STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

IN THE MATTER OF PROPOSED
RULES RELATING TO
HEALTH MAINTENANCE ORGANIZATION
AVAILABILITY AND ACCESSIBILITY
OF SERVICES,
AND QUALITY ASSURANCE
MINNESOTA RULES CHAPTER 4685

STATEMENT OF NEED
AND REASONABLENESS

The Minnesota Commissioner of Health (Commissioner), pursuant to Minn. Stat., section 14.05 through 14.20 presents facts establishing the need for and reasonableness of the proposed repeal of rules and replacement with all new rules relating to health maintenance organization (HMO) availability and accessibility of services, and proposed amendments to rules relating to quality assurance and to definitions of terms.

STATUTORY AUTHORITY

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

Additional specific references to other statutory provisions relating to these rules will be provided as appropriate in the part by part statements of need and reasonableness.

SMALL BUSINESS CONSIDERATIONS

These rules are exempt from the provisions of Minn. Stat., section 14.115 relating to the impact of rules on small businesses. The small business consideration provisions do not apply to services regulated by government bodies for standards and costs, such as providers of medical care, (Minn. Stat., section 14.115 subdivision 7, (3).) HMOs are providers of medical care regulated by the Minnesota Department of Health for standards and costs. A "health maintenance organization" is defined in Minn. Stat., 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 8-0900-247-1, HLTH-86-006-JL which found that the small business consideration requirements in Minn. Stat., section 14.115 did not apply to proposed HMO rules.

SOLICITATION OF PUBLIC COMMENT AND INPUT

On November 23, 1987 the Department of Health published a Notice of Intent to Solicit Outside Opinion in the State Register. This notice invited interested or affected persons or groups to submit information or opinions regarding the amendment of HMO rules governing emergency care, medical necessity of services, provider terminations, coverage for referrals and geographic service area, in addition to other areas. No comments were received in response to this notice.

On April 1, 1991 the Department of Health mailed copies of draft proposed rules governing Accessibility of Services and Utilization Review to approximately 200 individuals on the Commissioner's mailing lists of people interested in receiving copies of proposed rules. We also mailed copies of the proposed rules to individuals and associations that we believed would represent consumers of health care services who were not on the Commissioner's mailing list. We asked that comments be submitted to the Department by May 15, 1991 but we accepted comments submitted after that date. We received ten written comments as well as one telephone comment. On May 8, 1991 we met with representatives of several Minnesota HMOs to hear their comments, concerns and suggestions in person.

On Sept. 23, 1991 a second draft of these proposed rules was mailed to everyone who submitted comments about the first draft. This second draft reflected many changes made in response to the comments and suggestions made concerning the April 1 draft of the proposed rules. We asked for comments by

Oct. 25 but we accepted all comments no matter when received. Eight written comments were received. The proposed rules were again extensively revised in light of the comments, suggestions and questions contained in these written comments.

On March 16, 1992 a Notice of Intent to Solicit Outside Information and Opinions was published in the State Register. The notice informed the public that draft rules were available upon request. The Department also mailed copies of these draft rules to all persons and organizations that had commented on the two earlier drafts. Eight written comments were received in response to this published notice. The written comments were carefully reviewed and extensive changes were made to the proposed rules.

Subsequent to the publication of the Notice of Intent to Solicit Outside Information and Opinions on March 16, 1992, the Department determined that it might be necessary to define the term "medically necessary care" in the proposed rules. This term was not defined in any of the three previous drafts that were sent out for informal comment. Therefore, the Department invited all persons on its list of interested persons to attend a meeting at which the definition of "medially necessary care" would be discussed. Twenty one interested people attended the meeting which was held on June 17. Following a detailed discussion, we invited these individuals to submit written comments and suggestions as soon as possible. All of the written and oral testimony has been considered in drafting the definition of "medically necessary care" contained in the proposed rule.

In April, 1992, the Minnesota Legislature passed the Minnesota Utilization Review Act of 1992 (Minn. Laws 1992, Ch. 574). This law, which is effective January 1, 1993, regulates prospective and concurrent utilization review activities of HMOs as well as other entities carrying out utilization review in Minnesota. It requires that any rule-making activities be jointly undertaken by the departments of health and commerce. Therefore, these proposed rules do not address utilization review which will be addressed in future rules to be jointly proposed by the departments of health and commerce.

PART BY PART STATEMENT OF NEED AND REASONABLENESS - Chapter 4685, DEPARTMENT OF HEALTH, HEALTH MAINTENANCE ORGANIZATIONS

4685.0100 **DEFINITIONS**

It is necessary to define the following terms because they are used in the proposed rules as well as in existing rules.

ANCILLARY SERVICES. This term is given its ordinary and accepted meaning in the community. These are health services that are provided pursuant to the orders of a physician or other authorized provider. The proposed definition is reasonable as it is consistent with common usage and understanding.

EMERGENCY CARE. This definition replaces the definition of "emergency care" in the rules currently in effect.

The proposed definition is more precise than the current definition. The proposed definition is consistent with generally accepted principles of practice in specifying the various reasons for which medical care might be needed immediately. It is also consistent with the definition of emergency services used by the Department of Human Services in its Medical Assistance rules and with the definition contained in 42 C.F.R. 417.401 governing Medicare and in 42 U.S.C. 1395dd (COBRA) of 1985 as amended by OBRA of 1987, 1989 and 1990.

Minnesota HMOs define emergency services in their contracts and certificates

of coverage. While each HMO has its own definition, there are certain common concepts or terms that the Department has incorporated into its proposed definition. These include the concept of care that is needed immediately, and care that is needed to save life or prevent serious impairment of health. We have defined serious impairment of health more specifically to include impairment to bodily functions, organs or parts. We have also included in the definition the concept of prevention of placing the physical or mental health of the enrollee in jeopardy.

This definition recognizes that emergency services may be needed for mental health crises as well as for reasons of physical accident and injury. This is consistent with definitions and explanations of benefits contained in several HMO certificates of coverage in which emergency psychiatric care or emergency care arising from mental illness are cited. See, Share Seniorcare Benefit Contract (1991), Share Master Group Contract, State of Minnesota (1989), Group Health Inc. Standard Group Membership Contract (1987), MedCenters Certificate of Coverage (1989).

URGENTLY NEEDED CARE. This definition replaces the definition of "Immediately and urgently needed service" currently in the rules.

The proposed definition is intended to distinguish care which is needed as soon as possible from immediately necessary care (emergency care). There are many situations in which an enrollee needs to be seen as soon as possible for assessment and treatment of an urgent medical condition. However, what distinguishes urgently needed care from emergency care is the immediate threat

to life and health. Emergency care must be provided immediately while urgently needed care may be delayed several hours without adverse effects on the enrollee's health. Urgently needed care can be thought of as falling between routine care and emergency care on a health care continuum.

The proposed definition is consistent with common usage in the community which recognizes a distinction between emergency care and urgently needed care. This distinction is reflected in the establishment of urgent care centers which may be free standing or affiliated with hospital emergency rooms. Some conditions can be treated in the urgent care center while some require the emergency room. Moreover, all HMOs have triage personnel who determine, when an enrollee calls for assistance, whether emergency or urgent care is needed.

MEDICALLY NECESSARY CARE. In drafting this definition, the Department looked very closely at many definitions of this term, including those used by Minnesota HMOs in their certificates of coverage and by the Department of Human Services in its Medical Assistance Program rules. While all of the definitions had certain concepts in common, there is substantial variation both in the words used and the meanings of the several definitions. In addition, different criteria and sometimes no stated criteria are used in these definitions. The Department believes that uncertainty as to the meaning of medically necessary care will be reduced if one common definition is used by all HMOs, and if criteria and standards are identified in this definition.

