STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

IN THE MATTER OF PROPOSED

AMENDMENTS TO RULES RELATING

TO HEALTH MAINTENANCE ORGANIZATION

QUALITY EVALUATION AND COMPLAINT SYSTEMS

MINNESOTA RULES CHAPTER 4685.

STATEMENT OF NEED

AND REASONABLENESS

The Minnesota Commissioner of Health (hereinafter "commissioner"), pursuant to Minnesota Statutes, section 14.05 through 14.20 presents facts establishing the need for and reasonableness of the proposed amendments to rules relating to health maintenance organization (HMO) quality evaluation.

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Statutory Authority

The commissioner's general legal authority for adopting these rules is found in Minnesota Statutes, section 62D.20 which provides that the commissioner may adopt rules which are reasonable in order to carry out the provisions of chapter 62D.

Specific authority for adopting rules relating to quality evaluation is found in Minnesota Statutes section 62D.04, subd. 1 (b)(c) which requires HMOs to arrange for the ongoing evaluation of the quality of health care as well as develop, compile, evaluate, and report statistics relating to the quality, availability and accessibility of its services. In addition, Minnesota Statutes, section 62D.03, subd. 4 (o), requires HMOs to describe their procedures and programs to monitor the quality of health care provided to enrollees.

Specific authority for adopting rules relating to complaints is found in Minnesota Statutes section 62D.11 which requires health maintenance organizations to establish and maintain complaint systems.

Specific references to other statutory authority will be given as appropriate

in the part by part statement of need and reasonableness.

Small Business Consideration

These rules are exempt from the provisions of Minnesota Statutes, section 14.115 relating to the impact of rules on small businesses. The small business consideration requirements do not apply to services regulated by government bodies for standards and costs such as providers of medical care, (Minnesota Statutes, section 14.115, subdivision 7 item c.) HMOs are providers of medical care regulated by the Minnesota Department of Health for standards and costs. A "health maintenance organization," is defined in Minnesota Statutes, section 62D.02 as a nonprofit corporation which provides or arranges the provision of health care services.

This small business consideration exemption is consistent with the Report of the Administrative Law Judge, OAH Docket No. 8-0900-247-1, HLTH-86-006-JL which found that the small business consideration requirements in Minnesota Statutes, section 14.115 did not apply to proposed HMO rules.

General Statement of Need and Reasonableness- Quality Assurance

The proposed rules delineate guidelines for a health maintenance organization's (HMO) quality assurance (QA) program. The purpose of the proposed rules is to describe reasonable standards which address 1) the elements required of the QA program; 2) the scope of QA activities; 3) the type of QA activities; and 4) the level of QA activities.

HMOs, as health care delivery systems, use various organizational strategies for controlling health care costs. Certain legislators, consumer advocates, and health care professionals have voiced a concern that cost containment pressures could lead to sacrifices in the quality of health care services. To these people, too much emphasis on containing health care costs may become unsafe, unless balanced by an assessment of the quality of health care. While the Minnesota HMO Act of 1973 (HMO Act) gives HMOs permission to use cost containment systems, this opportunity is balanced by the requirement that the HMO must have a program to assess quality of care.

Existing HMO quality assurance rules require HMOs to meet the standards of quality review set forth in federal law relating to peer review; provide for ongoing internal peer review; and set standards for provider selection, Minnesota Rules 4685.1100.

The standards of quality review in federal statutes relating to peer review of utilization and quality of health services are not easily translated into standards that can be applied as requirements for an HMO's QA program. The federal law generally provides for the federal government's contracting with organizations to conduct reviews of the health services provided to Medicare enrollees. The peer review law requires the contracted review organization to review all health services to ensure that the quality of such services meet professionally recognized standards of health care. The peer review statutes were initially enacted by Congress in 1972, and the peer review organizations were referred to as Professional Standards Review Organizations, (PSROs). Subsequently, Peer Review Organizations, (PROs) have taken the place of PSROs.

While the standards of quality review followed by PROs are not specifically described in federal law, the PRO program developed methodologies for assessing quality of care. One researcher writes that although the PRO program had mixed results, it "played a critical role in the rapid development of meaningful methodologies to assess medical care," (M. Mattson, "Quality Assurance: A Literature Review of a Changing Field," Hospital and Community Psychiatry, June 1984.)

The PRO worked with the Joint Commission on Hospital Accreditation, (now the Joint Commission on Accreditation of Health Care Organizations, JCAHO) in

defining the quality evaluation component of the PRO program. Their definition includes the following elements:

1) collection of data related to patient care;

2) assessment of data using criteria in order to determine problems in care;

3) corrective actions; and documentation of the preceding steps, (H. Palmer and H. R. Nesson, "A Review of Methods for Ambulatory Medical Care Evaluations," Medical Care, August 1982).

This definition of quality evaluation was incorporated by the Federal Office of HMOs in 1979 into requirements for an HMO's quality assurance program, (Office of Health Maintenance Organizations, Public Health Service, U.S. Department of Health, Education and Welfare, "Quality Assurance Strategy for HMOs," Washington DC, September, 1979). The PRO and JCAHO quality evaluation standards were also adopted by the Accreditation Association for Ambulatory Health Care (AAAHC). Most physicians are familiar with this type of quality evaluation because they have been used routinely in hospital care evaluations through JCAHO for several years, (R. H. Palmer and H. R. Nesson, 1982).

JCAHO has determined the accreditation status of health care institutions on the basis of an on site survey since 1952. The founding members of JCAHO were from the American College of Surgeons, American College of Physicians, American Hospital Association, and the American Medical Association. JCAHO

gained additional authority when the 1965 Medicare legislation recognized the JCAHO standards as the norm in determining quality levels of patient care, (A. Lieske, "Standards: The Basis of a Quality Assurance Program," in Quality Assurance: A Complete Guide to Effective Programs, Aspen, 1985).

The PRO and JCAHO standards for quality assurance are widely understood and followed by health care organizations conducting QA activities. While the existing HMO rules indirectly require the HMO to conduct quality assurance activities which meet PSRO program standards by referencing the federal statute, the proposed rules directly require the HMO to conduct activities which meet such standards. Existing rules simply reference federal statutes. The proposed rules directly define the minimum standards for a QA program including the structure and organization of a QA program and the scope and type of QA activities required. The proposed rules will benefit both the HMOs and the commissioner because they are a complete and explicit description of the requirements for an HMO's QA program instead of a vague reference to federal law.

The proposed rules allow a certain amount of flexibility to permit HMOs to devise their own methods of assessing quality of care delivered. In 1980, when the JCAHO and PRO program revised their definition of quality evaluations, the organizations emphasized flexibility as to the choice of methods used for conducting QA activities, (R. H. Palmer and H. R. Nesson,

1982). The Accreditation Handbook for Ambulatory Health Care used by AAAHC specifically states that flexibility in conducting QA activities is desirable. The Handbook provides that "no particular method of conducting quality assurance activities is specified or required for accreditation" to permit flexibility and encourage innovation and variation.

A rigid, prescriptive approach to QA would not be appropriate given the varying structures for organizing the HMO's specific delivery systems. HMOs in Minnesota differ widely in enrollment size, product mix, provider arrangements and financial arrangements. As such, different HMOs will conduct their quality assurance activities differently. Both the structure and financial arrangements of the HMO must be individually addressed if an HMO is to effectively evaluate its own quality of care.

It is important to note that the purpose of the proposed rules is not to measure quality of care in any HMO. The proposed rules are designed to ascertain whether or not an HMO is monitoring its quality of care provided in a manner which makes it likely that services delivered will be of high quality. This is consistent with the statutory requirement that HMOs have arrangements for the ongoing evaluation of the quality of health care, (Minnesota Statutes, section 62D.04, subdivision 1) and programs to monitor the quality of health care provided to enrollees, (Minnesota Statutes, section 62D.03, subdivision 4). Similarly, the Federal Office of HMOs requires

federally qualified HMOs to have organizational arrangements for ongoing quality assurance programs, (R. H. Palmer and H. R. Nesson, 1985).

There are several references in the following part by part statement of need and reasonableness to articles, review organizations' standards manuals, and guidelines from units of government and associations. These references are intended to demonstrate the reasonableness of the requirements proposed in the rules relating to an HMO's QA program. The proposed rules define the minimum standards of an effective QA program which are accepted by practitioners and providers. These minimum standards, which are described in the proposed rules, are found repeatedly in QA literature, auditing tools, manuals and guidelines.

Five references are especially significant and have been used as resources in developing these rules. These references are as follows:

1) the Office of Prepaid Health Care, Health Care Financing Administration, (HCFA), "Quality Assurance Guidelines for HMOs and Competitive Medical Plans," Draft, Washington D.C., 1988;

2) the National Association of Health Maintenance Organization Regulators (NAHMOR), "Recommended Regulatory Guidelines for HMO Quality Assurance Programs," adopted by NAHMOR membership April 2, 1987;

3) the Joint Commission on Accreditation of Health Care Organizations (JCAHO), "Ambulatory Health Care Standards Manual," Chicago, Illinois, 1988;

4) Accreditation Association for Ambulatory Health Care, " Accreditation Handbook for Ambulatory Health Care, 1987-88 Edition;" and

5) "The Minnesota Project: A focused Approach to Ambulatory Care Quality Assurance," August 1987, Minnesota Department of Health.

The Department worked with representatives from the HMOs in drafting these proposed rules. In July of 1988, the Department sent out a working draft of the proposed QA rules to people who had contacted the Department to receive information relating to HMO rulemaking. Department staff met with industry representatives in August and September and received their comments on the draft QA rules. Many of the HMO representatives' suggestions were incorporated into the final draft of these rules.

Part by Part Statement of Need and Reasonableness- Quality Assurance

4685.1100 Quality Evaluation

Items A, B and C of the existing rule are deleted because the proposed rules are a more complete and explicit description of the requirements for an HMO's QA program. These provisions in the existing rule are retained in the proposed rules; however, the proposed rules expand on these provisions.

As indicated in the General Statement of Need an Reasonableness, the existing rule references federal law relating to peer review, provides for ongoing peer review, and sets standards for provider selection. The proposed rules include provisions for peer review and provider selection. Instead of referencing federal law, the proposed rules completely define the minimum standards for for a QA program including the organization, scope of activities and types of activities required. The proposed rules are necessary because they are more complete and direct then the existing rules.

4685.1105 Definitions

Subpart 1. Scope

This part defines specific terms in order to establish a common understanding at the onset of the activities required by the proposed rules. Most of these terms have specific meanings when used in the context of quality assurance activities which are generally understood by QA professionals. The definitions are taken from literature about quality assurance. Specific citations to sources are indicated where appropriate in the following subparts.

