Department of Health

Adopted Permanent Rules Relating to HMO's Quality Assurance

Rules as Adopted

4685.0100 DEFINITIONS.

Subpart 1. to 3. [Unchanged.]

Subp. 4. **Complaint.** "Complaint" means any written grievance by a complainant, as defined in subpart 4a, against a health maintenance organization which has been submitted by a complainant under part 4685.1700 and which is not under litigation. If the complaint is from an applicant, the complaint must relate to the application. If the complaint is from a former enrollee, the complaint must relate to services received during the time the individual was an enrollee.

Examples of complaints are the scope of coverage for health care services; denials of service; eligibility issues; denials, cancellations, or nonrenewals of coverage; administrative operations; and the quality, timeliness, and appropriateness of health care services rendered.

Subp. 4a. **Complainant.** "Complainant" means an enrollee, applicant, or former enrollee, or anyone acting on behalf of an enrollee, applicant, or former enrollee who submits a complaint, as defined in subpart 4.

Subp. 5. to 8. [Unchanged.]

Subp. 8a. **Immediately and urgently needed service.** "Immediately and urgently needed service" means a service that, if not provided promptly, could reasonably be expected to result in serious jeopardy to mental or physical health, serious impairment of bodily functions, or serious dysfunction of any bodily organ or part.

Subp. 9. to 15. [Unchanged.]

QUALITY ASSURANCE

4685.1100 QUALITY EVALUATION.

The commissioner of health or each health maintenance



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organization may conduct enrollee surveys of the enrollees of each health maintenance organization to ascertain enrollee satisfaction as a part of the overall quality evaluation program.

4685.1105 DEFINITIONS.

Subpart 1. **Scope.** The following definitions apply to parts 4685.1100 to 4685.1130, unless the context clearly requires another meaning.

Subp. 2. **Criteria.** "Criteria" means standards that can be used to determine attainment of quality health care. Criteria may be explicit or implicit. Explicit criteria are a set of norms or indicators that are developed by health care professionals and are predetermined. Implicit criteria are the judgments of health care professionals regarding information related to quality of care.

Subp. 3. **Data.** "Data" refers to the following and similar types of information: patient charts, reports, records, enrollee surveys, staff surveys, staff concerns, performance appraisals, research, financial information, observation, professional organization credentialing reviews, and complaints registered.

Subp. 4. **Focused study.** "Focused study" means a study that begins with a hypothesis and includes systematic data collection, to provide information to identify or resolve problems or potential problems with quality of care. Focused studies include a written methodology and corrective action strategies when appropriate.

Subp. 5. **Monitoring.** "Monitoring" means collection of information relating to quality of care. Monitoring may be in the form of prospective, concurrent, or retrospective audits; reports; surveys; observation; interviews; complaints; peer review; or focused studies.

Subp. 6. **Outcome.** "Outcome" means the end result of care, or a change in patient health status. Examples of outcomes of care include a hospital admission or readmission, an advanced stage of a disease, recovery, alleviation of symptoms, or death.



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Subp. 7. **Process.** "Process" means the nature of events and activities in the delivery of health care.

Subp. 8. **Structure.** "Structure" means the institutional or organizational aspects of care. Structure includes the organizing framework that brings the provider and patient together, organizational processes, policies, financial resources, and staff qualifications.

4685.1110 PROGRAM.

Subpart 1. **Written quality assurance plan.** The health maintenance organization shall have a written quality assurance plan that includes the following:

A. mission statement;

B. philosophy;

C. goals and objectives;

D. organizational structure;

E. staffing and contractual arrangements;

F. a system for communicating information regarding quality assurance activities;

G. the scope of the quality assurance program activities; and

H. a description of peer review activities.

Subp. 2. **Documentation of responsibility.** Quality assurance authority, function, and responsibility shall be delineated in specific documents, including documents such as bylaws, board resolutions, and provider contracts. These documents shall demonstrate that the health maintenance organization has assumed ultimate responsibility for the evaluation of quality of care provided to enrollees, and that the health maintenance organization's governing body has periodically reviewed and approved the quality assurance program activities.