This proposed definition incorporates certain elements that we found to be

reasonable and necessary to define the concept of medically necessary care. We believe that our proposed definition is consistent with the DHS definition contained in Minn. Rule 9505.0175, Subp. 25 although it is worded differently. The DHS definition is as follows:

> "Medically necessary" or "medical necessity" means a health service that is consistent with the recipient's diagnosis or condition and:
>
> A. is recognized as the prevailing standard or current practice by the provider's peer group; and
>
> B. is rendered in response to a life threatening condition or pain; or to treat an injury, illness, or infection; or to treat a condition that could result in physical or mental disability; or to care for the mother and child through the maternity period; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition; or
>
> C. is a preventive health service under part 9505.0355.

We also considered adopting the definition of medical necessity pertaining to small employer groups contained in the new Minnesota HealthRight Act of 1992 (Minn. Laws 1992, Ch. 549). This definition is contained in Art. 2, Sec. 2, Subd. 21 and is as follows:

> "Medical necessity" means the appropriate and necessary medical and hospital services eligible for payment under a health benefit plan as determined by a health carrier.

We believe that the definition proposed in these rules is consistent with the legislative intent of the new HealthRight law, namely that medically necessary services be covered. This proposed definition assures that the definitions used by Minnesota HMOs will be consistent across the board.

Under the current system there is considerable variation between the definitions of medically necessary care used by Minnesota HMOs. This variation, coupled with the lack of common standards and criteria, makes it

almost impossible for consumers to reasonably anticipate which health care services will be determined by an HMO to be medically necessary. For example, Group Health Inc. defines this term to be "diagnostic testing and medical treatment for an injury or illness, which, in the judgment of a GHI physician, will help restore or maintain health . . . ." MedCenters uses the criteria of "generally accepted principles of medical practice . . . performed in the most cost effective manner . . . ." Blue Plus uses the criteria of "generally accepted medical standards." Medica Choice uses several criteria including "consistent with the medical standards of the community" while Medica Primary uses the phrase "consistent with the commonly recognized standards of the medical community." NWNL defines medically necessary to mean "a state that is defined by an M.D. as needing medical care." Mayo Health Plan defines this term to mean "necessary, in the opinion of the Medical Director for treatment, maintenance or improvement of health."

It is clear from the above examples that there is much variation between Minnesota HMOs both in the manner in which this term is defined and in the criteria to be applied by an HMO in determining whether a health care service falls within its definition of medically necessary care. The definition proposed in these rules is intended to provide a uniform definition and identify the criteria to be used by an HMO in determining if a health care service meets the definition of medically necessary care.

This proposed definition identifies three types of medically necessary care: diagnostic testing, health care services appropriate to the enrollee's diagnosis or condition, and preventive services. Diagnostic testing may be

needed in order to diagnose the enrollee's condition. In the written and oral comments submitted in response to the Department's June, 1992 solicitation of opinions regarding this definition, there was general agreement that diagnostic testing is one component of medically necessary care.

The next component of medically necessary care is health care services appropriate to the enrollee's diagnosis or condition. This is consistent with the DHS definition which uses the phrase "consistent with the recipient's diagnosis or condition." We believe that the term "appropriate" is a better choice than the term "consistent." We believe that this is the meaning of "consistent" in this context. As suggested in written and oral comments, we have modified the term "appropriate" by including the phrase "in terms of type, frequency, level, setting and duration." We believe that these are the factors that must be considered when determining what health care services are appropriate to treat the enrollee's diagnosis or condition.

The third component of medically necessary care is preventive services. This is also contained in the DHS definition. There was considerable discussion of the need to include preventive services in this definition at the June 17, 1992 meeting with interested persons. While there was a consensus that HMOs must and do provide preventive services, there was a difference of opinion as to whether preventive services should be included in the definition of medically necessary care. We agree with those persons who believe that it is important for clarity and completeness of the definition to include preventive services as one component of medically necessary care. Preventive services are provided through the criteria stated in Subp.d, to "prevent the possible

onset of a health problem or detect an incipient problem." The type and frequency of preventive services must also be provided according to the criteria of Subp. a, consistent with generally accepted principles of practice.

Subp. a. of the proposed definition modifies all three components, namely, diagnostic testing, health care services and preventive services. The initial definition required that the care "either meet or exceed accepted standards of medical practice of the provider's peers." This phrase generated extensive discussion and comments from interested persons. At the June 17, 1992 meeting the suggestion was made that the phrase "generally accepted principles of practice" be substituted for the phrase "accepted standards of practice."

Accepted standards of practice refers to the type and level of care that is commonly provided in the community for a specific diagnosis or condition, e.g. the level of care that may be cited as a defense against a medical malpractice claim. Generally accepted principles of practice refers to a standard of care that may differ from what is actually being provided in the community. Principles of practice are recognized as goals to which health care providers should strive. The position of this agency is that HMOs and their participating providers should strive to modify their practices with the goal of conforming to generally accepted principles of practice to the greatest extent possible. Therefore, we believe that the definition of medically necessary care should adopt the phrase principles of practice rather than standards of practice.

In situations in which accepted standards of practice deviate from accepted principles of practice, the proposed definition would require the HMO to follow practice principles. For example, use of mammography to screen for breast cancer is not actually done as frequently as the accepted principles of practice dictate. On the other hand, tests may be performed more frequently than accepted principles of practice would dictate. In these examples, the accepted standards of practice differ from the accepted principles of practice. We believe that better health care will be provided if principles of practice are followed.

By replacing the phrase "accepted standards of practice", the Department was also able to delete the phrase "meet or exceed" which was contained in the original draft definition. The purpose of this phrase was to encourage Minnesota HMOs to strive to provide health care services that exceed accepted standards, which were looked at as the minimum or floor. We believe that the use of the term "principles" accomplishes this goal so that "meet or exceed" is no longer needed in the definition.

The rest of Subp. a. is adapted from language in the Minnesota Utilization Review Act of 1992, Sec. 6, Subd. 3.(f) (Minn. Laws 1992, Ch. 574). Rather than using the phrase "provider's peers" as originally proposed, we believe that this proposed language is a more reasonable way to identify peers. There was much discussion of the difficulty of defining peers at the June 17, 1992 meeting. It was pointed out that certain health conditions can be managed or treated by providers in different fields of practice, who could all be considered peers under certain circumstances. For example, heart disease can

be treated by surgery or by medication, diet and exercise. Therefore, cardiologists and cardiac surgeons may be considered peers under certain circumstances. The Department believes that this proposed definition provides an excellent way to identify peers without being unnecessarily rigid.

We have modified the language of the UR law, which is limited to "physicians" in the same or similar general specialty, to include "health care providers" in the same or similar general specialty. This change was made in recognition of the fact that HMOs provide health care services through providers other than physicians. These providers must also be held to the generally accepted principles of practice of their peers.

Subp. a. provides criteria that apply to all three components of medically necessary care. If the service meets the criteria of Subp. a., it must then meet the criteria of either Subp. b., c., or d. As explained earlier, Subp. d. applies to preventive services. All other services must therefore be provided in accordance with Subp. b. or c., either to restore or maintain health or prevent deterioration of a condition.

Subp. b. and c. generated considerable discussion and comments at the June 17 meeting. There was general agreement that services required to restore health are necessary and must be provided. There was less agreement concerning services provided to maintain health or to prevent deterioration.

HMOs raised objections about including the criteria of "help . . . maintain the enrollee's health." Specifically, they feared that they might be forced

to continue to provide therapies and other services needed to maintain the person whose condition has stabilized and is not expected to further improve. Examples cited were physical and other therapies for nursing home residents and therapies provided at home which a family member could be trained to provide.