Subpart 2. Criteria

Criteria is defined in these rules because analysts agree that the essence of quality assurance is comparison of actual care and/or its results with criteria. (R.H. Palmer, R. K. Hill, 1980, C. G. Meisenheimer, 1985, J. Weiner, "Assuring Quality of Care in HMOs: Past Lessons, Present Challenges, and Future Directions, GHAA Journal, Spring 1986.)

As stated previously, the PSRO program definition of QA included "the assessment of data using criteria in order to determine problems in care." "Criteria" are defined in the proposed rules as standards which can be used to determine attainment of quality health care. The proposed rules distinguish between explicit and implicit criteria. Explicit criteria are standards which are developed by health care professionals and are predetermined. Implicit criteria are judgments by health care professionals.

Explicit criteria are agreed upon by a group of health care professionals and are set down on paper. Examples of explicit standards may be how often individuals should get physical examinations, what should be done for patients with a certain condition, or at what age children should get immunizations. Not all health care activities have predetermined standards; therefore it is necessary for the QA program to utilize implicit criteria. Implicit criteria involve the opinions of the health care practitioners who are analyzing the

data. Implicit criteria are more flexible than explicit criteria; implicit criteria "can take into consideration special circumstances which might alter the usual course of action." (R. K. Hill, "Quality Assurance in Ambulatory Care," Primary Care, December, 1980)

The definition of criteria is consistent with Websters New World Dictionary of the American Language, Second College Edition, The World Publishing Company, 1974, which defines criteria as " means of judging, a standard, rule or test by which something can be judged."

"Norm" is defined by Websters New World Dictionary, Second College Edition, World Publishing Co.,1974, as "a standard, model or pattern for a certain group," and "a standard of conduct that should or must be followed...a way of behaving typical of a certain group." When evaluating the quality of health services, a norm is a pattern that is regarded as typical by health care providers. It follows that the norms which are used as criteria for evaluating health care are developed by health care professionals.

Analysts agree that health care professionals establish norms for QA activities. One analyst points out that criteria must be derived from professional values, (C. G. Meisenheimer, "Designing QA Programs," in Quality Assurance, A Complete Guide to Effective Programs, Aspen Publishers, Rockville, 1985.) Another researcher explains that criteria "are developed

either by experts or practicing providers, (J. Weiner, 1986). In addition, the JCAHO Standards Manual requires health care professionals to develop norms or criteria. The JCAHO Manual specifies that "practitioners participate in the development... of criteria relating to the care or service they provide."

Subpart 3. Data

For the purposes of this rule, "data" is defined to refer to information that can be used to assess quality of care. Data is defined because a critical step in evaluating the quality of care is the collection of information which can be used as a data base from which to identify problems.

Webster defines datum to be "a fact from which conclusion can be inferred." For the purposes of the proposed rules, data is restricted to facts or information which relate to quality of care in an effort to draw conclusions about quality from such facts. Examples of the types of facts or information to be collected for QA activities include patient charts, records, surveys, research, etc.

This definition of data is reasonable as it is the definition used in QA literature. One quality assurance researcher gives examples of sources of data as "the chart, a special form filled out at the time care is provided

(encounter form), the submitted bill, the written prescription, direct observation of the doctor-patient encounter..." (R. K. Hill, "Quality Assurance in Ambulatory Care," Primary Care, December, 1980.) Another researcher defines data in the same manner as the rules: patient charts, reports, surveys, performance appraisals, audits, staff research, financial data, observation, literature, and professional organization and review bodies, (Meisenheimer, 1985).

Subpart 4. Focused Study

The proposed rules require the HMOs to conduct "focused studies," which are a specific and defined activity. The definition of "focused studies" is included to establish a common understanding of the focused study activity required later in the proposed rules. While the term "focused studies" is unique to these rules, the individual terms of "focus" and "study" are not original and are currently understood by quality assurance practitioners.

The proposed rules define a focused study as a study which is targeted towards a problem or potential problem with care. A focused study includes a hypothesis, data collection, written methodologies and corrective action as necessary.

Websters defines study as "...critical examination of any subject." A study is also well defined in QA literature. Essentially, a QA study follows the basic steps of any scientific research including selection of a topic which is formulated into a hypothesis; data collection; data analysis; and interpretations of the research findings, (A. M. Lieske, "Quality Assurance and Research," in Quality Assurance, A Complete Guide to Effective Programs, Aspen, 1985). The proposed rules describe these basic steps that must be included in any research or focused study activity.

HMOs routinely conduct studies as part of their quality assurance activities. Current rules require the HMO to conduct one study related to a disease, condition or age group, (Minnesota Rules, Part 4685.2100, item D).

The term "focused" is used in the proposed rules to convey that a study must be fixed on specific areas where there are problems, potential problems, or areas with potential for improvements in care. The problem-focused approach to studying quality of care issues was ushered in by JCAH in 1979. One researcher writes that "to obtain maximal benefit, any approach to quality assurance must focus on the resolution of known or suspected problems, ... or when indicated, on areas with potential for improvements in patient care." (C. Wilbert, "Selecting Topics/Methodologies," in Quality Assurance a Complete Guide to Effective Programs, edited by C. Meisenheimer, Aspen Publishers, Rockville, 1985.)

Focused study therefore, denotes a study, conducted according to basic research steps, which is fixed on one aspect- a problem, potential problem, or area for improvement in quality of care.

Subpart 5. Monitoring

Monitoring is defined as data collection activities which are related to quality of care. The examples of monitoring activities are taken from Meisenheimer.

As stated previously, the essence of quality assurance activities is a range of assessment methods for identifying deficiencies. A 1988 survey on the structure of quality assurance programs in HMOs enrolling Medicare subscribers summarizes the two quality assurance activities of the plans as monitoring and problem solving activities, (B. S. Brown, "The Structure of Quality Assurance Programs in Risk-Based HMOs/CMPs Enrolling Medicare Beneficiaries," Paper presented at the Group Health Institute, 1988.)

Again, these terms are defined in order to establish a common understanding of the activities required for QA under the following provisions of the proposed rules.

Subpart 6. Outcome

Outcomes are defined because the proposed rules require the HMO to monitor outcomes of care. Outcomes are one part of the three classic approaches used to define quality of care: outcomes, process, and structure. Avedis Donabedian delineated this classic triad as a framework for assessing quality of care in the 1960s and this framework has been used to this day, (A. Donabedian, "Evaluating the Quality of Medical Care," Millbank Memorial Fund Quarterly 44, 1966.) Outcomes are well defined in the QA literature, and the proposed rules follow the standard definitions. Specifically, "outcomes are the end results of medical care: what happened to the patient in terms of palliation, control of illness, cure, or rehabilitation." (K. Lohr, "Outcome Measurement: Concepts and Questions," Inquiry, Spring 1988, page 37).

Subpart 7. Process

The proposed QA rules require the HMO to monitor process of care. Again, process is another part of the the three classic approaches to defining quality of care delineated by Donabedian. The definition of process follows the definitions found in QA literature. Process of care monitoring focuses on the steps in care, or "the actions carried out by health professionals in the belief that adherence to agreed upon standards results in high quality care," (Meisenheimer, 1985, page 107).

Subpart 8. Structure

The last part of the classic approach for assessing quality of care is structure. Again, structure is defined because the proposed rules require the HMO to monitor structure of care. Monitoring of structure of care is defined by one researcher as approaches "focused on the institutional or system aspects of care," (Meisenheimer, 1985).

The examples of structural aspects are also taken from Meisenheimer.

4685.1110 Program

The following subparts describe the elements that must be included in the HMO's QA program.

Subpart 1. Written Quality Assurance Plan

This subpart requires the HMO to have a written QA plan. Minnesota Statutes, section 62D.03, subd. 4, requires the HMO to have a description of the procedures and programs it has for its arrangements for an ongoing evaluation of the quality of health care. This proposed subpart is necessary to describe

the elements that must be included in the HMO's written QA plan. The elements listed in the proposed rules are reasonable, as they are the same elements that are required by national review organizations and described in QA literature as minimum standards.

Currently, all of the HMOs operating in Minnesota have a written description of the programs implemented for ongoing evaluation of the quality of health care filed with the commissioner as a requirement for applying for a certificate of authority and operating as an HMO, (Minnesota Statutes, section 62D.04 subdivision 1). Because current laws and rules do not define the requirements for this written description, the content of these written descriptions or plans varies among HMOs.

The proposed rules require the written plan to include a mission statement, philosophy, goals and objectives because these are key components of any organization's written plan. The requirement for describing organizational structures, staffing and contractual arrangements, and a system for communicating QA activities are necessary because these are key elements of the QA program's organization.

According to one researcher, the cornerstone of QA is the written QA plan, and such a plan should include the philosophy, goals and objectives of the program, (Meisenheimer, 1985). The NAHMOR Guidelines require HMOs to have a

written quality assurance plan. In addition, the Office of Prepaid Health Care Guidelines require the HMO to have a written plan which describes goals, objectives, scope, and organizational arrangements of the program.

The JCAHO Standards Manual also requires ambulatory care organizations to have a written quality assurance plan. JCAHO specifies that a written plan must include the "program's objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and problem solving activities," (JCAHO, 1988)

The written plan must also include a description of the peer review activities conducted. Existing rules require the HMO to have an ongoing internal peer review system, (Minnesota Rules 4685.1100). Peer review activities are an important component of an HMO's quality assurance program. The proposed rules retain the requirement for peer review activities by requiring a description of such activities.

Subpart 2. Documentation of responsibility

This proposed section requires the HMO to demonstrate, through appropriate documents, that it has assumed responsibility for the evaluation of the quality of care provided to enrollees. Such documents shall also demonstrate quality assurance authority, function and responsibility. For example, the

organization's by-laws must describe who is responsible for QA, and provider contracts must include language that describes the HMO's authority to conduct quality assurance activities.

It is necessary to require documentation of quality assurance authority, function and responsibility in order for the commissioner to be assured that the organizational arrangements are supportive of quality assurance. Because quality assurance activities affect providers, appropriate documents should describe the HMO's authority and quality assurance functions.

The HMO is a deliverer of health care services and is ultimately responsible for assessing the quality of care delivered to its enrollees. Currently, many HMO's have written documentation that they have assumed responsibility for evaluation of quality of care. For example, Group Health, Inc.'s written quality assurance plan filed with the commissioner states the philosophy of its quality assurance program and its responsibility for quality evaluation. Their QA plan says in part,

> "As deliverers of health care, we are accountable for our actions. We must demonstrate high quality care to our members, colleagues, accrediting and regulatory agencies and to ourselves. We must evaluate our performance to assure high quality patient care and identify areas leading to compromised quality of care.