Subp. 3. **Appointed entity.** The governing body shall designate a quality assurance entity that may be a person or persons to be responsible for operation of quality assurance program activities. This entity shall maintain records of its



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by Revisor _____

quality assurance activities and shall meet with the governing body at least quarterly.

Subp. 4. **Physician participation.** A physician or physicians designated by the governing body shall advise, oversee, and actively participate in the implementation of the quality assurance program.

Subp. 5. **Staff resources.** There must be sufficient administrative and clinical staff with knowledge and experience to assist in carrying out quality assurance activities. In determining what is sufficient staff support, the commissioner shall consider the number of enrollees, types of enrollees, numbers of providers, the variety of health care services offered by the health maintenance organization, the organizational structure of the health maintenance organization, and the quality assurance staffing levels used by other health care organizations that perform similar health care functions.

Subp. 6. **Delegated activities.** The health maintenance organization may delegate quality assurance activities to providers, review organizations, or other entities. If the health maintenance organization contracts with another organization to conduct quality assurance activities, the health maintenance organization shall have review and reporting requirements developed and implemented to ensure that the organization contracting with the health maintenance organization is fulfilling all delegated quality assurance responsibilities.

Subp. 7. **Information system.** The data collection and reporting system shall support the information needs of the quality assurance program activities. The quality assurance program shall have prompt access to necessary medical record data including data by diagnoses, procedure, patient, and provider.

Subp. 8. **Program evaluation.** An evaluation of the overall quality assurance program shall be conducted at least annually. The results of this evaluation shall be communicated to the governing body. The written quality assurance plan shall be

amended when there is no clear evidence that the program continues to be effective in improving care.

Subp. 9. **Complaints.** The quality assurance program shall conduct ongoing evaluation of enrollee complaints that are related to quality of care ~~and that are registered with the complaint system~~. Such evaluations shall be conducted according to the steps in part 4685.1120. The data on complaints related to quality of care shall be reported to the appointed quality assurance entity at least quarterly.

Subp. 10. **Utilization review.** The data from the health maintenance organization's utilization review activities shall be reported to the quality assurance program for analysis at least quarterly.

Subp. 11. **Provider ~~credentials~~ qualifications and selection.** The health maintenance organization shall have policies and procedures for provider selection and ~~credentials~~ qualifications. The health maintenance organization shall have policies and procedures for contracting with or hiring staff and providers that are accredited or appropriately trained for their positions or, as in the case of durable medical equipment, offer products that meet standards generally accepted by the medical community.

Subp. 12. **Qualifications.** Any health maintenance organization staff or contractees conducting quality assurance activities must be qualified by virtue of training and experience.

Subp. 13. **Medical records.** The quality assurance entity appointed under subpart 3 shall conduct ongoing evaluation of medical records.

A. The health maintenance organization shall implement a system to ~~assess~~ assure that medical records are maintained with timely, legible, and accurate documentation of all patient interactions. Documentation must include information regarding patient history, health status, diagnosis, treatment, and referred service notes.

B. The health maintenance organization shall maintain



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a medical record retrieval system that ensures that medical records, reports, and other documents are readily accessible to the health maintenance organization.

4685.1115 ACTIVITIES.

Subpart 1. **Ongoing quality evaluation.** The health maintenance organization, through the health maintenance organization staff or contracting providers, shall conduct quality evaluation activities according to the steps in part 4685.1120. The quality evaluation activities must address each of the components of the health maintenance organization described in subpart 2.

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

A. Clinical components that include the following services:

(1) acute hospital services;

(2) ambulatory health care services;

(3) emergency services;

(4) mental health services;

(5) preventive health care services;

(6) pharmacy services;

(7) chemical dependency services;

(8) other professional health care services provided to enrollees, such as chiropractic, occupational therapy, and speech therapy;

(9) home health care, as applicable;

(10) durable medical equipment, as applicable; and

(11) skilled nursing care, as applicable.