We agree with those who believe that this rule section may be used by enrollees to obtain health care services needed to maintain their health status after their condition has stabilized. However, we disagree with those who believe that these maintenance services are never medically necessary and that HMOs should never be required to provide maintenance services. These rules are proposed to regulate "health maintenance organizations." Health maintenance organizations are organized and operated to provide "comprehensive health maintenance services . . . without regard to the frequency or extent of services furnished to any particular enrollee." Minn. Stat. 62D.02, Subd. 4. Comprehensive health maintenance services means "a set of comprehensive health services which the enrollees might reasonably require to be maintained in good health." Minn. Stat. 62D.02, Subd. 7. It is clear from the governing statute that HMOs are expected and required to provide services needed to maintain their enrollees in good health. The proposed definition of medically necessary care is consistent with this statutory requirement.

The original language included the phrase "prevent deterioration of the enrollee's physical or mental health." There was much concern that enrollees would demand services, such as cosmetic surgery not otherwise covered, based

on perceived deterioration of their mental health if the surgery was not provided. We have revised this language to specify that the service must be needed to prevent deterioration of the "condition" being treated, not the general health of the enrollee. We believe that this change responds to the concerns raised by some HMOs while not changing the underlying purpose of this section.

We would also like to acknowledge the strong support the proposed definition received from several interested persons and organizations, both at the June 17 meeting and in written comments. We believe that the definition, as proposed and as revised, strikes a fair balance between consumer needs and the needs of HMOs to be fiscally responsible while providing health care services. We do not believe that this proposed definition will require HMOs to provide unnecessary services. We agree that HMOs may be required, in specific cases, to provide some services that they have not provided in the past, such as maintenance therapies to certain enrollees under certain circumstances. However, we believe that these services should be provided and this definition will help clarify this requirement.

Several HMOs suggested that the proposed definition also include the criteria that the service "be provided in the least invasive manner for the treatment of the condition" and "be performed in the most cost effective setting appropriate for the condition." Other interested persons strongly objected to each of these suggestions. The Department also objects to these suggestions. We do not believe that either of these suggestions belong in an operational definition of the term "medically necessary care." The decision as to whether

the least invasive manner is appropriate must be made by the enrollee and the treating health professional. It would be totally inappropriate to define "medically necessary care" to always be the least invasive option. Likewise, the choice of setting is a coverage issue and not appropriate for inclusion in the definition of the term "medically necessary care." While these are valid considerations for an HMO, they are not appropriate criteria for the Department to include in its proposed definition.

Some definitions of medically necessary care include the requirement that care be proven and effective in order to be considered medically necessary. The Department believes that the concept of proven and effective is incorporated into the criteria of "accepted principles of practice" and need not be separately identified.

It is important to point out that medically necessary care must be provided and paid for by an HMO only if it is a covered service under the enrollee's benefit contract or certificate of coverage. It is possible that certain items or health care services may be determined to be medically necessary according to this proposed definition yet not be covered in the contract. For example, disposable medical supplies are clearly medically necessary to treat diabetes, yet they are routinely excluded from coverage. This definition cannot be used to require an HMO to cover health care that is excluded by the benefit contract. Minn. Stat. 62D allows HMOs to limit or exclude from coverage many health care services and items that may be determined to be medically necessary. Therefore, it is important to remember that this proposed definition will apply only to health care that is potentially covered

under the enrollee's benefit contract.

PRIMARY CARE PHYSICIAN. It is necessary to distinguish the primary care physician from specialty physicians for purposes of the proposed rules.

The proposed definition is reasonable in that it is consistent with common usage in the health care community in Minnesota and nationally. For example, Medica Primary defines "Primary Care Office" to mean "an individual or group of Medica Primary Physicians which a member has selected for the provision or coordination of all health services covered under the contract, whose practice predominantly includes pediatrics, internal medicine, obstetrics/gynecology, or family or general practice . . . " Physicians in general practice, as well as physicians who specialize in family practice, obstetrics, pediatrics and internal medicine, are generally considered to fall within the definition of primary care physician. This definition is not intended to imply that physicians who practice in these areas are not specialists in their chosen fields of practice. Rather, the purpose of this definition is to identify physicians who are expected to provide the primary care function of coordination of care and referral to other areas of specialty for HMO enrollees, in addition to providing care within their own area of expertise.

"Primary care physician" is similarly defined in rules and regulations of the Pennsylvania Department of Health (28 PA. Code Ch. 9) §9.2, Alabama State Board of Health (Chapter 420-5-6) (3)(p), and the Michigan Department of Health and Insurance Bureau, R 325.6125 Rule 125 (f).

The definition of primary care physician elicited some comments when the draft proposed rules were sent out for informal comment in April, 1991. We have carefully considered all of the comments and made some changes in response to these comments. For example, the proposed definition no longer requires board certification or board eligibility as did the April, 1991 draft. This change was made in response to comments that as many as 40 percent of Minnesota physicians are not board certified or board eligible, and this requirement would adversely affect the ability of HMOs to contract with primary care physicians. The Department believes that the proposed definition is reasonable and accurately reflects the practice areas of physicians, both in Minnesota and nationally, who provide primary care services.

SPECIALTY PHYSICIAN. The purpose of this definition is to distinguish the specialty physician from the primary care physician. The specialty physician is not required to supervise, coordinate or provide continuity of care for HMO enrollees as is the primary care physician. The specialty physician is required to provide specialized medical care consistent with the area of medical expertise.

The proposed definition is consistent with common and accepted medical practice in Minnesota. The areas of practice identified in the definition of primary care physician are the areas that commonly provide routine care and coordinate medical care. All other areas of medical specialty are not considered to commonly provide routine care nor to coordinate care. Therefore, all areas of specialty not identified in the definition of primary care physician are considered to be specialty physicians. This is a

reasonable distinction and easily understood. The proposed definition is consistent with definitions contained in regulations of the Texas Department of Health (Tex. Admin. Code 119.1) and rules of the Michigan Department of Public Health (Mich. Admin. Code r.325.6635).

REFERRAL. The proposed definition clarifies an area that has been confusing to HMO enrollees, and sometimes to HMO administrators and providers. The definition specifies that referrals must be in writing. The purpose of requiring written referrals is to avoid confusion and misunderstanding between enrollees, providers and administrators as to what exactly has been authorized. Without a written referral, the enrollee may not understand what services the HMO intends to cover, and the referral provider is not sure what services he or she is expected to provider for the enrollee. By requiring written referrals, unnecessary confusion should be avoided.

The proposed definition follows accepted medical practice by listing the various reasons for which enrollees may be given referrals. The definition is specific, clear and easily understood.

GENERAL STATEMENT OF NEED AND REASONABLENESS - AVAILABILITY AND ACCESSIBILITY

The rules governing availability and accessibility currently in effect are very brief. They provide little detailed information to an applicant or operating HMO about how it must ensure that health care services are both available and accessible. They do not provide the commissioner with standards to measure an HMO's compliance with the statutory requirements to ensure availability and accessibility of services. The proposed rules incorporate the provisions of the current rules while providing greater detail. In addition, some of the proposed additions and revisions have been prompted by problems that were not anticipated when the current rules were adopted. Rather than amending the current rules, the commissioner determined that it would be preferable in terms of clarity and understanding to repeal the current rules and replace them with new rules governing availability and accessibility of services.

In addition to the specific authority to adopt rules provided by Minn. Stat. 62D.20, authority to adopt rules regarding availability and accessibility is implied in other provisions of state law. Section 62D.04, Subd. 1 (a) requires an applicant for an HMO certificate of authority to demonstrate the willingness and ability "to assure that health care services will be provided in such a manner as to enhance and assure both the availability and accessibility of adequate personnel and facilities." Section 62D.04, Subd. 1 (c) requires applicants to have a procedure to "develop, compile, evaluate, and report statistics relating to the . . . availability and accessibility of its services. . ." Finally, 62D.04, Subd. 4 requires that an HMO, once

granted a certificate of authority, must continue to operate in compliance with the standards set forth in Subd. 1. The proposed rules regarding availability and accessibility implement the statutory standards of 62D.04, Subd. 1. They specify in detail the manner in which an HMO is expected to assure that health care services will be both available and accessible as required by state law.