The description of MedCenter's QA plan in its certificate of authority application filed with the commissioner also indicates the HMO's responsibility for evaluating quality. Their program description states in part, "(T)his (QA) committee meets monthly and is charged with overall responsibility for the manner in which health services are provided plan members."

There is agreement in the QA literature and among review organizations that the governing body must be responsible for QA and that QA responsibilities be documented. Literature on designing successful QA programs indicates that "to ensure success (of a QA program) the (QA) plan must be adopted by the appropriate persons in the organization," (Meisenheimer, 1985). The Office of Prepaid Health Care Guidelines require documentation (in by-laws or by resolution) that the governing body has assumed accountability for quality assurance. These Guidelines further provide that the governing body should receive routine reports of QA activities. NAHMOR Guidelines specifically state that the governing body is ultimately accountable for QA and that the HMO must implement a program of accountability which determines QA responsibilities. Finally, JCAHO requires the governing body to adopt a quality of care evaluation program.

Donald M. Berwick, M.D., is responsible for the QA program at the largest staff model HMO in New England. He writes that "(Q)uality improvement must begin with commitment at the very top of the organization." Berwick notes that an organization will be effective in improving quality if QA reports to the top of an organization, (D. M. Berwick, "Quality Assurance and Measurement Principles: The Perspective From One Health Maintenance Organization," in **Perspectives on Quality**, edited by E. F. X. Hughes, McGraw-Hill Book Co., Washington, D.C., 1988).

Subpart 3. Appointed entity

This section requires the HMO's governing body to designate a quality assurance person or persons or a quality assurance committee. The designated quality assurance person or persons must maintain records of quality assurance activities and meet with the governing body at least quarterly.

The requirement for an appointed responsible quality assurance person or persons and quarterly reports follows the requirement in proposed subpart 2. Essentially, the governing body must be accountable for QA. However, it is not feasible for a governing body to actually implement QA activities. Therefore, the governing body must designate a responsible person(s) to implement quality assurance activities. In order for the governing body to remain ultimately accountable for QA, the governing body must be kept informed

of all QA activities conducted by the responsible person(s).

The proposed rule is written to be flexible as to the manner in which the appointed entity may be structured. The entity may be a physician, a management executive, a committee of physicians, or any other combination of persons capable of implementing the quality assurance program.

Several organizations include this type of requirement in their quality assurance guidelines. NAHMOR Guidelines provide that the governing body determines the accountable person and any associated committees or entities. These Guidelines further provide that there must be regularly scheduled meetings of all entities performing QA. Similarly, the Office of Prepaid Healthcare Guidelines require a governing body assigned committee or entity to meet, maintain records, and report to the governing body on a scheduled basis. AAAHC requires an "organized mechanism" to be responsible to the governing body for QA activities. Finally, JCAHO requires a "designated individual or group" to be responsible for implementing the QA program.

Literature on designing QA programs emphasizes the importance of the governing body's role in QA, and the need for reporting. One researcher writes that quarterly and annual reports to the governing body are a <u>minimum</u> requirement, (emphasis added), (Meisenheimer, 1985).

Finally, most HMOs currently comply with this requirement. In its quality assurance plan, Group Health, Inc., explains that the Board of Directors has final authority for the QA program, but the Board delegates the responsibility for implementing the program to the Medical Director.

Subpart 4. Physician Participation

According to this subpart, a physician, designated by the governing body, must actively participate in the QA program.

Given that quality assurance activities are related to medical care, it is necessary to require physicians to participate in the program. This requirement is actually a concise restatement of the numerous references to physician involvement in QA activities in other parts of these proposed rules.

The terms "advise" and "oversee" are used to assure active, regular physician participation, yet allow a degree of flexibility. Often it may be appropriate for non-physician personnel to be involved in specific QA activities.

The Office of Prepaid Healthcare Guidelines include the requirement that a designated physician supervise implementation of the QA program.

Subpart 5. Staff Resources

This section requires the HMO to have enough staff resources to conduct quality assurance activities. This requirement is in line with the requirements described above which require the HMO's structure to support quality assurance activities.

Various organizations support this type of requirement. NAHMOR guidelines provide that "the quality assurance program shall demonstrate the presence of adequate support staff to carry out its responsibilities." HCFA Guidelines also require sufficient staff to assist with QA activities. Finally, Quality Quest, in its QA audit tool, requires "sufficient professional and administrative staff dedicated to carry out quality assurance functions." (Quality Quest, 1987).

Quality Quest is a quality assurance review organization which has secured a contract with the Federal government to perform independent external reviews of HMO Medicare Risk contracts in Illinois, Missouri and Kansas.

Subpart 6. Delegated Activities.

This section allows the HMO to delegate any quality assurance activities to providers, review organizations or other entities. While the HMO may rely on

these other organization's quality assurance systems to perform functions, the HMO may not fully delegate its responsibility for quality assurance. As indicated above, the HMO is ultimately accountable for quality assurance. Consequently, the HMO must have review and reporting requirements in place to ensure that contractees are meeting their delegated quality assurance responsibilities.

Again, review organizations and QA literature include this type of requirement regarding delegated QA activities. HCFA Guidelines acknowledge that certain functions of the quality assurance program may be delegated to other organizations. However, the HCFA Guidelines state that the HMO maintains the responsibility for quality assurance.

One researcher writes that specific functions related to QA may be delegated. However, all delegated activities should interface with the QA committee or entity "in order to demonstrate a comprehensive approach to monitoring care and ensure that all activities relating to professional practice will be monitored." (Meisenheimer, 1985, page 75).

In actuality, HMOs generally delegate some QA activities to providers. For example, Group Health Inc., contracts with hospitals that are approved by JCAHO and consequently must have QA activities in place which meet JCAHO standards. Group Health explains in its QA program that it will not duplicate

JCAHO reviews, but will utilize the information from such reviews in its comprehensive QA program.

Subpart 7. Information System

According to this section, the HMO must have an information system which is capable of supporting the information needs of the QA program activities. This subpart requires the HMO to have prompt access to medical record data which can be sorted by diagnosis, procedure, patient, and provider. Quality assurance activities begin with the collection of data. Without an information system, the HMO cannot collect the data necessary to conduct QA activities. When an HMO conducts monitoring activities or focused studies, it must be able to obtain information from medical record data by patient, provider, diagnosis, and procedure.

The HCFA Guidelines provide for a data collection and reporting system which has the capacity to efficiently support the QA function. Quality Quest's audit tool measures whether or not the health plan has the capability to profile data by diagnosis, procedure, practitioner and patient.

Subpart 8. Program evaluation

This section requires the HMO to evaluate the quality assurance program at

least annually. The governing body must be given the results of this evaluation. If the evaluation points out weaknesses in the program, the QA program must be amended to correct such weaknesses.

This requirement is identical to the HCFA Guidelines requirement that there be an annual evaluation of the overall quality assurance program and this evaluation must be communicated to the governing body. The HCFA Guidelines state "Unless there is clear evidence that the program has been effective in improving care, a plan for modifying the approach to quality assurance should be developed."

JCAHO also requires an overall evaluation of the QA program. According to the Standards Manual, "(T)the objectives, scope, organization and effectiveness of the quality assurance program are evaluated at least annually and revised as necessary." (JCAHO, 1988).

Quality Quest specifically looks to see if the organization has conducted a formal evaluation at least annually. In addition, Quality Quest looks for a plan for modifying the QA program "when there is not clear evidence that program continues to be effective in improving care."

Subpart 9. Complaints

This section requires the HMO to conduct ongoing evaluation of enrollee complaints related to quality of care registered with the complaint system. HMOs are required by law to have a system for handling enrollee complaints, Minnesota Statutes, section 62D.11. The proposed rules require this system to be tied into the QA program. Enrollee complaints provide an excellent source of information about pertinent quality of care issues. Obviously, a complaint about care received signals a problem or potential problem in the delivery of health care.

Patient satisfaction with medical care is considered by a number of investigators and policy makers to be pivotal in investigating quality of care. Avedis Donabedian claims that "achieving and producing health and satisfaction, as defined for its individual members by a particular society or subculture, is the ultimate validator of quality of care." (P. Cleary and B. McNeil, "Patient Satisfaction as an Indicator of Quality Care," Inquiry, Spring, 1988, p. 25).

The HCFA Guidelines specify that enrollee grievances be tied into the quality assurance program. In addition, these Guidelines provide that the QA program receive regular reports on enrollee grievance and conduct a "vigorous follow-up program."

Subpart 10. Utilization review

This section requires the QA program to receive and analyze all data from the health maintenance organization's utilization review activities.

Utilization review and quality assurance are two activities conducted by HMOs which are not mutually exclusive. Utilization review activities include the examination of potential overutilization of medications or procedures or the potential under utilization of certain services. Many utilization review issues are similar to quality of care issues. For example, utilization review and quality assurance activities may assess the range of treatment possibilities for a specific condition. The utilization review would primarily be focused on the differences in costs of services, while the QA assessment would focus on the probability of improved outcomes under certain treatment regimens. Any data from utilization review activities should be reviewed by the quality assurance program.

HMOs are currently required by statute to conduct utilization review activities. Minnesota Statutes 62D.04, subdivision 1, requires HMOs to have a procedure to evaluate the pattern of utilization of its services.

The HCFA Guidelines require the HMO's QA program and utilization review program to work together. The Guidelines specifically require the HMO to use its utilization review system "to target areas for examination that may have

quality implications."

Subpart 11. Provider credentials and selection

This section requires the HMO to have a policies for provider selection and policies about provider credentials. Essentially the HMO should have policies for contracting with or hiring providers that are accredited, (which may included licensed, registered, or trained from accredited institutions) or are appropriately trained for their positions.

The current rules provide that an HMO have "a defined set of standards and procedures in selecting providers to serve enrollees," Minnesota Rules 4685.1100. The proposed rules expand this requirement by explaining that there should be consideration of a provider's credentials and training. In addition, the only major clinical component of HMO health care services provided by a supplier who is not credentialled is durable medical equipment. The proposed rules require an HMO which contracts with durable medical equipment suppliers to have policies to ensure that the suppliers offer products that meet standards generally accepted in the medical community.

HCFA Guidelines require using additional criteria beyond state licensure to select physicians. According the the Federal Guidelines, "A rigorous credentialling program is an important component of the larger picture of

quality assurance, and provides an indication of the organization's commitment to providing quality care for enrollees." Quality Quest includes the same credentialling requirement in their evaluation manual.

