatient prescription drug products that is subject to periodic review and update.

[For text of subps 8 and 9, see M R.]

Subp 9a NAIC Blank. "NAIC Blank" means the most recent version of the National Association of Insurance Commissioners' Blank for Health Maintenance Organizations published by the Brandon Insurance Service Company, Nashville, Tennessee The NAIC Blank is incorporated by reference and is available for inspection at the State Law Library, Judicial Center, 25 Constitution Avenue, Saint Paul, Mmnesota 55155 The NAIC Blank is subject to annual changes by the publisher. Health maintenance organizations must use the version current on December 31 of the year preceding the filing of a required report

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[For text of subps 9b and 9c, see MR]

Subp 10 **Open enrollment.** "Open enrollment" means the acceptance for coverage by health plans of group enrollees without regard to underwriting restrictions, and coverage of individual or nongroup enrollees with regard only to those underwriting restrictions permissible under Minnesota Statutes, section 62D.10, subdivision 4

[For text of subps 11 to 13, see M R]

Subp. 13a. **Referral.** "Referral" means a prior written authorization for specified services that is issued by a health maintenance organization or an authorized provider and that identifies the provider to which an enrollee is referred and the type, number, frequency, and duration of services to be covered as a benefit under the enrollee's health maintenance organization contract.

[For text of subps 13b to 16, see M.R.]

Statutory Authority: MS s 62D.20

History: 23 SR 1238

4685.0200 AUTHORITY, SCOPE AND PURPOSE.

Parts 4685 0100 to 4685 3400 are adopted pursuant to Minnesota Statutes, sections 62D 03, subdivision 4, clause (m), 62D 04, subdivision 1, clauses (c), (d), and (g); 62D 06, subdivision 2, 62D 08, subdivisions 1 and 3, 62D 12, subdivision 2, clause (g), and 62D 20 relating to health maintenance organizations in particular, and Minnesota Statutes, sections 14.02, 14 04 to 14 36, and 14 38 relating generally to the adoption of administrative rules Parts 4685 0100 to 4685 3400 and all future changes herein apply to all health maintenance organizations operating in Minnesota at the time of their adoption, to all health maintenance organizations hereafter certified, and to all community integrated service networks currently and hereafter licensed, with the exceptions specified in Minnesota Statutes, chapter 62N, and are adopted to carry out the Health Maintenance Act of 1973 and to facilitate the full and uniform implementation and enforcement of that law

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.0300 APPLICATION.

[For text of subps 1 to 4, see M.R.]

Subp 5 **Statistics.** The application shall detail procedures established to develop, compile, evaluate, and report statistics which shall include the collection and maintenance of at least the following data:

A. operational statistics sufficient to meet the requirements of Minnesota Statutes, section 62D 08, subdivision 3, clause (a), relating to annual financial reports,

[For text of items B to E, see M R]
[For text of subp 6, see M R]

Subp 7 Other requirements. Each application must also include documentation or evidence of compliance with all of the requirements of the act and parts 4685.0100 to 4685 3400, and the commissioner of health may require such other information in applications for certificates of authority as the commissioner feels is necessary to make a determination on the application

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.0400 OPERATING REQUIREMENTS AND REQUIREMENTS FOR ISSUANCE OF A CERTIFICATE OF AUTHORITY.

Each health maintenance organization must submit the information required in part 4685.0300 and Minnesota Statutes, chapter 62D, and the commissioner must find that each health maintenance organization meets the statutory requirements and the standards of parts 4685 0100 to 4685 3400 before the commissioner may issue a certificate of authority. The failure of an operating health maintenance organization to comply with the requirements is proper basis for disciplinary action under Minnesota Statutes, sections 62D 15 to 62D 17

Statutory Authority: MS s 62D 20

History: 23 SR 1238

HEALTH MAINTENANCE ORGANIZATIONS 4685.0700

4685.0700 COMPREHENSIVE HEALTH MAINTENANCE SERVICES.

Subpart 1 **Providing health maintenance services.** All health maintenance organizations shall provide comprehensive health maintenance services, as defined in part 4685.0100, subpart 5, to enrollees

Subp 2. Minimum services. Such comprehensive health maintenance services shall melude but need not be limited to

[For text of items A and B, see MR]

C all mpatient hospital care, including mental health and chemical dependency care, except as exclusions or limitations are hereafter permitted;

[For text of item D, see M R.]