In addition to the statutory authority allowing the Commissioner to adopt rules, there are several policy reasons for adopting rules dealing with accessibility of services. HMOs are fundamentally different from the traditional fee-for-service insurance plans regulated by the Commerce Department. HMOs do not simply pay for health care services, but actually control the delivery of such services. A health maintenance organization may be described as an "organization which brings together a comprehensive range of medical services in a single organization to assure a patient of convenient access to health care services. It furnishes needed services for a prepaid fixed fee paid by or on behalf of the enrollees." (Health Maintenance Organization Model Act, National Association of Insurance Commissioners, July 1989.) HMOs have two key features which distinguish them from fee-for-service plans: 1) health care providers often hold some financial risk for the cost of health care services they deliver, and 2) enrollees are restricted in their choice of provider. Both features have the potential for affecting the availability and accessibility of health care services.

1. Provider Risk-Sharing: There has been increasing concern among health care professionals about how payment arrangements may influence the

accessibility and availability of professional health care services. To date, there have been no conclusive studies on the effect of provider payment systems. However, some analysts suggest that in HMO systems, reimbursement arrangements may lead to underutilization of services. In a fee-for-service system, an insurer pays claims submitted for services delivered to an insured. The only issue is whether or not a service is a covered benefit. Because the provider will be paid for any covered service provided, there is no incentive for the provider to limit or deny services he or she thinks the insured may need. Quality of care is compromised to the extent that there may be incentives to provide unnecessary services. On the other hand, "HMOs with their capitation payments and contractual obligations to provide services, present a set of economic incentives that depart significantly from those of the conventional fee-for-service medical care system. It might be expected that these incentive differences will result in different approaches to the allocation of medical resources." (Loft, H. "Health Maintenance Organizations and the Rationing of Medical Care." Securing Access to Health Care. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, March 1983.)

Subpart 2.B. of the proposed rules addresses this subject. This subpart deals with the issue of enrollees who are in need of a referral to a specialty physician. Regardless of the particular physician payment plan, the HMO may be called upon to explain its policy of referral procedures and criteria for enrollees with certain medical conditions.

2. Accessibility of Services. Compounding potential problems with provider

risk sharing are the limitations of access to care imposed on enrollees by HMOs. In a fee-for-service system, an insured who is dissatisfied with the care he or she received can simply switch providers. HMOs are relatively closed systems. While some switching of providers may take place, enrollees' choices are limited to providers who are part of the HMO network. Due to these limitations of access, it is important that rules should define more clearly, the services to which an enrollee has access.

The proposed rules provide that health services shall be geographically accessible and available on a timely basis. The Department of Health has received numerous complaints relating to accessibility and availability of services. A number of these complaints will be described in the part by part section of the Statement of Need and Reasonableness. The proposed rules are written to address those issues and to provide more regulatory guidance in this area.

There are several references in the following part by part statement of need and reasonableness to articles, review organizations' standards manuals and guidelines from associations. These references are intended to demonstrate the reasonableness of the requirements proposed in the rules relating to the access and availability of health care services. The proposed rules define the minimum standards of access and availability of health care services. These standards are found repeatedly in HMO literature and statutes and rules.

PART BY PART STATEMENT OF NEED AND REASONABLENESS - AVAILABILITY AND ACCESSIBILITY

Subp. 1. Definitions. It is necessary to define the following terms because they are used in the proposed rules. Using undefined terms can lead to unnecessary confusion and misunderstanding on the part of both HMOs and enrollees.

A. CENTERS OF EXCELLENCE. This term was included in the proposed rules at the suggestion of several HMOs. The suggestion arose in the context of specialty physician services. The HMOs were concerned that the rules governing specialty physician services would preclude referral of enrollees to "centers of excellence" located outside their geographic service areas. The Department agreed with this concern and decided to define the term and include it in the rules governing specialty physician services.

The basic concept of a "center of excellence" is a facility that provides high quality, cost effective care for specific medical or surgical procedures or diagnoses. "Yet another benefit change some companies are introducing entails channeling surgical, oncology, and transplant cases to so-called centers of excellence - medical facilities that perform certain procedures with enough frequency to become expert at them. The centers usually are willing to give insurers or companies better price terms for sending cases their way. . . employers may be willing to send their employees great distances to get care at designated centers of excellence because of the results - patients get

better care, have fewer complications, and incur fewer costs, even when transportation and lodging costs are included." M.R. Traska, "How to untangle health benefit redesign," Business & Health, February, 1989.

In 1988, HCFA's Office of Research and Demonstrations decided to conduct a Participating Heart Bypass Center demonstration to test the feasibility and cost effectiveness of a negotiated package price for coronary artery bypass graft surgery. In November, 1988, HCFA solicited letters of interest nationwide from 744 hospitals and their associated physicians. After completing a detailed review process, four hospitals were selected to participate in the demonstration project. While these hospitals are not designated by HCFA as "centers of excellence" per se, the criteria for assessing and selecting institutions for the demonstration project is quite similar to that used by HMOs, insurers and employers in assessing and selecting centers of excellence. The basic qualification requirements included sufficient volume of coronary artery bypass grafts annually, expertise and commitment of the medical and nursing staff, willingness to receive a single negotiated payment for all services and rigorous utilization review and quality assurance programs. "The principal provider incentives are the potential for an increase in the volume of patients and an enhanced reputation through designation as a Medicare Heart Bypass Center, offering coordination of service delivery and benefit administration. Cost efficiencies that can be realized through coordination of services and increased volume should allow participating institutions to provide the procedure at a discounted price." Medicare Participating Heart Bypass Center Demonstration, Project Summary, p.O-2.

The Department believes that the definition of centers of excellence in the proposed rules is consistent with common usage in the medical community and the literature. As such the definition is reasonable and should be adopted.

B. Service Area. This proposed definition is consistent with common usage. An HMO is approved by the Commissioner to market its products in designated geographic locations in Minnesota. These locations will be defined by political subdivisions so as to be clear and unambiguous. The proposed rule would require an applicant for a certificate of authority, or an HMO seeking to expand its approved service area pursuant to Minn. Stat. 62D.03, to demonstrate that health services are available and accessible in the areas in which it intends to market its products.

The service area is not necessarily identical to the areas in which an HMO may have contracts or other arrangements with health care providers. For example, an HMO may have contracts with providers outside of its service area. Similarly, an HMO may enroll individuals who live outside its service area, so long as enrollment is consistent with state law.

The proposed definition is reasonable because it links availability and accessibility to the area in which an HMO markets its services. It will be possible to assess compliance with the rule requirements.

Subp. 2. BASIC SERVICES. This section proposes basic staffing requirements that all HMOs must satisfy. The fundamental concept behind this rule

provision is that an HMO will be responsible to employ or contract with sufficient professional and support staff to enable it to fulfill its contractual agreements with its enrollees and the statutory requirements of 62D.04, Subd. 1. The proposed rule requires an HMO to determine its staffing needs based on the projected needs of its enrollees for covered services. This rule allows each HMO to adjust its staffing pattern in accordance with its projected needs. For example, an HMO that has a higher than average population of young families will need to employ or contract with a higher than average number of pediatricians and obstetrician-gynecologists. Similarly, an HMO with a large population of senior citizens will need a proportionately high number of physicians and other providers who specialize in geriatric care. The Department believes that it is reasonable to require each HMO to project its enrollment and provide staff in accordance with the projected needs of its enrollees. This allows the rule to accommodate differences in enrollment patterns among the several Minnesota HMOs governed by the rule.

Some states mandate a specific physician to enrollee ratio that all HMOs must follow. The Department has rejected this method because of some inherent problems. A specific ratio is reasonable for a pure staff model HMO that accepts only HMO patients. However, this approach is unrealistic and administratively difficult for both IPA (independent practice association) model HMOs where contracted providers have both HMO and non HMO patients and for mixed model HMOs which have partial staff model and partial contract providers. It is virtually meaningless to have a ratio of physician to enrollees if an unknown percentage of patients are not HMO enrollees.