Subpart 12. Qualifications

This subpart requires individuals involved in quality assurance activities to be qualified by experience or training.

This subpart is reasonable and necessary because it is inappropriate for people with little training or experience to conduct the activities required in these proposed rules. Without a standard for qualifications, the HMO could potentially have unqualified individuals conduct the quality assurance activities required in these proposed rules. If such activities are conducted by unqualified people, the activities would be substandard and meaningless.

The issue of individual qualifications is addressed in the HCFA Guidelines which require HMO staff to have knowledge and experience in quality assurance activities.

Subpart 13. Medical Records

This section requires the HMO to evaluate medical records for accurate and

timely documentation. In addition, this section requires the HMO to maintain a medical record retrieval system to ensure that medical records are readily accessible.

All of the major QA resources include a medical record completeness requirement. AAAHC requires the quality assurance program to review medical records for completeness. NAHMOR Guidelines provide that the quality assurance program shall "ensure that providers maintain medical records in a legible, current, detailed, organized and comprehensive manner..." Similarly, JCAHO requires the quality assurance program to evaluate the "quality, content, and completeness of medical record entries. Finally, HCFA requires the HMO to have a system to assess the content of medical records to assure that they are legible, organized and complete.

HCFA Guidelines also require a "health recordkeeping system" for all enrollees. The Guidelines explain that medical record information is the only source of documented information about individual treatments. The medical record serves as the single most important communication tool regarding quality of health care services. According to the HCFA Guidelines, "it provides the underpinnings of the QA program." Without prompt access to the medical record, the HMO is missing the critical information source about quality of the health care services delivered.

4685.1115 ACTIVITIES

Subpart 1. Ongoing quality evaluation

This subpart requires the HMO to conduct quality evaluation activities that address the broad range of services offered by the HMO. The next part of the proposed rules defines the steps for conducting quality evaluation. This subpart explicitly defines the elements within an HMO that must be included in the HMO's QA program.

The reason for this subpart is to succinctly describe the HMO's requirements for QA activities. This part indicates that the HMO must conduct quality evaluation activities that are comprehensive in scope.

This prototype of a comprehensive QA program has been in use for many years with reported success at large, and well established HMOs such as Kaiser Permanente, Harvard Community Health Plan, and a well established medical group practice, St. Louis Park Medical Center. Each of these organizations uses "(T)he same general approach, an internally operated system which scans the horizon of care, identifying and dealing with problems," (R. H. Palmer and H. R. Nesson, "A Review of Methods for Ambulatory Medical Care Evaluations," Medical Care, August 1982).

Group Health, Inc.'s QA program is comprehensive in nature. In its description of the scope of its QA program, Group Health, Inc., explains that it will monitor and evaluate "all services provided" by the HMO.

HCFA guidelines provide that the HMO conduct ongoing quality assurance activities that are comprehensive in scope and look at a broad range of health care issues. Similarly, NAHMOR Guidelines require the HMO to evaluate a "representative sample of all types of services provided in institutional and noninstitutional settings." Finally, AAAHC requires a QA program to address clinical, administrative, and cost of care issues in addition to actual problems in patient care.

Subpart 2. Scope.

This section lists the specific components of the HMO which must be evaluated by the HMO's QA program. It is necessary to list each of these components because if the rules simply require quality assurance activities that are comprehensive in scope, there would be varying interpretations of what "comprehensive" means.

Item A. Clinical

Item A defines the clinical services which an HMO must evaluate. Essentially, the HMO must evaluate all of the clinical health services it offers. The clinical services described are consistent with the services that HMO's are required to provide by law. Minnesota Statues, Section 62D.02, subdivision 4 states that an HMO provides comprehensive health maintenance services. Subdivision 7, of that same section of Minnesota law defines comprehensive health maintenance services to include at a minimum emergency care, inpatient hospital and physician care, outpatient health services and preventive health care services. Minnesota Rules 4685.0100 further define outpatient health services to include ambulatory care, chemical dependency services, mental health services, pharmacy services, and other supportive treatment.

Home health care, durable medical equipment, and skilled nursing care must be included in the scope of the QA program if the HMO provides such services. HMOs are permitted to exclude these services, under Minnesota Rules 4685.0700, subpart 3.

Quality Quest describes the scope of the HMO's QA program to include all provider settings such as ambulatory, inpatient, emergency room, home care and nursing home care, and all aspects of clinical performance including physician, nurse practitioner, mental health, etc.

JCAHO Ambulatory Standards Manual requires the quality assurance program to

conduct a comprehensive review of all services related to ambulatory care. The minimum activities required to be evaluated in their standards manual include: clinical performance, pharmaceutical services, surgical and anesthesia services, emergency services, and laboratory services. In the same way the JCAHO requires a review of all services, the proposed quality assurance rules require a review of all services delivered or arranged by the HMO.

Item B. Organizational

This item requires the quality assurance program to review the organizational elements of the HMO which affect accessibility, availability, comprehensiveness and continuity of health care. Examples of organizational elements which should be reviewed which affect accessibility include waiting times for appointments; timely and appropriate linkages to necessary care through any referral systems, case management systems, or any requirements for second opinions or prior authorizations, and the nature of financial incentives present in some physician compensation arrangements.

It is necessary to define the HMO's organizational strategies which impact on availability and accessibility of services because Minnesota law specifically requires HMOs to have procedures and programs to conduct evaluations relating to availability and accessibility of services, (Minnesota Statutes, section

62D.03).

HMOs, as deliverers of health care, use various organizational strategies to contain health care costs and manage health care for its enrollees. Many of these strategies may potentially affect the accessibility and availability of health care services. Many HMOs rely on gatekeeping strategies with a primary care gatekeeper who "refers the patient to specialty services, as needed, as a condition for payment," (A. R. Somers, and H. M. Somers, "And Who Shall be the Gatekeeper?- The Role of the Primary Care Physician in the Health Care Delivery System," Inquiry, 1983, 20.) Typical gatekeeper-based systems in HMOs use organizational features such as prior authorization for certain services, referrals by the primary care physician for certain services, and case management by the primary care physician to coordinate the work of specialists and screen out unnecessary specialty consultations and hospital admissions, (K. E. Ellsbury, "Gatekeeping- Clinical and Administrative Issues, The Western Journal of Medicine, August, 1986). Briefly, the role of the gatekeeper is "to keep those who don't need special treatment from wasting the time of specialists, and to guide those who do need such treatment to the appropriate specialist," (C. M. Lindsay, "How Not to Control Medical Costs," Fortune, July 6, 1987.)

Gatekeeping strategies and the other organizational features described above control enrollee access to health care services. The benefit of these

strategies is containment of health care costs by controlling demand and channeling enrollees to appropriate levels of health care. However, some analysts point out that gatekeeping strategies may adversely affect accessibility and availability of services. These people point out that these organizational features may cause potential harm by "delaying diagnosis of conditions," (Lindsay, 1986). Another source points out that gatekeepers or case managers "may not be qualified to diagnose accurately all illnesses of the patient, as a consequence, needed care for patients may be postponed or never provided," (P.Politser, "The Gatekeeper Concept," American College of Surgeons Bulletin, June, 1986.)

In summary, it is necessary to require the HMO to evaluate specific organizational features including referrals, case management, second opinions, or prior authorizations, because of the potential adverse effect these strategies have on the availability and accessibility of health care services.

Another organizational feature of the HMO which may potentially impact on accessibility and availability of services is the financial arrangements between the HMO and its providers.

Many professionals have voiced concern about how payment arrangements may influence professional medical care services. To date, there have been no conclusory studies on the effect of provider payment systems. However, some

analysts suggest that in HMO systems, reimbursement arrangements may lead to underutilization of services. On the other hand, analysts have pointed out that in the traditional fee for service system, the financial incentives may lead to over utilization of services, such as uneccessary surgeries.

HMOs use financial incentives to promote efficient delivery of health care as well as to promote preventive care. It is reasonable to require the QA program to evaluate financial arrangements to assess the impact of financial incentives on efficient delivery of care including the provision of preventive care and the resulting outcomes.

The HCFA Guidelines require the HMO to have a system for monitoring payment arrangements to evaluate the potential impact on the delivery of health care services.

Finally, the length of waiting times and scheduling times to receive health care services impacts on the availability and accessibility of health care services. Because HMO enrollees must receive their health care services from providers who are participating with the HMO, there must be a sufficient number of providers to ensure timely access to health care services. HCFA Guidelines require measuring waiting times for appointments to evaluate whether services are accessible. Regulatory guidelines in "An HMO Regulatory Primer," National Association of Insurance Commissioners, March 1988, require

the HMO to monitor the providers appointment scheduling capacity.

HCFA as well as NAHMOR, AAAHC, and JCAHO, each provide that the quality assurance program shall review service elements of care that affect availability, accessibility and continuity of care. HCFA Guidelines give examples of specific organizational elements to evaluate including waiting times, timely access to health services, timely placement in institutions, and the nature of financial incentives.

Item. C. Consumer

This item requires the QA program to evaluate the consumer's perception of the health plan through surveys, complaints registered, and questions or comments.

As stated previously, enrollee satisfaction measures are important and useful in quality assessment. One reason that patient satisfaction is important is that many consider patient satisfaction an integral part of quality care, (P. Cleary and B. McNeil, "Patient Satisfaction as an indicator of Quality Care," Inquiry, Spring 1988). Again, one of the most renowned QA researchers, Donabedian (1983), argues that "the core of a quality assurance system is client satisfaction," (Health Care Financing Review, 1986 Annual Supplement, page 90.)

Researchers suggest that one reason enrollee satisfaction is a useful marker for determining quality of care is that "higher patient satisfaction may be a result of better patient-physician interactions in a variety of dimensions..." (P. Cleary, 1988). For example, patients who are more involved in their care and more satisfied may be more likely to comply with physician's orders. In addition, "(A) high level of consumer satisfaction is a desirable outcome in its own right," (K. Lohr, "Outcome Measurement: Concepts and Questions," Inquiry, Spring 1988).

HCFA Guidelines require HMOs to conduct enrollee satisfaction surveys and track member grievances. These Guidelines indicate that enrollee surveys will relate important information about the quality of care received in terms of attitudes of staff, accessibility of physician and the enrollee's perception of appropriateness of care. In addition, the AAAHC Handbook specifically requires the QA program to assess patient satisfaction

4685.1120 QUALITY EVALUATION STEPS

This part explains the structure of the QA program. Essentially, all QA program activities are contained within the five basic steps outlined in this part.