E all outpatient health services, including mental health and chemical dependency services, except as exclusions or limitations are hereafter permitted, and

[For text of item F, see M R.]

- Subp 3 **Permissible limitations.** A health service that may be excluded under subpart 4 may instead be limited. The following health services may be limited, but cannot be excluded
- A. A health maintenance organization may limit outpatient prescription drug benefits through the use of a formulary
- (1) The formulary must be periodically reviewed and updated by physicians and pharmacists to determine that formulary drugs are, at a minimum, safe and effective
- $(2) \, The \, formulary \, must \, contain \, all \, prescription \, drugs \, needed \, to \, provide \, medically \, necessary \, care$
- (3) A health maintenance organization shall promptly grant an exception to the formulary when the formulary drug causes an adverse reaction, when the formulary drug is contraindicated, or when the prescriber demonstrates that a prescription drug must be dispensed as written to provide maximum medical benefit to the enrollee
- (a) A health maintenance organization shall have written guidelines and procedures for granting an exception to the formulary that shall be available to the enrollee and prescriber upon request
- (b) When a health maintenance organization grants an exception to the formulary, it may charge the enrollee the approved flat fee copayment or a copayment that does not exceed 25 percent of the provider's charge, m accordance with part 4685.0801
- B. A health maintenance organization may limit durable medical equipment, orthotics, prosthetics, and nondurable medical supplies
 - C. A health maintenance organization may limit home health care services.
- D A health maintenance organization may limit inpatient hospital care as defined in part 4685.0100, subpart 5, item B, and required in subpart 2, item C, as specifically authorized by this item. Each health maintenance organization may have limitations upon the number of days of inpatient hospital care that at least correspond with the following minimum provisions
- (1) For health maintenance contracts issued to a specified group or groups, the coverage may be limited to 365 days of care m a given period of confinement for a condition arising from a single illness or injury, provided that if this coverage is exhausted the benefit must be renewed, or a new period of confinement commenced, upon the occurrence of a separate illness or injury or upon the passage of no more than 90 days without utilization of mpatient hospital care, and provided further, that if an enrollee group rejects in writing the limits of coverage in favor of lesser limits, the coverage may be limited to no less than 180 days, with no more than 90 days between periods of confinement.
- (2) For individual health maintenance contracts, the coverage may be limited to 90 days of care in a given period of confinement for a condition arising from a single illness or injury, provided that if this coverage is exhausted the benefit must be renewed or a new period of confinement commenced, upon the occurrence of a separate illness or injury or upon the passage of no more than 90 days without utilization of impatient hospital care
- (3) For inpatient hospital care out of the service area of the health maintenance organization as defined m parts 4685 1010, subpart 1, item B, and 4685 0100, subpart

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11, and as required in subpart 2, item B, the coverage may be limited to 60 days of care in each contract year.

These provisions relate to the aggregate number of days of both acute care and convalescent care, both of which must be rendered to enrollees by the health maintenance organization, but which may be limited, as indicated. These provisions do not relate to custodial care that may be limited or excluded completely pursuant to subpart 4, item H, nor do these provisions allow limitations relative to the spectrum of service during a covered day, which is provided for in subpart 4