Therefore, the Department believes it is more meaningful and realistic to require each HMO to project its staffing needs rather than follow a ratio.

This proposed rule section is very similar to rules and regulations governing HMOs in other states. Pennsylvania provides that "A health maintenance organization shall have and maintain adequate arrangements, such as written contracts, to provide the health service contracted for by its subscribers. A health maintenance organization shall have available sufficient personnel to meet the standards set forth in this chapter and its contractual obligations." 28 PA. Code. Ch.9, §9.75 Assurance of access to care. Florida requires "Maintenance of a professional staff or arrangements with providers, duly licensed as required to practice in Florida, sufficient to meet the health needs of the HMO or PHC membership in accordance with accepted professional practice." Fla. Admin. Code Ann. r.10D.100.006 Quality of Care. Rhode Island requires "the provision of appropriate personnel, physical resources and equipment to meet the contractual agreements with enrollees for the provision of health care services." Rules and Regulations for the Assessment of Health Care Services of Health Maintenance Organizations, R27-41-HMO, Department of Health (1985), Section 7.1 (c). Alabama requires that "A health maintenance organization shall have available sufficient personnel to meet the standards set forth in this Chapter and its contractual obligations." Rules of the Alabama State Board of Health, Division of Licensure and Certification, Ch. 420-5-6, (1987). Michigan provides that "A health maintenance organization shall assure the maintenance of professional staff sufficient to meet the needs of its membership." Mich. Admin. Code r.325.6635 (1988).

The proposed rule requires an HMO to develop written standards or guidelines regarding assessment of the capacity of its providers to provide timely access for enrollees in need of medical care. This provision is suggested by NAHMOR in its HMO Curriculum Workbook. It is intended to address the potential problem of HMO providers who cannot accept additional patients. Access to care will be seriously affected if an HMO's providers cannot accept new patients. In fact, the Department has become aware of this problem on occasion through complaints filed by HMO enrollees. Even though the HMO had contracts with providers of specialized services, none of the providers in the enrollee's area were accepting new patients. Thus the enrollee was forced to use a provider much further away. This proposed rule would require the HMO to monitor the capacity of its providers, through written standards or guidelines developed by each HMO, to provide timely access, thus identifying potential problems and providing a remedy.

A. The purpose of this section is to explain the obligation of the HMO to provide primary care physician services. The first requirement is to assure that primary care services (services of general practice, family practice, pediatric, internal medicine or obstetrics/gynecology physicians) are available 24 hours a day, 7 days a week when medically necessary. This rule does not require that the HMO clinic or physician's office be open 24 hours a day, 7 days a week. Primary care physicians would be available in the office or clinic during regular daytime business hours. Primary care physicians would also be available through back up physicians, after hours clinics, answering service and after hours at urgent care facilities or hospital emergency rooms. It is the responsibility of the HMO to assure that primary

care services are available in the appropriate setting when needed by its enrollees. The rule is necessary and reasonable because it recognizes that people get sick or injured at all hours of the day and night, not just during normal daytime business hours. It is reasonable to require an HMO to provide primary care services during all of these hours. This language is similar to language suggested by the NAHMOR Educational Foundation, HMO Curriculum Workbook.

It is reasonable to require the HMO to provide a 24 hour answering service as a required part of primary care services. Use of an answering service is a normal and accepted component of medical practice in Minnesota and nationally. The proposed rule specifies that the time allowed for calling back the enrollee must be based on what is medically appropriate to each situation. This is a reasonable and valid rationale. To implement the rule, the HMO or its contracting primary care physicians would be required to have standards to be used by their answering services so that call backs are made in a medically appropriate time.

This rule is very similar to regulations governing primary care physician services for Texas HMOs. See Tex. Admin. Code, Department of Health, HMO Regulations, 119.5.(a), (1990).

The rule requires HMOs to provide a sufficient number of primary care physicians to meet the projected needs of its enrollees. An alternative method would be to specify a ratio of primary care physicians to enrollees. For example, PA. Code §9.76 (Department of Health) specifies that "a health

maintenance organization shall have at least the equivalent of one full-time primary care physician per 1600 members." The Department has considered this approach and has determined that, for the reasons explained on page 29 pertaining to Subp. 2 Basic Services, it is not the best method of assuring a sufficient number of primary care physicians. Therefore, the Department has chosen not to specify a ratio in the proposed rules.

Furthermore, the Department believes that it is more appropriate to require an HMO to provide primary care physicians in accordance with the projected needs of its enrollees rather than with some mathematical ratio. This approach allows each HMO to contract with or employ physicians to meet its needs, not to satisfy some fixed formula.

The key to this rule provision is that the HMO is responsible to provide a "sufficient" number of primary care physicians. The burden is on each HMO to develop written standards or guidelines which address the assessment of provider capacity. These written standards or guidelines shall both project its needs and enable provision of an appropriate number of primary care physicians consistent with those needs. If the needs change, the HMO must adjust the number of primary care physicians accordingly. The needs could be provided by staff providers, contracted providers or a combination of both.

The rule provides that some, but not all, primary care physicians must have admitting privileges at general hospitals within the HMO's service area. This provision is reasonable because it is not necessary for every primary care physician to have hospital admitting privileges. In fact, some physicians do

not treat patients in the hospital and therefore do not seek admitting privileges. Each HMO has procedures that enable an enrollee to be admitted to a hospital if his primary care physician does not have admitting privileges. Therefore, access to inpatient hospital care should not be an issue. This is consistent with regulations governing Texas HMOs. See Tex. Admin. Code, HMO Regulations, 119.5.(a), 1990.

B. The purpose of this section is to explain the obligation of the HMO to provide the services of specialty physicians. The basic premise is that the HMO is required to provide those specialty physicians that are needed in order for the HMO to provide covered medical services to its enrollees. Each HMO must determine what covered medical services require the services of specialty physicians as opposed to primary care physicians. This provision is reasonable because it recognizes that HMO contracts vary in the health services covered; therefore, the need for specialty physicians also varies. The determination of which services require the use of specialty physicians is a medical decision based on generally accepted principles of practice in the community.

The proposed rule distinguishes between specialty physician services to which enrollees have continued access and those to which enrollees do not have continued access. The distinction is based on the purpose of the service and the number of visits allowed or anticipated. If enrollees are referred for one visit, as for consultation or a second opinion, this would not be considered as continued access. If enrollees are referred for several visits or a series of treatments, this would be considered as continued access. The

rule requirements for the availability and accessibility of specialty physician services to which enrollees have continued access is identical to that for primary care physician services in Subp. A.

Specialized physician services to which enrollees do not have continued access can be provided either by providers under contract with the HMO, or by other arrangements made by the HMO. These services can be treated differently because it is anticipated that they will not be needed as often and the HMO should be allowed to make arrangements for these services when they are needed. It is not reasonable to require an HMO to contract for all possible specialty physician services so long as it can arrange for appropriate services to be available when needed.

As with Subp. A, the proposed rule requires that some specialty physicians have admitting privileges to assure that enrollees can be admitted to hospitals when necessary. Unlike Subp. A, this section does not require that specialty physicians have admitting privileges specifically in the HMO's service area. Rather, the rule recognizes that specialty physicians may admit patients to certain hospitals that may not be located in the HMO's service area. This is a reasonable provision as it recognizes and is consistent with generally accepted principles of practice in Minnesota. The basic purpose of this provision is to assure that enrollees can be admitted to a hospital on a timely basis when necessary and the proposed rule carries out this purpose.

This rule is similar to rule provisions in other states. See, Tex. Admin. Code, Department of Health, Health Maintenance Organizations Regulations,

119.5(b) (1990); Pennsylvania Department of Health, 28 PA. Code Ch. 9, Section 9.75 (d) (1983); Mich. Admin. Code R. 325.6635 Rule 635 (2) (1988).