Subpart 1. Problem Identification

This subpart requires the HMO to have active, ongoing monitoring of quality of care and evaluation of the data collected from monitoring activities in order to identify problems or potential problems in quality of health care. Further, this subpart provides that health care practitioners participate in the evaluation of the data, or participate in the development of criteria which will be applied to the data to determine actual or potential problems in care. Briefly, this subpart requires the QA program to collect and evaluate information related to quality on an ongoing and active basis.

For certain health care services, health care practitioners will have developed explicit, or predetermined, criteria. The advantage of explicit criteria is that they can be applied to data collected about health care services, by clerical personnel or even by computer to detect problems or potential problems in care, (R. K. Hill, 1980). Data related to health care services where there are no explicit criteria established, will have to be evaluated by health care practitioners using implicit criteria. In these situations, trained health care professionals will identify problems by evaluating information collected regarding health care services.

This subpart describes an essential first step in quality assurance. It is reasonable as it is taken directly from QA literature, from actual QA program

operations, and from accreditation manuals. Analysts agree that quality evaluation involves a comparison of patient care with criteria, (R. H. Palmer, 1988, J. Weiner, 1986, R. K. Hill, 1980, C. G. Meisenheimer, 1985). One researcher, in describing the major steps of a "typical" QA process followed by most HMOs, specifies that one step is the "collection of data from within the delivery system that will allow for a comparison with predetermined criteria." These standards or "criteria of quality" are developed either by experts or practicing providers," (J. Weiner, 1986).

Group Health Inc. describes this problem identification step of quality assurance activities in its written QA plan filed with the Department. Essentially, Group Health's quality assurance program uses "monitors" or data sources to detect possible problem areas. Examples of data sources Group Health uses are similar to the definition of data in the proposed rules, part 4685.1105 subpart B.

Once the data is collected, Group Health analyzes the data to determine whether problems exist. For example, data relating to peer review activities or medical records evaluations, "will be analyzed by the medical director, director of the quality assurance department and clinic service coordinator(s)." (Group Health, Inc.'s Quality Assurance Plan, January, 1987)

The AAAHC Handbook for Ambulatory Health Care requires the organization to

provide ongoing monitoring of health care services provided. The Handbook provides that data collected from ongoing monitoring are evaluated periodically. Finally, AAAHC requires health care practitioners to participate in the development and application of the criteria used to evaluate the care they provide.

JCAHO has similar requirements for health care organizations conducting QA. The JCAHO Standards Manual requires ongoing monitoring and evaluation activities including ongoing data collection, and use of objective criteria developed by health care practitioners. HCFA Guidelines also contain these types of problem identification requirements. According to HCFA Guidelines, problems are identified on an on-going basis for further follow-up. Explicit criteria which are developed by health care professionals are used to identify problems. In certain situations, health care practitioners may use implicit criteria to "make a credible determination as to whether a quality problem exists."

One analyst, in describing the basic elements of a QA program, explains the problem identification step as follows.

> The evaluation of data usually involves a screening process in which a comparison is made with preestablished standards followed by further evaluation of any care falling outside the threshold. Where warranted, the care is then subject to review by peers examining the full clinical

context of the case or cases in question, (James S. Roberts, M.D., "Quality Health Care: Its Definition and Evaluation," in Perspectives on Quality in American Health Care, edited by E. F. X. Hughes, McGraw-Hill Book Co., Washington D.C., 1988)

Subpart 2. Problem Selection

This proposed subpart requires the HMO to identify and select problems for further study or corrective actions based on frequency and severity of the problem.

Meisenheimer (1985) specifically describes the importance of selecting and prioritizing problems while considering, among other things, the impact on patient care and professional practice, quantity of persons involved, and duration of problem.

One of the six major steps of a typical QA program at most HMOs, as identified by Weiner, is the "identification of problems or issues to be targeted as the focus of the QA process." (J. Weiner, 1986)

QA literature and practice both emphasize the problem-focused approach to QA activities. One analyst explains that the problem focused approach was

ushered in by JCAHO in 1979. JCAHO emphasized focusing QA activities on areas with potential for substantial improvements in patient care, areas where the problem is solvable, or areas where the problem is prevalent, (C. Wilbert, 1985).

HCFA Guidelines have a similar emphasis. The Guidelines state that HMOs "can focus their activities in QA by identifying areas of vulnerability which would have the highest rate of return in terms of significant problems found for resources invested." HCFA also specifically mentions areas which are considered high volume, high risk, problem prone, or represent possible adverse outcomes.

Subpart 3. Corrective Action

This subpart requires the HMO to document corrective actions designed to address any problems identified. The documentation of corrective actions is required to contain measurable objectives, time frames and identification of responsible person(s).

This step in the proposed rules is essential to QA activities. As stated earlier, QA activities are essentially a range of assessment methods for identifying deficiencies and corrective action strategies to bring performance

in line with standards (J. Weiner, Meisenheimer, Palmer, Wilbert, Graham, et al.) Weiner specifically emphasizes the importance of corrective action. He writes that "(Q)uality assurance is the formal process by which a delivery organization monitors and improves the care it delivers. This statement implies that *quality monitoring* should not be considered QA, because it does not involve any improvement process," (J. Weiner, 1986).

Another researcher concurs with the importance of corrective action strategies by explaining that the goal of the QA system is improvement, (N. O. Graham, Quality Assurance in Hospitals, Aspen Systems, Rockville, 1982).

Accrediting organizations including JCAHO and AAAHC require documented corrective actions as an integral step in the QA process. HCFA Guidelines also include requirements for documented corrective actions.

One researcher specifically requires that any planned corrective actions include the same items required by these proposed rules: measurable objectives, person(s) responsible, and a time frame for reassessment, (Meisenheimer, 1985). This researcher maintains that accountability for implementation of corrective actions is a prerequisite for effective application of QA activities.

Subpart 4. Evaluation of Corrective Action

This subpart requires the HMO to monitor the effectiveness of any implemented corrective actions and communicate the results of any corrective actions to the governing body, providers and staff of the HMO.

HCFA Guidelines require the HMO to track any actions taken to improve care. These Guidelines also provide that the results of any evaluation of corrective actions should be documented and communicated to providers. Similarly, JCAHO requires that results of actions taken should be documented and reported through channels established by the organization. AAAHC requires problems to be re-evaluated to determine objectively whether the corrective action measures have achieved the desired result. AAAHC further provides that QA activities are reported to the governing body, the chief executive officer, and appropriate personnel.

In Wieners' description of typical QA program steps, the last step in the QA process is the collection of data to monitor whether or not the desired change has occurred. Similarly, Meisenheimer's last step in her description of a typical QA program, is problem assessment and problem evaluation until "sustained resolution occurs." Another analyst explains that any topic important enough to examine and implement corrective action is important enough to follow up," (C. Wilbert, "Selecting Topics/Methodologies," in Quality Assurance: A Complete Guide to Effective Programs, edited by C. G.

Meisenheimer, Aspen, 1985.)

4685.1125 Focused Study Steps

This part describes the steps required for focused study activities. Focused studies are a subset of the basic quality evaluation steps. Essentially, focused studies are research activities focused on quality assurance problems. One researcher defines the steps of QA research as follows:

1) selection of a topic and formulation of this topic into a researchable question or problem

2) formulation of a hypothesis

3) selection of research design

4) data collection

5) data analysis

6) interpreting research findings

7) formulate recommendation for action or further study, (A. Lieske, 1985)

Any focused study activities conducted by the HMO must follow these basic steps which are described in the following proposed subparts.

Subpart 1. Focused Studies

This subpart explains that the QA program shall conduct focused studies as part of its overall QA activities. Focused studies can be conducted as a means of identifying potential problems.

This subpart is intended to convey that focused studies are a subpart of overall quality evaluation activities. However, focused studies are special, targeted activities used to identify and correct problems. For example, a focused study conducted as part of a QA program's problem identification activity could be a study of all readmissions to a hospital within 30 days to ascertain whether prior discharges are premature, ("Restructuring Quality Assurance Programs in HMOs and Other Competitive Medical Plans," QRB, March 1988).

The concept of focused studies is included in both HCFA and Quality Quest quality assurance audits. HCFA reviews cases being hospitalized for 13 specific diseases conditions. Quality Quest reviews a minimum of three examples of systematic quality assurance studies when it conducts its quality assurance audits. The HCFA Guidelines also include a requirement for detailed analysis of patterns of care which is analogous to a focused study activity.

Various forms of focused study activities are currently used by HMOs operating in Minnesota. As stated previously, Minnesota Rules require HMOs to conduct a "study of the quality of care for at least one disease condition or age

group," (Minnesota Rules 4685.2100, item C). Group Health Inc.'s quality assurance plan filed with the Department describes its quality assurance activities to include monitoring activities and "studies of specific disease or procedures utilizing outcome criteria."

In addition, in early 1986, three HMOs completed a type of focused study as part of a working group to test a methodology for ambulatory care chart review. This study, (the Minnesota Project) included important characteristics such as: emphasis on outcomes of care, screening of charts likely to contain problems, use of prior approved criteria, and physician involvement in final problem definition and remedial actions. While only minimum problems were identified, substantial actions followed including provider education, patient education and minimum standards for documentation and legibility.

The authors of the Minnesota Project concluded that the focused study approach appears to be feasible and unusually efficient. The study was found by the authors to be efficient and "a way to stimulate internal quality actions." The manual for the Minnesota Project is available through the Minnesota Documents Section to the general public.

Subpart 2. Topic Identification and Selection

This proposed subpart requires the HMO to select topics for focused study which meet certain considerations: areas which are of high volume, high risk, problem prone, correctable, or areas which have potential for adverse outcomes.

As explained previously, QA literature and practice each emphasize the problem-focused approach to QA activities. A decade ago, JCAHO started emphasizing the strategy of focusing QA activities on areas with potential for substantial improvements in patient care, areas where the problem is solvable, or areas where the problem is prevalent, (C. Wilbert, 1985).

HCFA Guidelines have a similar emphasis. The Guidelines state that HMOs "can focus their activities in QA by identifying areas of vulnerability which would have the highest rate of return in terms of significant problems found for resources invested." HCFA also specifically mentions areas which are considered high volume, high risk, problem prone, or represent possible adverse outcomes.

Finally, Group Health, Inc.'s QA program currently prioritizes problems for analysis and review based on: 1) severity of impact on patient care; 2) ability to effect change; 3) volume or frequency; 4) resources needed to analyze problem.

Subpart 3. Study

This subpart requires the HMO to document the steps it takes to implement a focused study including the study question, sample selection, data collection, criteria employed, and measurement techniques.