- Subp 4 **Permissible exclusions.** The following services may be excluded
 - A personal convenience devices;
- B cosmetic services, except for reconstructive surgery as required under Minnesota Statutes, section 62A 25,
 - C dental services,
- D nonemergency ambulance services and special transportation services, except as provided by Mmnesota Statutes, section 62J.48,
 - E the fitting and provision of contact lenses, eyeglasses, and hearing aids,
- F a drug, device, medical treatment, diagnostic procedure, technology, or procedure that is experimental, investigative, or unproven as defined in part 4685 0100, subpart 6a. The health maintenance organization shall make its determination of experimental, investigative, or unproven based upon a preponderance of evidence after the examination of the following reliable evidence, none of which shall be determinative m and of itself
- (1) whether there is final approval from the appropriate government regulatory agency, if approval is required,
- (2) whether there are consensus opinions and recommendations reported in relevant scientific and medical literature, peer—reviewed journals, or the reports of clinical trial committees and other technology assessment bodies, and
- (3) whether there are consensus opinions of national and local health care providers in the applicable specialty or subspecialty that typically manages the condition as determined by a survey or poll of a representative sampling of these providers,
 - G custodial care,
- H care for mjuries incurred while on military duty, to the extent that care for the mjuries is covered or available in another program of coverage,
- I services and other items not prescribed, recommended, or approved by a provider who is providing services through the enrollee's health maintenance organization or a provider to whom the enrollee is referred,
 - J the following services relating to inpatient hospitalization.
- (1) television, telephone, and similar convenience or amenity items that are available in connection with inpatient hospital care but that are not medically necessary as a part of the enrollee's care,
 - (2) hospital private room accommodations unless medically necessary, and
- (3) inpatient hospital care under any circumstances where inpatient physician care or the procedure is not otherwise covered; and

K services for those conditions subject to underwriting restrictions when the imposition of the restrictions is otherwise proper, provided that underwriting restrictions may only relate to preexisting health conditions, and those acute health conditions for which an applicant is being treated at the time of the proposed enrollment

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.0900 SUBROGATION AND COORDINATION OF BENEFITS.

The health maintenance organization may require an enrollee to reimburse it for the reasonable value of health maintenance services provided to an enrollee who is injured through the act or omission of a third person or in the course of employment to the extent the enrollee collects damages or workers' compensation benefits for the diagnosis, care, and treatment of

an injury The subrogation clause in an evidence of coverage must contain the information required by Minnesota Statutes, section 62A 095, subdivision 2 The health maintenance organization may be subrogated to the enrollee's rights against the third person or the enrollee's employer to the extent of the reasonable value of the health maintenance services provided including the right to bring suit in the enrollee's name.

The health maintenance organization shall provide covered health services first, and coordinate benefits according to parts 4685 0905 to 4685.0950

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.1010 AVAILABILITY AND ACCESSIBILITY.

[For text of subpart 1, see M R]

Subp 2 Basic services. The health maintenance organization shall have available, either directly or through arrangements, appropriate and sufficient personnel, physical resources, and equipment to meet the projected needs of its enrollees for covered health care services. The health maintenance organization, in coordination with participating providers, shall develop and implement written standards or guidelines that assess the capacity of each provider network to provide timely access to health care services in accordance with subpart 6

[For text of items A to I, see MR]

- J Referral procedures must be described in an enrollee's evidence of coverage and must be available to an enrollee upon request for information regarding referral procedures Effective July 1, 1999, information regarding referral procedures shall clearly describe at least the following
 - (1) under what circumstances and for what services a referral is necessary;
 - (2) how to request a referral,
 - (3) how to request a standing referral, and
 - (4) how to appeal a referral determination.

[For text of subps 3 and 4, see M.R.]

Subp 5 Coordination of care.

A The health maintenance organization shall arrange for the services of primary care providers to provide initial and basic care to enrollees

- (1) An enrollee who is dissatisfied with the assigned or selected primary care provider shall be allowed to change primary care providers in accordance with the health maintenance organization's procedures and policies
- (2) If requested by an enrollee, or if determined necessary because of a pattern of inappropriate utilization of services, an enrollee's health care may be supervised and coordinated by the primary care provider
- $\,\,$ B $\,$ In plans in which referrals to specialty providers and ancillary services are required $\,^{\prime}$
- (1) the primary care or other authorized provider or the health maintenance organization shall initiate the referrals, and
- (2) the health maintenance organization shall inform its primary care and other authorized providers of their responsibility to provide written referrals and any specific procedures that must be followed in providing referrals
- C The health maintenance organization shall provide for the coordination of care for enrollees given a referral or standing referral. When possible, the health maintenance organization shall provide this coordination of care through the enrollee's primary care or other authorized provider.