C. The purpose of this rule section is to address the availability of inpatient hospital services for HMO enrollees. The proposed rule recognizes a distinction between general hospitals and specialized hospitals. This is consistent with Minn. Rule 4640, Hospital Licensing and Operation. The terms "general hospital" and specialized hospital" are defined in Rule 4640. The proposed rule requires an HMO to arrange for general hospital services to be available 24 hours a day, 7 days a week because enrollees can be expected to require these services at all hours of the day or night. The rule also requires an HMO to make appropriate arrangements so that specialized hospital services are available as needed for its enrollees. This is reasonable because specialized hospital services would be provided on referral and would be arranged by the HMO in advance. It would not be necessary or reasonable to require an HMO to have specialized hospital services available 24 hours a day, 7 days a week.

D. The purpose of this rule section is to specify the HMO's responsibility to provide ancillary services consistent with the projected needs of its enrollees. By definition, ancillary services encompasses several disciplines and areas of health practice. Each HMO is in the best position to assess the expected needs of its enrollees for these various health services. Needs will vary based on the age and other characteristics of its enrolled population. It is reasonable to require each HMO to project its need for each ancillary service it covers and arrange for a sufficient number of providers to satisfy

these needs.

E. The purpose of this rule section is to specify the HMO's responsibility to provide outpatient mental health and chemical dependency services. It is necessary to address the provision of outpatient mental health and chemical dependency services in the rule because this has been an area that has generated many complaints to the Department from enrollees. The proposed rule therefore contains specific requirements intended to eliminate confusion about the nature and scope of mental health and chemical dependency services to be provided.

As with all other health services it provides, this rule section requires each HMO to provide mental health and chemical dependency services sufficient to meet the projected needs of its enrollees. It is reasonable to require the HMO to project the needs of its enrollees, based on their age and other characteristics. Rather than specify a ratio of providers to enrollees, it is more reasonable to allow each HMO to provide these services in accordance with the projected needs of its specific enrollee population. Such needs are proposed to be consistent with generally accepted principles of practice with the understanding that professionals other than physicians often are providers of mental health and chemical dependency services.

The proposed rule requires HMOs to use outpatient chemical dependency programs that are licensed by the Minnesota Department of Human Services. This agency has licensing rules which contain specific requirements governing staff, records, supervision and other aspects of services provided. It is reasonable

to rely on the expertise of the Department of Human Services in determining what is an acceptable outpatient treatment program. If the proposed rule is adopted, an HMO will only be allowed to use licensed treatment programs for outpatient chemical dependency treatment. The Department believes that virtually all HMO enrollees are currently referred to licensed programs so there should be virtually no impact on actual practice. However, even if there is an impact on actual practice, we believe that it is very important that HMO enrollees be referred to providers who are qualified by virtue of the licensing rules to provide quality services.

Chemically dependent adolescents have special needs and treatment requirements that are addressed in rules of the Minnesota Department of Human Services. The proposed rules would require HMOs to comply with these special requirements in providing outpatient chemical dependency treatment to adolescent enrollees. Again we believe that it is appropriate to rely on the expertise of this agency in determining the adequacy of services and treatment programs for chemically dependent adolescent enrollees.

The proposed rules would require HMOs to use only licensed providers to provide outpatient mental health services. The five professionals listed in the rules are each licensed by their respective licensing boards. The mental health centers and mental health clinics are licensed by the Department of Human Services. We believe that use of licensed providers is an appropriate quality control tool. Licensing boards have minimum standards governing provider education, training and experience, and also have the authority to impose sanctions for violations of the licensing rules. We believe that

requiring HMOs to use only licensed providers of outpatient mental health services will not unduly limit their access to providers while enhancing the quality and professionalism of the services provided to enrollees.

The proposed rule requires that culturally specific or appropriate services be provided to enrollees. This provision is based on provisions of Department of Human Services rules (Minn. Rule 9530.6650) governing chemical dependency care for public assistance recipients. This rule acknowledges that effectiveness of treatment can be dependent on referral to a culturally appropriate provider. This is true for HMO enrollees in general as well as for public assistance recipients.

F. The purpose of this rule section is to clarify the responsibility of the HMO to provide emergency services to its enrollees. Emergency services must be covered 24 hours a day, 7 days a week (Minn. Rule 4685.0700). The proposed rule recognizes that, within its service area, an HMO has a number of ways to make emergency services available and accessible to its enrollees. During normal business hours, an HMO can provide some emergency services at its clinics or through its participating providers at their offices. An HMO also can make emergency services available by contracting with general hospitals so that its enrollees can obtain services at hospital emergency rooms. An HMO may also make emergency services available at after hours clinics and urgent care facilities, either owned by the HMO or under contract. An HMO can also make emergency services available and accessible by paying for services provided by a non-participating provider under emergency circumstances, e.g., a hospital emergency room with which the HMO does not have a contract.

G. The purpose of this provision of the rules is to specify the responsibility of the HMO to assist an enrollee in choosing a new provider if a specific provider refuses to continue to accept this enrollee as a patient. The Department has had complaints from enrollees who were refused appointments for health services by a provider. One reason for refusal is because the enrollee had unpaid bills to that provider dating from before enrollment in the HMO. Of course the HMO is not responsible for paying these prior unpaid bills. However, once the individual is enrolled in the HMO, health care services must be available and readily accessible to that individual. If the provider to whom the bills are owed refuses to provide any additional services, the rule designates the HMO as the party responsible for providing information to assist the enrollee in choosing a new provider.

The Department believes that this is reasonable and proper. It would be outside the scope of ordinary responsibility to require the provider who is refusing services to make alternative arrangements for an HMO enrollee. It is the HMO that has a network of providers and that is in the best position to provide this information to the enrollee.

H. The purpose of this provision is to require the HMO to implement a system that will, to the greatest possible extent, assure that routine referrals are made to HMO participating providers rather than to providers that are not part of the HMO network.

When enrollees are referred for specific services, it is natural for them to assume that the referral is to a participating provider for whom coverage will

be provided. In fact, enrollees rely on their physicians and other providers to given them referrals to participating providers unless otherwise specified. The Department has handled several complaints from enrollees who were told that the referral would be paid for by the HMO, only to find out after the fact that the provider was not part of the HMO and the services therefore were not covered. This result is very unfair to HMO enrollees and leads to dissatisfaction with the entire HMO system. The proposed rule would clarify that an enrollee cannot be held liable for referrals to the wrong provider. The proposed rule requires the HMO to implement its own system to address this problem.

Subp. 3. GEOGRAPHIC ACCESSIBILITY. The purpose of this rule section is to specify the meaning of geographic accessibility of HMO services. When applying for a certificate of authority to operate as an HMO, an entity is required to include a "statement reasonably describing the geographic area or areas to be served." Minn. Stat. §62D.03 Subd. 4(m). Before issuing a certificate of authority to an applicant, the commissioner of health shall determine "whether the applicant. . . demonstrated the willingness and potential ability to assure that health care services will be provided in such a manner as to enhance and assure both the availability and accessibility of adequate personnel and facilities." Minn. Stat. §62D.04 Subd. 1(a). In making this determination, the commissioner of health takes into consideration how far or how long potential enrollees may be required to travel in order to access health services within the proposed service area. Similarly, availability and accessibility of services is evaluated when an HMO applies to expand its service area. In addition, once it is granted a certificate of authority to operate as an HMO, the organization must continue to operate in compliance with the standards set forth in 62D.04 Subd. 1, including continued availability and accessibility of adequate personnel and facilities.