These steps are essentially basic research steps as explained above. This subpart is necessary to guarantee that any quality assurance study is conducted according to accepted, basic research steps. It is necessary that such steps be documented to permit the commissioner to validate the fact that a study was conducted according to the appropriate steps.

Subpart 4. Corrective Actions

This subpart requires the HMO to follow the corrective action steps described in part 4685.1130. The same rationale for corrective actions applies to corrective actions implemented as a result of focused studies.

As stated previously, the purpose for quality assurance is improvement in services. Corrective actions are an integral step in any QA activities. As the HCFA Guidelines explain, "when instances of poor quality are found, the

cause should be fully analyzed and documented...Action should be initiated to address the problem."

Subpart 5. Other Studies

This proposed subpart permits HMOs to satisfy the requirement to conduct focused studies through activities such as external audits, or multiple plan surveys. For example, the Professional Review Organizations (PROs) conduct focused reviews at HMOs which may satisfy the criteria for focused studies.

In 1987, the PRO's mission was expanded to include assessment of quality of care in HMOs offering Medicare risk contracts. Currently, the PRO's objectives are to 1) provide strong incentives for an HMO to have a comprehensive internal QA program; 2) identify HMOs which may be providing substandard care; and 3) give HMOs an opportunity to correct deficiencies identified by external reviewers. In order to meet these objectives, the PROs review the HMO's internal QA program, conduct individual case review, and oversee HMO corrective action plans, (T. Cleland, "Quality in the Prepaid Health Care Setting: The Federal Perspective," in Perspectives on Quality in American Health Care, edited by E. F. X. Hughes, McGraw-Hill Book Company, Washington D. C., 1988) In conducting individual case review, the PRO reviews the quality of ambulatory care received for 13 different disease conditions as explained previously. An HMO undergoing an external review by the PRO for

specific conditions may use such a review to fulfill the requirement for focused studies.

4685.1130 Filed Written Plan and Work Plan

This part describes the QA filing requirements.

Subpart 1. Written Plan.

This subpart states that an HMO's written plan is required to be filed with the commissioner prior to the HMO being granted a certificate of authority.

Minnesota Statutes, section 62D.03, subdivision 4, item o, requires an HMO to file a description of the procedures and programs to be implemented to monitor the quality of health care provided to enrollees. As explained previously, each of the HMO's operating in Minnesota has filed a written description of its QA program. However, since there are no standards as to the elements required to be described, the written plans do not all contain a complete description of the activities generally considered necessary for successful quality assurance.

This subpart is necessary to ensure that each HMO files a written plan which

contains the elements described in part 4685.1110.

Subpart 2. Annual Work Plan

This subpart requires the HMO to annually file a QA work plan. The work plan will describe the HMO's proposed quality evaluation activities and the proposed focused studies to be conducted.

Currently, the HMOs are required by rule to submit a description of the method and results of the system used to evaluate quality of care for at least one disease condition or age group. This requirement is deleted below. Instead of requiring the HMO to report results of QA activities, the Department proposes requiring a description of QA activities. If the HMO is required to report the results of QA activities, the HMO has little incentive to conduct QA activities in a manner in which the HMO will identify important quality of care problems. Realistically, no organization willingly will conduct a rigorous search for potential problems within its system and then report such problems to a regulatory agency for public review. However, if the Department requests a description of proposed QA activities, the HMO can conduct a rigorous evaluation of issues that are meaningful, without the disincentive of having to report the findings of any evaluations.

An annual description of activities is necessary as the nature of QA

activities will likely change on approximately a yearly basis as evaluation activities are modified and focused study activities are revised according to the needs of the health delivery system.

Item A

The proposed rules require HMOs to conduct evaluation activities that address each of the components of the health care plan. This item requires the HMO to conduct quality evaluation activities which shall address all of the components of the health care plan as defined in part 4685.1115. The commissioner will take several factors into consideration in determining whether or not the HMO's quality evaluation activities are sufficient to address all of the components of the health plan.

It is impossible to prescribe the type and amount of quality assurance activities necessary. The amount of activity is definitely dependent on several variables. For example, the size of the health plan affects the amount of QA activities conducted. An HMO with 5,000 enrollees does not need to conduct the same type and amount of activities as an HMO with 50,000 enrollees. The larger HMO should conduct proportionately more activities than the smaller HMO. If the HMO puts a percentage of resources into QA activities, the larger HMO obviously has more resources to spend, and correspondingly can conduct more activities.

A new HMO will not be able to conduct the same level of activities as a well established HMO. It is reasonable to require more activities from an HMO which has been in operation for many years as compared to an HMO which is just beginning operations. HCFA Guidelines also expect that the level of quality assurance activities will be commensurate with the enrollment and age of the health plan. The Guidelines explain that organizations which have been in existence for several years and have large enrollments should have the capability to conduct a higher level of activities than newer organization without significant ongoing quality assurance programs.

The HMO's organizational structure and numbers of providers also affect the level of QA activities necessary to address each of the components of the health plan. For example, a staff model HMO that employs its own providers and operates in limited locations, will conduct different activities than an HMO that contracts with several providers at many clinics and hospitals. Finally, the proposed rules require the commissioner to consider the amount of quality evaluation activities conducted by health care organizations which perform similar functions.

HMO's currently conduct quality assurance activities; however, there is considerable variability in the amount of activities conducted by HMOs in Minnesota. Hospitals, large clinics, and other health care organizations also

currently conduct quality assurance activities. Because many health care organizations conduct quality assurance activities, the commissioner can determine a community standard or average level of activities conducted by organizations. Based on recent history, this standard is increasing as time passes. The commissioner will assess the standard level of quality assurance activities being conducted by health care organizations from year to year, and will use this standard to evaluate the HMO's level of activity, taking into consideration the variables listed above.

Because of the variety in structure and organization of the HMOs operating in Minnesota, and because the standards for quality assurance activities are changing rapidly, it is impossible to describe the exact amount of activities required. Therefore, the proposed rules describe several factors that the commissioner will consider in determining the appropriate level of quality assurance activities.

Item B.

According to the proposed rules, the HMO must describe its proposed focused studies to be conducted during the following year. This item defines the elements that must be included in the description of the proposed focused studies. These elements generally follow the focused study steps described in

proposed part 4685.1125. The HMO must describe the topic and the reason for choosing the topic according to criteria in part 4685.1125. The HMO must also include a description of the benefits to be gained by conducting the study. This is required to ensure the HMO chooses topics which are important and will benefit the operations of the HMO.

The HMO must also define the methodology, sample size, and criteria to be used for evaluation. These requirements are necessary for the commissioner to be assured that the HMO is conducting focused studies in accordance with the focused study steps as proposed in part 4685.1125. Finally, the HMO must include the approval of the medical director or qualified director of health services. The approval of the medical director is considered validation that the HMO's proposed focused studies are approved and accepted by medical staff which will most likely be involved in the study, and that the study is a valid and important issue.

This item also requires the HMO to annually complete a minimum of three focused studies. As stated previously, HMOs are currently required to conduct one study of the quality of care for at least one disease condition or age group, (Minnesota Rules, part 4685.2100, item D.) This requirement was adopted in 1975, when the quality assurance rules were adopted. Since then, the community standards for quality assurance activities have increased considerably. The current requirement for one study is repealed under the

4685.2100 in these proposed rules.

As stated previously, the PRO studies 13 conditions in each HMO in each of their reviews. By comparison, three focused studies was selected to require an increased minimum level of activities in focused studies and for a broader scope of minimum activity. A number larger than three was not chosen because there is concern that flexibility is desirable; an HMO should be able to chose to put its emphasis either into focused studies or on ongoing activities. Also, if a larger number of studies was required, the studies may tend to be more limited in scope or less comprehensive than if three are required.

The proposed rules require focused studies to use a sample which represents the HMO's total enrollment. In other words, the HMO cannot only study a problem at one of their health care facilities. This study would not be representative of the HMO's services. Similarly, the HMO cannot simply study a disease by only looking at Medicare enrollees. Most HMOs in Minnesota have a majority of enrollees under the age of 65. Focused studies that only examine services rendered to Medicare enrollees would not be representative of the HMO's health services. In order for a focused study to be representative of the total HMO enrollment, the study must sample all enrollees who are at issue. For example a focused study relating to diabetes must use a sample which draws on all of the HMO's diabetes patients. Similarly, a focused study on preschool immunizations would include a sample representative of the HMO's

total preschool enrollment.

Subpart 3. Amendments to Plan

This proposed subpart requires the HMO to file notice with the commissioner 30 days prior to amending its written quality assurance plan and/or proposed work plan. This subpart is necessary to comply with Minnesota law which requires the HMO to file notice with the commissioner prior to modifying its procedures and programs implemented to monitor the quality of health care, Minnesota Statutes, section 62D.08, subdivision 1.

The proposed rules reiterate the existing law which states that if the commissioner does not disapprove of the changes within 30 days of submission, the modifications will be deemed approved.

Subpart 4. Plan Review

This proposed subpart explains that the commissioner shall review the HMO's annual proposed work plan. This subpart is necessary to enforce the requirements included in the preceding parts of the proposed rules. Essentially, the work plan will be evidence of the HMO's compliance with the proposed rules. The work plan will describe how the HMO intends to operationalize the QA guidelines contained in these proposed rules.

If the work plan does not comply with the rules, it is reasonable that the commissioner will disapprove of the plan and require the HMO to propose a work plan which meets the requirements of the proposed rules.

This subpart also provides that if the work plan is not disapproved by the commissioner within 30 days of its submission, it will be deemed approved. Again, this reiterates existing law which states that any notice of modifications of quality assurance programs filed with the commissioner will be deemed approved if not disapproved within 30 days of submission.

4685.2100 Annual Reports

The existing requirement for an annual report on quality assurance activities, including one disease study, is deleted. As explained above, the proposed rules require the HMO to submit a description of proposed QA activities rather than report the results of activities. In addition, the proposed rules require three focused studies instead of one study limited to a disease or age group.

General Statement of Need and Reasonableness

Since the complaint rules were originally promulgated in the early 1970's enrollment in HMOs has greatly increased, as have the numbers of complaints received by HMOs and by the Department of Health. With time and experience the Minnesota Department of Health has determined that although the basic framework of the complaint rules is sound, changes are needed to better meet the needs of HMO enrollees who have grievances.

The proposed rules make the following major improvements to the current complaint rules. They strengthen the current provisions whereby enrollees are notified about the HMO's complaint system. They make it easier for individuals to submit a written complaint by requiring HMOs to make complaint forms available. They substantially shorten the time it takes for a complaint to be resolved. They make impartial arbitration affordable for enrollees. They add flexibility to the current rules by 1) allowing for extensions to the time frames; 2) treating serious complaints in an expedited fashion; and 3) allowing enrollees who do not wish to participate in a formal hearing the opportunity for a written reconsideration. They expressly describe the role of the commissioner in resolving complaints.