Subp 6 Timely access to health care services.

A The health maintenance organization, either directly or through its provider contracts, shall arrange for covered health care services, including referrals to participating and nonparticipating providers, to be accessible to enrollees on a timely basis in accordance with medically appropriate guidelines consistent with generally accepted practice parameters

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B The health maintenance organization, in coordination with its participating providers, shall develop and implement written appointment scheduling guidelines based on type of health care service. Examples of types of health care services include well baby and well child examinations, prenatal care appointments, routine physicals, follow up appointments for chronic conditions such as high blood pressure, and diagnosis of acute pain or injury

[For text of subps 7 and 8, see MR]

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.1100 [Repealed, 23 SR 1238]

4685.1105 DEFINITIONS.

Subpart 1 **Scope.** The following definitions apply to parts 4685 1105 to 4685 1130, unless the context clearly requires another meaning

[For text of subps 2 to 4, see M.R.]

Subp 5. **Monitoring.** "Momtoring" means collection of information relating to quality of care Monitoring may be m the form of prospective, concurrent, or retrospective audits, reports, surveys, observation, interviews, complaints, peer review, or evaluation of claims or encounter level data.

[For text of subps 6 to 8, see M.R.]

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.1110 PROGRAM.

[For text of subps 1 to 5, see MR.]

Subp 6. **Delegated activities.** The health maintenance organization may delegate performance of quality assurance activities to other entities. The health maintenance organization shall retain responsibility for performance of all delegated activities. If the health maintenance organization delegates performance of quality assurance activities, the health maintenance organization shall develop and implement review and reporting requirements to ensure that the delegated entity performs all delegated quality assurance activities.

[For text of subps 7 and 8, see M.R.]

Subp 9 Complaints.

A Effective July 1, 1999, a health maintenance organization shall conduct ongoing evaluation of all enrollee complaints as defined in part 4685.0100, subpart 4, including complaints filed with participating providers. Ongoing evaluations must be conducted according to the steps in part 4685.1120.

B Evaluation methods must permit a health maintenance organization to track specific complamts, assess trends, and establish that corrective action is implemented and effective in improving the identified problem

C The quality assurance program shall conduct ongoing evaluation of enrollee complaints that are related to quality of care. The evaluations shall be conducted according to the steps in part 4685-1120. The data on complaints related to quality of care must be reported to and evaluated by the appointed quality assurance entity at least quarterly.

[For text of subp 10, see M.R.]

Subp 11 **Provider qualifications and selection.** The health maintenance organization shall have policies and procedures for provider selection, credentialing, and recredentialing that, at a minimum, are consistent with accepted community standards

[For text of subps 12 and 13, see MR]

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.1115 ACTIVITIES.

[For text of subpart 1, see M R]

part 1;

Subp 2 **Scope.** The components of the health maintenance organization subject to evaluation include the following

[For text of items A and B, see MR]

- C Consumer components that are the enrollees' perceptions regarding all aspects of the quality of the health plan's services, and that mclude:
- (1) enrollee satisfaction surveys, which must meet validity standards m the following areas:
 - (a) assessment of enrollee health care experiences,
- (b) statistical methodology for population sampling and analysis of the results, with a focus on membership affected by the issue being researched, and
 - (c) ease of completion and interpretation by enrollees;

[For text of substems (2) and (3), see M.R.]

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.1130 FILED WRITTEN PLAN AND WORK PLAN.

[For text of subpart 1, see M R.]

Subp 2 Annual work plan. The health maintenance organization shall annually prepare a written work plan. The health maintenance organization shall file the work plan with the commissioner, as requested The work plan must be approved by the governing body and meet the requirements of items A and B.