B. Organizational components which are the aspects of the health plan that affect accessibility, availability, comprehensiveness, and continuity of health care, and which include the following:

(1) referrals;

(2) case management;



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(3) discharge planning;

(4) appointment scheduling and waiting periods for all types of health care of providers;

(5) second opinions, as applicable;

(6) prior authorizations, as applicable;

(7) provider reimbursement arrangements; and

(8) other systems, procedures, or administrative requirements used by the health maintenance organization that affect delivery of care.

C. Consumer components which are the enrollees' perceptions regarding all aspects of the quality of the health plan's services, and which include:

(1) enrollee surveys;

(2) enrollee complaints; and

(3) enrollee written or verbal comments or questions.

4685.1120 QUALITY EVALUATION STEPS.

Subpart 1. **Problem identification.** The health maintenance organization shall identify the existence of actual or potential quality problems or identify opportunities for improving care through:

A. ongoing monitoring of process, structure, and outcomes of patient care or clinical performance <u>including the consumer components listed under part 4685.1115, subpart 2, item C</u>; and

B. evaluation of the data collected from ongoing monitoring activities to identify problems or potential problems in patient care or clinical performance using criteria developed and applied by health care professionals.

Subp. 2. **Problem selection.** The health maintenance organization shall select problems or potential problems for corrective action or focused study based on the prevalence of the problem and its impact on patient care and professional practices.

Subp. 3. **Corrective action.** The health maintenance

organization shall identify and document any recommendations for corrective action designed to address the problem. The documentation of corrective action shall include:

A. measurable objectives for each action, including the degree of expected change in persons or situations;

B. time frames for corrective action; and

C. persons responsible for implementation of corrective action.

Subp. 4. **Evaluation of corrective action.** The quality assurance entity shall monitor the effectiveness of corrective actions until problem resolution occurs. Results of the implemented corrective action must be documented and communicated to the governing body and involved providers.

4685.1125 FOCUSED STUDY STEPS.

Subpart 1. **Focused studies.** As part of its overall quality evaluation activities, the health maintenance organization shall conduct focused studies to acquire information relevant to quality of care. The focused study must be directed at problems, potential problems, or areas with potential for improvements in care. The focused studies shall be included as part of the health maintenance organization's problem identification and selection activities.

Subp. 2. **Topic identification and selection.** The health maintenance organization shall select topics for focused study that must be justified based on any of the following considerations:

A. areas of high volume;

B. areas of high risk;

C. areas where problems are expected or where they have occurred in the past;

D. areas that can be corrected or where prevention may have an impact; ~~and~~

E. areas that have potential adverse health outcomes; and

F. areas where complaints have occurred.



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Subp. 3. **Study.** The health maintenance organization shall document the study methodology employed, including:

A. the focused study question;

B. the sample selection;

C. data collection;

D. criteria; and

E. measurement techniques.

Subp. 4. **Corrective actions.** Any corrective actions implemented to address problems identified through focused studies shall follow the requirements defined in part 4685.1120, subparts 3 and 4.

Subp. 5. **Other studies.** An activity in which the health maintenance organization participates that meets any of the criteria in subparts 2 to 4 may satisfy in part or in total the focused study requirements. Examples of other activities that may satisfy the focused study requirements include external audits conducted by the professional review organization or other review organizations, multiple health plan surveys, or quality assurance studies across the community.

4685.1130 FILED WRITTEN PLAN AND WORK PLAN.

Subpart 1. **Written plan.** The health maintenance organization shall file its written quality assurance plan, as described in part 4685.1110, subpart 1, with the commissioner, before being granted a certificate of authority.

Subp. 2. **Annual work plan.** The health maintenance organization shall annually file a proposed work plan with the commissioner on or before November 1 of every year. The proposed work plan must meet the requirements of items A and B.

A. The work plan shall give a detailed description of the proposed quality evaluation activities that will be conducted in the following year. The quality evaluation activities shall address the components of the health care delivery system defined in part 4685.1115, subpart 2. The quality evaluation activities shall 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 plan, the commissioner shall consider the number of enrollees, the number of providers, the age of the health plan, and the level of quality evaluation activities conducted by health care organizations that perform similar functions.