The proposed rules also make minor needed changes such as clarifying the kinds of records of complaints HMOs must keep, defining "complaint" more

completely, and deleting a section which exempted complaints processed through HMOs' counsel or liability insurer from the usual complaint process.

Part by Part Statement of Need and Reasonableness

4685.0100 DEFINITIONS

Subp. 4. Complaint

The definition of "complaint" has been revised as explained below. "Enrollee grievance" has been changed to "grievance by an enrollee, applicant or former enrollee" to make it clear that a complaint need not be submitted only by a current enrollee. The rule also specifies the circumstances in which a former enrollee and an applicant may file a complaint. The rule states that if the complaint is from a former enrollee, the subject of the complaint must relate to services received during the period in which the individual was an enrollee and if the complaint is from an applicant, the subject of the complaint must relate to an application. These guidelines are in accordance with current practice and they set reasonable, limited parameters as to who may file complaints on what topics.

The phrase [grievance . . . against a health maintenance organization] "or provider arising out of the provision of health care services and" has

been deleted. The reference to providers was deleted because any complaint against an HMO provider is, for purposes of Health Department regulation, a complaint against the HMO. The Minnesota Department of Health has jurisdiction over HMOs, not over providers. The rest of the phrase was deleted because it is expanded upon in a different section of the subpart. The last paragraph of the subpart gives examples of the allowable subjects of complaints. Three of the examples, scope of coverage; quality of care; and administrative operations, come directly from the statute, specifically, Minn. Stat. 62D.11. One other example, denials of service, was a response to new law, Minn. Stat 62D.11, Subd. 3, which singled out denials of service by HMOs as a particular concern. The remaining examples, eligibility issues and denials, cancellations or nonrenewals of coverage are other areas in which the Department frequently receives complaints about HMOs.

The term "filed", as in filing a complaint or grievance, has been changed to "submitted" to minimize confusion with filing requirements HMOs have as to contracts and other documents. A filing in that sense involves a filing fee whereas "filing" a complaint does not. The word "submitted" is also preferable because it has a less legalistic connotation.

The phrase [grievance. . . which] "is not or is not yet the cause or subject of an enrollee election to litigate" has been deleted. The phrase "which is not under litigation" has been substituted because it more clearly conveys the intended meaning, that a grievance that is currently being litigated need

not be treated procedurally as other complaints. To require an HMO to respond to complaints being litigated through the process described in the rules would interfere with the legal process, particularly discovery.

Subp. 16. Immediately and urgently needed service.

This subpart defines the term "immediately and urgently needed service" which is used in Minn. Rules pt. 4685.1700, Subpart 1 E. That subpart sets up a separate, expedited process for dealing with complaints regarding immediately and urgently needed services. "Immediately and urgently needed services" is defined as "those services, which if not provided promptly, could reasonably be expected to result in placing an enrollee's health in serious jeopardy, serious impairment of bodily functions or serious dysfunction of an bodily organ or part." This definition is written so that the judgment whether a service is immediately and urgently needed is not a subjective one for either the HMO or the enrollee to make; instead it is to be determined according to an objective standard of reasonableness. This is similar to the definition of "emergency care", a service HMOs must provide, found in Minn. Rules pt. 4685.0100, Subp. 5 A.

4685.1700 REQUIREMENTS FOR COMPLAINT SYSTEM

Subpart 1. Health maintenance organization's internal complaint system.

This new heading and the insertion of the word "internal" in the first sentence makes it clear that this section applies to the process HMOs must follow in dealing with complaints, as opposed to the process used by the Department of Health. The rules previously were silent on the Commissioner's role and the rules now explain that role, as well. Some language in the first paragraph was deleted because it was superfluous.

The Department proposes deleting existing item A. It required HMOs to "establish mechanisms through which written enrollee complaints may be filed by and presented by the enrollee or his authorized representative and considered and retained by the health maintenance organization." This language should be deleted because it is explained in more detail in subsequent items and is therefore unnecessary.

The proposed Item A requires the health maintenance organization to make available a complaint form to an enrollee, applicant or former enrollee who verbally notifies an HMO that he or she wishes to register a complaint. This form must include the telephone number of the HMO's member services department or some other department or person able to advise complainants, the address to which the form is to be sent, a description of the HMO's internal complaint system and applicable time limits and the telephone number to inform the Commissioner of Health of a complaint. This new item is necessary for several reasons. Supplying a complainant with a form will make

it easier and more convenient for some complainants to follow through with a written complaint. The reason for including the member services telephone number is to enable a complainant to get answers to questions he or she may have about the complaint process. The reason for including the address to which the form is to be sent is obviously to promote the ease and the likelihood of the complainant following through with the complaint. The reason for including a description of the HMO's internal complaint system is to put the complainant on notice of the process he or she can take advantage of; although this information is included in an enrollee's certificate of coverage, enrollees often do not refer to this document. Furthermore, as already stated, a complaint may be submitted by applicants and former enrollees, both of whom may not have evidences of coverage in their possession. Lastly, the reason for including the phone number of the Commissioner is to notify the complainant of another, alternative avenue for submitting a complaint. Including this information will also reduce confusion about which state agency regulates health maintenance organizations; at present, it is not unusual for HMO enrollees to submit complaints to the Department of Commerce.

The rule requiring use of the form also implements Minn. Stat. 62D.11, Subd. 3 which requires that if an enrollee communicates to the HMO about a lack of services or the poor quality of services, the HMO must provide the enrollee with a written statement which includes a description of the HMO's complaint process.

Item B. This item describes the first step of the complaint process, the informal stage. This item now provides for informal discussions, consultations or conferences between the enrollee and a person with authority to resolve or recommend the resolution of the complaint within 30 days after the complaint is filed. The proposed item adds "correspondence" to the types of interactions currently described, since in practice the communication between the complainant and the HMO may be in writing. Written communication can be more efficient and complete than face-to-face meetings; the Department wishes to allow this form of communication to be an option. The word "complainant" has been substituted for the word "enrollee" to make it clear that a complainant need not be an enrollee but may also be a former enrollee or an applicant. The phrase "within 30 days after it is filed" has been deleted because the existing timeline is vague; the informal discussions, consultations or conferences have to take place within 30 days. The present item is silent as to when the discussions, consultations or conferences must come to a resolution. Therefore, the proposed rules require the HMO to notify the complainant in writing of its decision and reasons therefor within 30 days after the written complaint is received. This sets up a definite deadline and also is explicit as to what is required of the HMO in terms of notifying the complainant of the resolution.

The proposed rules also provide that if the HMO cannot make a decision within 30 days, due to circumstances beyond its control, the HMO may take up to an

additional 14 days to notify the complainant, provided the HMO informs the complainant in advance of the reasons for the delay. This extension is necessary because there are times when an HMO can not respond within 30 days; the most common example is when an HMO must get a release for medical records from the complainant and then must get the records from the provider.

The proposed rules provide that if the HMO's decision is partially or wholly adverse to the complainant, the written notification must advise the complainant of the right to a hearing and the right to arbitrate. This provision does not alter the existing procedure but merely requires HMOs to put complainants on notice of what options are available in terms of pursuing the process.

Item C. This item describes the formal hearing stage of the complaint process. The current rules provide that the HMO must provide a hearing at which a complaint not otherwise resolved must be considered within 90 days after it is filed. The timeframe for the proposed rules focuses on when findings are completed, not when the hearing is held or considered.

The proposed rules specify that a complainant must notify the plan in writing of his or her desire to appeal the plan's initial decision. The current rule states that the complaint must be filed, but it is not clear whether the complaint referred to is the initial complaint or the appeal of the initial

decision. The current rule also does not specify whether the complainant must submit something in writing at this stage. It is reasonable to require a written notice of the complainant's intention to proceed further, so that there will less controversy over timelines.

The proposed rules give a complainant the option of choosing a written reconsideration instead of a formal hearing. Presumably, there are some people who would rather not participate in a formal hearing but do want to submit additional evidence or present their arguments again at a higher level.

The proposed rules add the requirement that if a complainant chooses a hearing, the person or persons presiding must not be solely the same person or persons who made the initial decision. Similarly, if a complainant chooses a written reconsideration, the person or persons investigating must not be solely the same person or persons who made the initital decision. These provisions increase the likelihood that the complaint will be considered objectively and without any preconceived biases. The word "solely" was used because the person who makes the initial decision is often a key staff person who may be part of a panel or committee which presides at the hearing. As long as others are involved as well, objectivity should not be unreasonably compromised.

Subitem 2 relates to the types of evidence which may be presented at a

hearing or for a reconsideration. The current subitem includes testimony, explanations or other information from enrollees, staff persons, administrators, providers and other necessary persons. The proposed rule adds "correspondence" to this list, since often the record will contain correspondence between the HMO and the complainant and sometimes between a provider and the HMO or the complainant. Again, in this subitem "complainant" has been substituted for "enrollee". The current rule refers to all the evidence which may be included "for a fair appraisal of the complaint". The phrase "and resolution" has been inserted after "fair appraisal" to make it clear that the goal of a hearing or reconsideration is a decision.

Subitem 3 currently provides that a written notice of the HMO's findings shall be given to the complainant within 30 days of the conclusion of the hearing. The focus of this subitem has been changed to reconsiderations. Hearings are dealt with in the next subitem. The proposed rule provides that in the case of a reconsideration, an HMO must give written notice of all findings to the complainant within 30 days of the HMO's receipt of the complainant's written notice of appeal. Thus, the time frame for resolving reconsiderations is identical to the existing time frame for notifying complainants of a decision after a hearing.

Subitem 4 sets up a new timeframe for handling hearings. Under the current rule, the HMO must provide a hearing within 90 days from the date the

complainant appealed. The current rule requires the HMO to notify the complainant 30 days from the time of the hearing of its findings. Thus, currently, the process can take up to 120 days (4 months). Department of Health staff perceive this to be an unreasonably long process which may be discouraging to complainants. The proposed rules approach this time frame differently and shorten the process considerably. The proposed rule requires the HMO to give the complainant concise written notice of all findings within 45 days of the HMO's receipt of the complainant's written notice of request for a hearing. Once an HMO is notified that a complainant requests a hearing, it should not take more than two weeks to arrange for and hold a hearing. The 30 day period after the hearing would remain unchanged. There is flexibility built in to the time frame; an HMO could schedule a hearing after just a few days and then have more than 30 days in which to reach a decision and to notify the complainant of its findings.