The question then becomes, what standards does the commissioner of health use in determining if services are available and accessible in a proposed or existing geographic area? The proposed rule sets some reasonable standards. The commissioner will look at maximum travel distance or time within the HMO's geographic services area to the nearest provider of primary or specialty care. In the past, the Department has followed the so-called "30 minute/30 mile standard" in approving HMO service areas. An HMO enrollee or potential

enrollee would be required to travel no more than 30 minutes or 30 miles to obtain primary care and general hospital services. The proposed rule codifies this long-standing policy with a minor change. The proposed rule would require that enrollees could not be required to travel more than 30 miles or 30 minutes, whichever is less, to obtain primary care services. This change is being proposed as a method of enhancing accessibility and availability of services.

Some examples may help clarify the rationale for this rule provision. In the Twin Cities area, where most HMOs are located, the distance between most cities is 30 miles or less. For example, it is no more than 30 miles between Coon Rapids and Apple Valley or between Cottage Grove and Plymouth. However, during normal business hours, when most primary care services are provided at clinics and physicians' offices, it would usually take more than 30 minutes to drive these distances. It is the position of this agency that it would be unfair to allow HMOs to force enrollees to travel more than 30 minutes to reach primary care providers. By specifying that the travel distance or time must be "the lesser of" 30 miles or 30 minutes, enrollees will be protected from being forced to travel more than 30 minutes to reach primary care providers. Of course, the rule does not prohibit enrollees from choosing providers who are more than 30 minutes travel time away, but the choice must be the enrollee's, not the HMO's.

In 1989 the Minnesota Department of Health published a report entitled "Access to Hospital Services in Rural Minnesota." This report was prepared for the Minnesota Legislature pursuant to 1988 Minn. Laws, Chapter 689, Art. 1,

Section 255. The purpose of this report was to examine the financial condition of Minnesota's small, rural hospitals, and to explore the impact of potential hospital closures on access to hospital services in rural areas. The report analyzes access to hospitals within 30 to 45 minute travel times. "The federal health planning program in the mid-1970s relied on an informal standard of 30 minutes maximum travel time to judge the adequacy of access to acute care hospital services. While hospitals, health care delivery, and rural demographic trends have undergone significant changes since that time, a panel of rural health care experts consulted for this study generally believed that this standard is still relevant: that residents of rural areas should be able to access a hospital within 30 to 45 minutes travel time. . . Assuming an average travel speed of 50 miles per hour, we plotted 30 minute and 45 minute time circles around every hospital in Minnesota. . . The 30 minute travel time analysis reveals nine Minnesota counties which have sizeable pockets of inadequate access to a hospital. These counties, all in the northern part of the state, are Aitkin, Beltrami, Cass, Cook, Itasca, Koochiching, Lake, Lake of the Woods, and St. Louis counties. . . we can estimate that there are roughly 19,000 Minnesotans (0.4% of the state's population) living in the identified areas of inadequate access." pp. 30-33. Based on this report, we can estimate that approximately 99% of the state's population lives within 30 minutes travel time of a hospital.

The proposed rule is also consistent with rules in other states governing average travel times to obtain primary care services and general hospital services. "The travel time from the health maintenance organization's geographic service area boundary to the nearest primary care delivery site and

to the nearest institutional service site shall be approximately 30 minutes. The Department may waive this requirement as to why the 30 minute travel time is not feasible in a particular geographic area." Ala. Admin. Code r.420-5-6.06 (15) (1987). "Average travel time from the HMO or PHC geographic services area boundary to the nearest primary care delivery site or to the nearest institutional service site of no longer than 30 minutes under normal circumstances." Fla. Admin. Code Ann. r.10D.100.006 (2)(a) (1988). California provides guidelines regarding geographic accessibility. "All enrollees have a residence or workplace within 30 minutes or 15 miles of a contracting or plan-operated primary care provider..." Cal. Admin. Code 1300.51 H. (1985).

There seems to be some agreement that it is reasonable that primary care services, both inpatient and outpatient, be available to an enrollee within 30 minutes travel time under normal circumstances. The proposed rule would require each HMO to market its services accordingly. This is consistent with guidelines issued by the Metropolitan Council in its 1986-1988 Health Services Plan for the Twin Cities Metro Area. "Guideline 6: Acute care services should be convenient to the population served. Every resident should be able to obtain general short-term acute services within 30 minutes normal travel time."

The proposed rule requires that all health services other than primary services be available within 60 minutes/60 miles of the HMO's geographic services boundary. This has been the standard recommended by the Department in the past. The Department has recognized the distinction between primary

and specialty care in terms of availability. The Department believes that enrollees generally accept that they may need to travel further to obtain specialized medical and health services than to obtain primary care services. There are many different areas of medical specialty. A partial list includes allergy, anesthesiology, dermatology, cardiology, neonatology, neurology, oncology, ophthalmology, pathology, psychiatry, radiology, surgeries, otolaryngology, and urology. Ancillary services include speech therapy, physical therapy, occupational therapy, audiology, laboratory, pharmacy and durable equipment. It would be unrealistic to expect an HMO to provide all specialty services within 30 minutes/30 miles of every enrollee. While some specialty services will probably be available within 30 minutes/30 miles, or less, it is more reasonable to require that all specialty services be available within 60 minutes/60 miles, which is a more realistic time period.

The proposed rule authorizes the Commissioner to allow exceptions from the 30 and 60 minute access standards if these standards are not feasible in a specific geographic location in Minnesota. The rules put the burden on the HMO requesting the exception to sufficiently justify its request. It is the policy of this department that exceptions to rule provisions and standards should be discouraged to the greatest possible extent. Therefore, an exception will only be granted for good cause and if adequately justified. It is reasonable to allow for the possibility of exceptions in the area of geographic access. There are some parts of Minnesota that have a shortage of physicians, either primary care or specialists or both, as well as providers of ancillary services. Therefore, HMO enrollees who live in these areas have no choice but to travel further to obtain necessary care. These rules are

necessary and reasonable as they are based on the reality of physician and other health care provider availability in this state.

The proposed rule exempts centers of excellence from the time and mileage requirements of Subp.3 A. and B. By definition, a center of excellence may be located either within or outside an HMO's area of service. There may be only one or two facilities that provide certain specific health services or procedures in Minnesota. Therefore, it would make no sense to require an HMO to refer only to centers of excellence that are located within 60 miles or 60 minutes of their geographic service area boundary. It is necessary and reasonable to specifically exempt centers of excellence from the general geographic accessibility rule provision so that there is no future confusion on this point.

Subp. 4. EXCEPTIONS FOR ACCESS TO CARE AND GEOGRAPHIC ACCESSIBILITY. The purpose of this section is to explain the factors that the Commissioner will consider if an HMO requests an exception to the access requirements of this rule. All requests must be supported by specific data that justify the need for an exception. The purpose of treating such requests as filings under state law is to assure that the requests will be considered in accordance with the applicable time limits.

A. The HMO may be able to demonstrate that residents of a specific service area ordinarily travel further than 30 or 60 miles or minutes to obtain health care services. This information by itself is not sufficient to justify an exception to the geographic access requirements. The purpose of requiring advance approval of an HMO's service area is to ensure that health services will be readily available and accessible in this area. If they will not be readily available and accessible, it may be reasonable to deny the HMO the approval to market in this area. However, the Commissioner recognizes that there are some areas of Minnesota in which health care providers simply are not available, either through an HMO or fee for service. There also may be specific health services for which residents routinely choose to travel beyond these limits. For example, residents in the St. Cloud area often travel to the Twin Cities to obtain certain specialized care even though it is more than 60 miles or minutes away. It is reasonable for the Commissioner to consider utilization patterns of the existing health care delivery system when an HMO requests an exception to the geographic access rules.

When an HMO proposes providing services in a new service area, it is

reasonable for the HMO to project utilization patterns of its potential enrollees. The HMO needs to make these projections in order to determine if it can provide required services in this location. This information should be available to the Commissioner in determining if an exception to the geographic access requirements is warranted. For example, an HMO may be able to provide reasonable projections which show that certain health care services will not be widely needed and therefore need not be available within 60 miles or minutes of its enrollees.