B. The work plan shall give a description of the proposed focused studies to be conducted in the following year. The focused studies shall be conducted according to the steps in part 4685.1125. The description of the proposed studies shall include the following elements:

(1) topic to be studied;

(2) rationale for choosing topic for study according to part 4685.1125, subpart 1;

(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 organization shall annually complete a minimum of three focused studies. The focused study sample shall be representative of ~~the total health maintenance organization population~~ 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 and proposed work 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 modifications are considered approved.

Subp. 4. **Plan review.** The commissioner shall review the health maintenance organization's annual proposed work plan to

determine if it meets the criteria established in parts 4685.1100 to 4685.1130. If the commissioner does not disapprove the plan within 30 days of its submission, it is considered approved.

Subp. 5. **Extension to filing annual work plan.** The commissioner may, upon a health maintenance organization's showing of good faith efforts to meet the November 1 deadlines, grant an extension of up to 90 days for a health maintenance organization filing an annual work plan due November 1, 1989. The extension will not be granted for work plan filings in succeeding years.

4685.1700 REQUIREMENTS FOR COMPLAINT SYSTEM.

Subpart 1. **Health maintenance organization's internal complaint system.** A health maintenance organization's internal complaint system is considered reasonable and acceptable to the commissioner of health if the following procedures are followed.

A. If a complainant orally notifies a health maintenance organization that the complainant wishes to register a complaint, the health maintenance organization shall ~~make available~~ promptly provide a complaint form that includes:

(1) the telephone number of member services, or other departments, or persons equipped to advise complainants;

(2) the address to which the form must be sent;

(3) a description of the health maintenance organization's internal complaint system and time limits applicable to that system; and

(4) the telephone number to call to inform the commissioner of health.

B. A health maintenance organization shall provide for informal discussions, consultations, conferences, or correspondence between the complainant and a person with the authority to resolve or recommend the resolution of the complaint. Within 30 days after receiving the written complaint, the health maintenance organization must notify the complainant in writing of its decision and the reasons for it.



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If the decision is partially or wholly adverse to the complainant, the notification must advise the complainant of the right to appeal according to item C, including the complainant's option for a written reconsideration or a hearing, the right to arbitrate according to item D, and the right to notify the commissioner. If the health maintenance organization cannot make a decision within 30 days due to circumstances outside the control of the health maintenance organization, the health maintenance organization may take up to an additional 14 days to notify the complainant provided the health maintenance organization informs the complainant in advance of the extension of the reasons for the delay.

C. If a complainant notifies the health maintenance organization in writing of the complainant's desire to appeal the health maintenance organization's initial decision, the health maintenance organization shall provide the complainant the option of a hearing or a written reconsideration.

(1) If the complainant chooses a hearing, a person or persons with authority to resolve or recommend the resolution of the complaint shall preside, but the person or persons presiding must not be solely the same person or persons who made the decision under item B;

(2) if the complainant chooses a written reconsideration, a person or persons with authority to resolve the complaint shall investigate the complaint, but the person or persons investigating must not be solely the same person or persons who made the decision under item B;

(3) hearings and written reconsiderations shall include the receipt of testimony, correspondence, explanations, or other information from the complainant, staff persons, administrators, providers, or other persons, as is deemed necessary by the person or persons investigating the complaint in the case of a reconsideration, or presiding person or persons in the case of a hearing for a fair appraisal and resolution of the complaint;

(4) in the case of a written reconsideration, a

written notice of all key findings shall be given the complainant within 30 days of the health maintenance organization's receipt of the complainant's written notice of appeal; and

(5) in the case of a hearing, concise written notice of all key findings shall be given the complainant within 45 days after the health maintenance organization receives the complainant's written notice of appeal.

D. A health maintenance organization shall provide the opportunity for impartial arbitration of any complaint which is unresolved by the mechanisms set forth in item B. Arbitration must be conducted according to the American Arbitration Association Minnesota Health Maintenance Organization Arbitration Rules, as amended and in effect November 1, 1988. These rules are incorporated by reference and are available for inspection at the State Law Library, 117 University Avenue, Saint Paul, Minnesota 55155.