A The work plan must give a detailed description of the proposed quality evaluation activities that will be conducted in the following year and a timetable for completion The quality evaluation activities must address the components of the health care delivery system defined in part 4685 1115, subpart 2. The quality evaluation activities must be conducted according to the steps in part 4685.1120.

In determining the level of quality evaluation activities necessary to address each of the components of the health maintenance organization, the commissioner shall consider the number of enrollees, the number of providers, the age of the health maintenance organization, and the level of quality evaluation activities conducted by health care organizations that perform similar functions

- B The work plan must describe the proposed focused studies to be conducted in the following year The focused studies must be conducted according to the steps in part 4685 1125 Each proposed study must include the following elements:
 - (1) topic to be studied,
 - (2) rationale for choosing topic for study according to part 4685 1125, sub-
 - (3) benefits expected to be gained by conducting the study,
 - (4) study methodology,
 - (5) sample size and sampling methodology,
 - (6) criteria to be used for evaluation, and
- (7) approval by the health maintenance organization's medical director or qualified director of health services designated by the governing body

Each health maintenance orgamization shall annually complete a inimmum of three focused studies. The focused study sample must be representative of all health maintenance organization enrollees who exhibit characteristics of the issue being studied.

- Subp 3 Amendments to plan. The health maintenance organization may change its written quality assurance plan by filing notice with the commissioner 30 days before modifying its quality assurance program or activities. If the commissioner does not disapprove of the modifications within 30 days of submission, the inodifications are considered approved.
- Subp 4 **Plan review.** Upon receipt of the filing, the commissioner shall review the health maintenance organization's annual proposed work plan to determine if it meets the criteria established in parts 4685 1105 to 4685 1130.

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Subp 5 [Repealed, 23 SR 1238] Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.1300 EFFECTIVE DATE OF OPERATING REQUIREMENTS.

When changes are required in existing evidences of coverage or health maintenance contracts m order to implement the provisions of parts 4685 0100 to 4685 3400, the changes shall be implemented upon the renewal date of the documents commencing with the first renewal after May 29, 1999 New contracts or evidences of coverage to be implemented after May 29, 1999, must be in compliance with parts 4685 0100 to 4685 3400 upon implementation

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.1900 RECORDS OF COMPLAINTS.

Subpart 1 **Record requirements.** Every health maintenance organization shall maintain a record of each complaint filed with it during the prior five years. The record must, where applicable, mclude

A the complaint or a copy of the complaint and the date of its filing,

B documentation of all informal discussions, consultations, conferences, and correspondence relative to each complaint, including the date or dates of each interaction and the outcomes of each interaction,

C. a copy of the hearing or reconsideration findings given the complainant,

D a copy of the arbitrator's decision, and

E all documents that have been filed with a court relating to a complaint and all orders and judgments of a court relating to the complaint

Subp 2 Log of complaints.

- A A health maintenance organization shall keep retrievable documentation of complaints submitted to the health maintenance organization by complainants
- B The retrievable documentation must include the date the complaint was initially submitted; the name, address, and telephone number of the complainant, if provided, the enrollee's identification number, and the location of the complainant's complaint records
- C The retrievable documentation must include the following information regarding an enrollee who complains orally to the health maintenance organization
 - (1) name,
 - (2) address,
 - (3) telephone number, if provided to the health maintenance organization,
 - (4) identification number,
 - (5) nature of the grievance; and
 - (6) dates when
 - (a) the enrollee complained orally,
 - (b) the enrollee was provided the telephone number of the commission-

er, and

(c) the complaint form was mailed, if applicable

Statutory Authority: MS s 62D 20

History: 23 SR 1238

4685.2800 FEES.

[For text of subpart 1, see M R]

Subp 2. **Renewal fee.** The renewal fee for a certificate of authority is \$16,000 for each health maintenance organization plus 46 cents for each person enrolled in the health maintenance organization on December 31 of the preceding year. The fee applies to the calendar year in which the fee is required to be paid.

Statutory Authority: MS s 62D 20

History: 23 SR 1238