Item D describes the arbitration mechanism available to complainants. The current rule is vague as to how arbitration should be structured. It says merely that the impartial arbitration procedure shall specify the method by which the neutral arbitrator shall be mutually selected by the parties, the costs of the procedure and how they shall be borne. The rule does require the arbitrator(s) to render an award within 30 days from the date of the closing of the hearing unless otherwise mutually agreed by the parties. However, on the important issues of costs, methods of choosing arbitrator(s) and other important procedural issues the rule gives no guidance. Thus, HMOs

have great leeway in deciding how to set up an arbitration process.

The proposed rules provide that arbitration shall be conducted according to the American Arbitration Association Health Maintenance Organization Arbitration Rules. This approach promotes uniformity among HMOs; all arbitration proceedings, regardless of the HMO involved, will have to operate under the same set of procedural rules regarding method of choosing an arbitrator, qualifications of an arbitrator, timeframes, and cost of arbitration.

A key element of the AAA rules is the administrative fee schedule whereby enrollees who arbitrate pay $50 and the HMO pays $150. The current rule is silent on the issue of which party bears what portion of the arbitration costs. Typically, the costs have been shared equally between the HMO and the complainant. Since the HMO could require the use of three arbitrators, the costs could be high. The administrative fee schedule contained in the AAA HMO Rules is identical to the fee schedule used in the AAA Accident and Health Claims Arbitration Rules. The Department also points to the alternative dispute resolution process provided under Minn. Stat. 325F.665 (commonly referred to as the "lemon law") as support for the reasonableness of the AAA's fee schedule. Minn. Stat. 325F.665, Subd. 6 (i) states that a consumer may be charged a fee to participate in an informal dispute settlement mechanism but the fee may not exceed the conciliation court filing fee in the county where the arbitration is conducted. In Hennepin County,

the conciliation court filing fee is $15 and in Ramsey County it ranges from $11 to $26. The Department considers a fee of $50 for the enrollee to be reasonable and affordable; it considers the $150 fee for the HMOs to be affordable, considering the relative resources of the parties.

The proposed rules restate the statutory prohibition that if the subject of a complaint relates to a malpractice claim, such a complaint shall not be subject to arbitration.

Item E is a new provision which relates to disputes concerning services which are immediately and urgently needed. The Legislature recognized this as an issue; in the 1988 Session, it passed a law which provided that where a complaint to an HMO involves a dispute about a HMO's coverage of an immediately and urgently needed service, the commissioner could order the HMO to use an expedited system to process the complaint. Minn. Stat. 62D.11, Subd. 1(a)(b). Another indication that the Legislature was concerned about these cases is that it passed a law in 1988 which requires the commission on health plan regulatory reform to make recommendations for expedited review mechanisms for complaints concerning health maintenance organization coverage of an immediately and urgently needed service. 1988 Session Laws, Chapter 434, Section 23.

It makes sense that complaints of this nature, because time is of the essence, be exempted from the usual complaint process which, under the

proposed rules, could take 75 days and under the current rules, could take at least 150 days (or five months). This item recognizes the Legislature's direction. As already stated in the definition section, an immediately and urgently needed service is defined as "a service, which if not provided promptly, could reasonably be expected to result in placing an enrollee's health in serious jeopardy, serious impairment of bodily functions or serious dysfunction of any bodily organ or part."

Under the proposed rules, the complaint mechanisms and timelines already described do not apply in these situations and the complaint need not be in writing. This item requires an HMO to notify the commissioner within 24 hours or by the end of the next working day of when a complaint about an immediately and urgently needed service is received. The HMO must notify the commissioner of the nature of the complaint and the description of the review process. It then must use an expedited review process appropriate to the particular situation. This flexible approach is necessary because some cases will require a faster response than others. Because the Department will have notice of these situations, the commissioner will be able to monitor that review process.

Item F (currently Item E) currently requires HMOs to give notice to all enrollees of the existence and operation of its complaint system. The proposed rule is more specific in requiring that the explanation of the complaint system appear in the evidence of coverage and enrollee handbooks,

if used by an HMO. The law already requires that evidences of coverage include a description of an HMO's complaint system. Some HMOs also provide their enrollees with handbooks which are summaries of the evidence of coverage; it is assumed that many people refer to their handbooks more than to their evidences of coverage because they are generally in more useable, readable form. Therefore, it is reasonable that these handbooks put enrollees on notice of the complaint system.

Subp. 2. Dispute resolution by commissioner.

Subpart 2 is a proposed new subpart which explains the role and authority of the commissioner in dispute resolution. There are two references to this role in statute. Minn. Stat. 62D.07, Subd. 3(c)(6) states that HMOs must notify enrollees on the cover page of the evidence of coverage of their right, among others, to file a grievance with the HMO and the commissioner when experiencing a problem with the HMO or its health care providers. More directly, Minn. Stat. 62D.11, Subd. 1a states that where a complaint involves a dispute about a health maintenance organization's coverage of an immediately and urgently needed service, the commissioner may review the complaint and any information and testimony necessary in order to make a determination and order the appropriate remedy pursuant to sections 62D.15 to 62D.17. This subpart explains how the commissioner handles HMO complaints she receives.

The proposed rules state that a complainant may at any time submit a complaint to the commissioner, who may either independently investigate the complaint or forward it to the HMO for further investigation. This is a reasonable approach, allowing the commissioner to initially request that the HMO investigate routine complaints and also giving her the option of independently investigating complaints of a more serious nature or ones where an outside, expert opinion seems appropriate. The law mentioned above relates to these types of situations. In practice, most complaints received by the commissioner are forwarded to the HMO with specific questions highlighting the issues presented. The proposed rules state that if the commissioner refers the complaint to the HMO, the HMO must follow the procedures set out in Subpart 1. It makes sense that complaints which are sent to the commissioner instead of the HMO should ordinarily not be accorded preferential treatment in terms of timelines and procedures followed. An exception would be complaints involving immediately and urgently needed services which the commissioner receives. In those cases, if the commissioner refers the complaint to the HMO, she could request an expedited review.

The rule provides that the commissioner may order a remedy, including an order to provide a service or reimburse an enrollee for a service already provided and which has been paid for by the enrollee; such an order may be issued after the commissioner investigates a complaint or after she has reviewed the HMOs decision regarding a complaint. Such enforcement authority

is exercised pursuant to Minn. Stat. 62D.17 and would only be used if the commissioner determined that the HMO had violated Chapter 62D or had failed to fulfill its contract with the complainant. Such an order would be subject to the administrative procedure act and therefore could be appealed.

4685.1800 OTHER PROCESSING OF COMPLAINTS

The Department proposes to delete this part in its entirety. This part provides that an HMO need not utilize the procedures described in Minn. Rules pt. 4685.1700 if a complaint is processed by the HMO's legal counsel or liability insurer, provided that such processing fairly considers the rights of all parties to the complaint; is accompanied by a concise written record of all findings and recommendations which the complainant receives within 30 days of the processing; and results in the resolution of the complaint or an enrollee election to litigate within 90 days of its filing.

The Department considers this exception to the usual complaint process unnecessary and therefore proposes its deletion. Minn. Rule 4685.0100 already provides that grievances which are under litigation are not subject to the complaint process. Any other grievance which falls into the definition of a complaint should be treated procedurally as any other complaint.

4685.1900 RECORDS OF COMPLAINTS

Proposed subpart 1 makes some modifications of the provision dealing with the complaint records HMOs must keep. In the 1988 legislative session, Minn. Stat. 62D.11 was amended to require HMOs to maintain a record of each complaint filed with it during the prior five years. Previously, HMOs had to maintain records for three years. The proposed rule extends the time period from three to five years as well.

Items A through E describe the records which must be maintained. No change has been made to Item A, the complaint or a copy and the date of its filing.

Item B deals with records describing the first stage of the complaint process in which informal discussions, consultations and conferences take place between the complainant and the HMO. The proposed rules also add correspondence as an acceptable form of communication at this stage. Proposed Item B requires that the correspondence be kept. This correspondence would include the letter from the HMO to the complainant describing its decision and the reasons therefore. The present Item B requires that the HMO keep a brief written summary of the outcome of all informal discussions, consultations, or conferences and the date or dates each of those transactions occured. This requirement has been modified slightly to make it clear that the summary should be of the whole process and should include the dates of the transactions and the outcome. The existing requirement that the summary include an acknowlegment by those participating

in the form of their signatures has been deleted; the notice letter will serve as the best evidence of what transpired in relation to the complaint.

Item C describes what must be kept in relation to a hearing. The present rule requires the HMO to include in the record the date or dates of any hearing and a copy of the hearing findings given the enrollee. Since the findings will include the hearing date, the proposed rule requires only that the findings be maintained. The word "enrollee" has been changed to "complainant" to maintain consistency.

Item D describes the records of processing conducted in accordance with Minn. Rules pt. 1800 (Other Processing of Complaints) which the Department proposes deleting. The Department proposes deleting this provision as well.

Proposed Item D (currently Item E) describes what records must be kept in relation to arbitration. The current rule requires the HMO to keep the date of submission of any complaint to arbitration, a copy of the arbitrator's decision and the date of the decision. Since the arbitrator's findings should include the relevant dates, the proposed rule only requires that the HMO keep the findings.

Proposed Item E (currently Item F) describes what records must be kept in relation to litigated grievances. The rule requires that the HMO keep a brief summary of each complaint which becomes the subject of litigation, a

brief summary of the findings or outcome of any prior processing held relative to the complaint and a brief statement describing the outcome of the complaint or claim as determined in litigation. The proposed rule simplifies the requirement by stating that the HMO must keep all documents which have been filed with a court relating to a complaint and all orders and judgments of a court relating to it. If the complaint went through any other stages (informal discussions, hearing, arbitration), records of those processes would have to maintained in accordance with Items A through D.

Subpart 2 is a new provision requiring HMOs to keep a single, ongoing record of complaints. This new provision was added because Department staff experienced difficulty when auditing HMOs in accessing complaint files. In a particular HMO, there was no central list or log of complaints; the auditor had to locate the complaint records by randomly reviewing enrollees' general files. The proposed rule requires that a log contain the date the complaint was initially submitted; the name, address and phone number of the complainant; and the location of the complainant's complaint records. The log requirement is intended to assist Department auditors when reviewing an HMO's adherence to complaint system requirements. A central log of all complaints would be helpful in keeping track of numbers of complaints (required for the annual report), locating the complaint records and basically providing another reference point for accessing the HMO's complaint records.