The American Arbitration Association Minnesota Health Maintenance Organization Arbitration Rules are subject to changes by the American Arbitration Association. Only those rules in effect November 1, 1988, are incorporated by reference.

If the subject of the complaint relates to a malpractice claim, the complaint shall not be subject to arbitration.

The judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction under Minnesota Statutes, sections 572.16 and 572.21.

E. If a complaint involves a dispute about an immediately and urgently needed service that the health maintenance organization claims is experimental, not medically necessary, or otherwise not generally accepted by the medical profession, and that the health maintenance organization has not yet provided to the complainant, the procedures in items A to D do not apply. The health maintenance organization must use an expedited dispute resolution process appropriate to the particular situation. ~~Within 24 hours~~

(1) By the end of the next business day after the



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complaint is registered, the health maintenance organization shall notify the commissioner of the nature of the complaint, the decision of the health maintenance organization, if any, and a description of the review process used or being used.

(2) If a decision is not made by the end of the next business day following the registration of the complaint, the health maintenance organization shall notify the commissioner of its decision by the end of the next business day following its decision.

(3) For purposes of this item, complaints need not be in writing.

F. A health maintenance organization must notify enrollees of the existence of its complaint system, including the procedure in item E, and must clearly and thoroughly describe the procedural steps of that system in:

(1) the evidence of coverage required by Minnesota Statutes, section 62D.07; and

(2) enrollee handbooks, if used by the health maintenance organization.

Subp. 2. **Dispute resolution by commissioner.** A complainant may at any time submit a complaint to the commissioner, who may either independently investigate the complaint or refer it to the health maintenance organization for further review. If the commissioner refers the complaint to the health maintenance organization, the health maintenance organization must notify the commissioner in writing of its decision and the reasons for the decision within 30 days after receiving the commissioner's initial correspondence to the health maintenance organization, unless otherwise ordered by the commissioner. If the health maintenance organization cannot make a decision within 30 days due to circumstances outside its control, the health maintenance organization may take up to an additional 14 days to notify the commissioner if the health maintenance organization notifies the commissioner in advance of the extension and the reasons for the delay. If the health maintenance organization's decision is partially or wholly

adverse to the complainant, the complainant may pursue a hearing or written reconsideration and arbitration according to subpart 1, items C and D. After investigating a complaint, or reviewing the health maintenance organization's decision, the commissioner may order a remedy~~,--including-one-or-more-of-the-following:~~

~~A.--imposition-of-a-fine-according-to-Minnesota Statutes,-section-62D.17;~~

~~B.--an-order-to-provide-a-service;-or~~

~~C.--an-order-to-reimburse-an-enrollee-for-a-service already-provided-that-the-enrollee-has-paid-for~~ as authorized by Minnesota Statutes, sections 62D.15, 62D.16, and 62D.17.

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 shall, where applicable, include:

A. the complaint or a copy of the complaint and the date of its filing;

B. all correspondence relating to informal discussions, consultations, or conferences held relative to each complaint; a brief written summary of all informal discussions, consultations, conferences, or correspondence held relative to each complaint that includes the date or dates on which each such informal discussion, consultation, conference, or correspondence occurred and their outcomes.

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

D. a copy of the arbitrator's decision; and

E. all documents which 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 health maintenance organization shall keep a single, ongoing log of complaints. The log shall contain the date the complaint was initially submitted; the name, address, and telephone number of the

complainant; and the location of the complainant's complaint records.

4685.2100 ANNUAL REPORTS.

In addition to all other information specified in the act, every health maintenance organization shall include in its annual report to the commissioner of health the following:

A. the results of any and all elections conducted during the preceding calendar year relative to consumer representation on the health maintenance organization's governing body;

B. a copy of the health maintenance organization's most recent information summary provided to its enrollees in accordance with Minnesota Statutes, section 62D.09; and

C. a schedule of prepayment charges made to enrollees during the preceding year and any changes which have been implemented or approved up to the reporting date.

REPEALER. Minnesota Rules, part 4685.1800 is repealed.



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