B. The Commissioner recognizes that sometimes an HMO cannot employ or contract with providers for certain health care services. For example, there may be one general hospital in the HMO's service area, and that hospital may refuse to contract with the HMO. Similarly, an HMO does not ordinarily contract with nursing homes to provide services to its enrollees. The HMO is providing all other health care services either under contract or through its employees. In these instances, the Commissioner may grant an exception to the geographic access rules if the HMO can demonstrate the ability to pay for these services when needed by its enrollees. Rather than making these services available through contract or through its employees, the HMO may make it available by paying for it as needed.

C. The purpose of this section is to require the HMO to have a system in place to handle referrals to nonparticipating providers when services cannot be provided by participating providers. It is necessary to have a system for transferring information to and from the nonparticipating provider. It is necessary that the enrollee's medical record with the HMO, or with the

referring provider, include a record of services provided by the nonparticipating provider. Necessary information must be shared so that the HMO or the referring provider can continue to coordinate and manage the enrollee's health care services, even when some services are provided by nonparticipating providers. In evaluating a request for an exception to the geographic access rules, it is important that the Commissioner be assured that information on the enrollee's health and treatment will be shared between the HMO and the nonparticipating provider.

The requirement of a system for orderly sharing of information between an HMO and nonparticipating providers is similar to provisions of Fla. Admin. Code Ann. r. 10D.100.006 (1988) and Ala. Admin. Code r. 420-5-6.06 (1987).

Subp. 5. COORDINATION OF CARE. The purpose of this section is to explain the responsibility of an HMO to provide for coordination and continuity of health care for its enrollees.

For purposes of coordination of care, HMOs can be distinguished from fee for service providers and from health care provided under traditional indemnity insurance. Under a non-HMO system, an individual is free to go to any number of health care providers. There is no system in place to coordinate the care received from the various providers. In fact, unless the individual informs the various providers of other services being received, one provider does not know that this person is also being treated by other providers. If the individual goes to more than one pharmacy to obtain prescription drugs, there is every possibility that drugs that are incompatible or even dangerous in

combination may be prescribed. Under this non-HMO system, it is up to the individual to coordinate his health care.

By providing a network of participating providers and clinics, HMOs are in an excellent position to provide for coordination and continuity of health care services for their enrollees. The Department recognizes that there are different models of HMOs and therefore coordination of care may differ in each model. For example, coordination of care will be most easily provided in gatekeeper and staff model HMOs. In the gatekeeper model, all health care is provided by the designated primary care clinic, either directly or by referral to specialty providers. Upon enrollment in the HMO, an enrollee is required to designate a primary care clinic. Basic health services are provided by primary care physicians at the primary care clinic. It is the responsibility of the primary care physicians to act as "gatekeepers" for their patients, e.g. controlling access to specialized and ancillary health services. Coordination of care is an integral component of the gatekeeper model HMO. For example, in its Certificate of Coverage (May 1991), Medica Primary defines Primary Care Office to mean "an individual or group of Medica Primary Physicians which a Member has selected for the provision or coordination of all health services covered under the contract, whose practice predominantly includes pediatrics, internal medicine, obstetrics/gynecology, or family or general practice, and who has entered into a service agreement with Medica Primary to provide primary care health services to members."

The staff model HMO provides services at facilities staffed by its employees, with some additional services being provided under contract, e.g. hospital and

some specialized medical services. Each enrollee has one medical record. Enrollees are either asked or required to designate a primary care physician to supervise and coordinate the enrollee's care. Some specialized and ancillary services require the referral of the primary care physician while others can be self-referred by the enrollee. The staff model HMO is readily able to coordinate the health care of its enrollees by the nature of its structure. For example, one Minnesota staff model HMO informs its enrollees that "your primary care physician coordinates your care with other specialists as medically appropriate. . . Your primary care doctor will communicate with the specialist and discuss your medical needs. . ." Group Health, Inc. Pulse, August 1990.

A third HMO model is the IPA model in which an enrollee is able to receive services from any provider who is part of the association for most types of health care. The IPA model HMO does not require an enrollee to designate a primary care clinic or a primary care physician. There is no centralized medical record and each provider keeps a separate medical record for his or her patients. Some services would require the prior approval of the HMO itself in order for coverage to be provided. In this model, coordination of care is not an integral part of the HMO system.

It is not the intent of the Department to force all Minnesota HMOs to adopt the gatekeeper model. Therefore, this section of the proposed rules is written to recognize that different model HMOs will coordinate care differently for their enrollees. The rule requires each HMO to provide the services of primary care physicians to provide initial and basic care.

Primary care physicians are defined to be physicians either in general practice or who practice in family practice, ob-gyn, internal medicine or pediatrics. The proposed rule therefore requires all HMOs to provide these medical professionals for their enrollees. This is a necessary and reasonable requirement because these are usual medical services that most enrollees will require and will expect to be readily available if needed.

The proposed rule requires primary care physicians to initiate referrals only "in plans in which referrals to specialty care and ancillary services are required." (Emphasis added.) It still remains up to each HMO to determine which services require a referral and which can be self-referred by the enrollee. The proposed rule does not impose any referral requirements nor force all HMOs to adopt the gatekeeper model. When the draft rules were sent out for informal comment in April and September, 1991, several HMOs expressed concern that the intent of this provision was to force all HMOs to adopt the gatekeeper model. We have revised this provision to make it clear that this is not the intent nor the effect of this rule provision. All this provision does is require that referrals required by the HMO should be provided by primary care physicians. This is reasonable and necessary in order to enhance the role of the primary care physician as the coordinator of the enrollee's health care by the HMO. It is also consistent with current practice in Minnesota HMOs where it is customary for the primary care physicians to have referral responsibility.

The proposed rule would allow an enrollee to request that his or her health care be supervised and coordinated by a primary care physician. This

provision would potentially affect services provided by an IPA model HMO where an enrollee may not ordinarily designate a primary care physician. The Department believes that some enrollees in IPA model HMOs may prefer to have their health care coordinated by a physician rather than coordinate their own care. Moreover, sometimes enrollees are forced to change from one HMO model to another when their employer changes health benefits. For example, recently the City of St. Paul moved from a dual choice HMO option offering staff model and IPA model HMOs, to a single choice offering only the IPA model HMO to its employees. A large number of employees had to change from the staff model, in which their care was coordinated by their primary care physician, to the IPA model in which coordination of care is not required. Under the proposed rule, enrollees in an IPA model HMO could request that a primary care physician undertake the responsibility of coordinating their care. While we do not expect a large number of enrollees in IPA model HMOs to request that their health care be supervised and coordinated by a primary care physician, we believe that it is reasonable that this service be available upon request. If this rule provision is adopted, HMOs could address the question of responsibility for the coordination and supervision of care in future contracts with primary care physicians.

The proposed rule also would require supervision and coordination of health care for enrollees who have shown "a pattern of inappropriate utilization of services." It would be the responsibility of the primary care physician to supervise and coordinate care to prevent further inappropriate utilization of services. This rule provision is intended to address enrollees who obtain duplicate services, multiple or duplicate prescriptions and who otherwise use

health services in an unnecessary, wasteful or potentially harmful manner. In order to comply with this rule provision, an HMO would be expected to devise and implement a program that looks for patterns of inappropriate services by enrollees, e.g. duplication of services, multiple visits, duplication of prescriptions, prescriptions that are incompatible, etc. We expect that an HMO would implement a computer program to monitor for inappropriate utilization of services, for example by examining bills submitted by participating providers. We understand that HMOs already monitor for inappropriate utilization of prescription drugs. See, for example, Section XX of PHP #92, "Harmful use of medical services" which applies "when PHP determines [you] are receiving benefits or prescription drugs in a harmful quantity or manner."

This rule provision is necessary and reasonable for both health and economic reasons. It is clearly in the best interests of enrollees to obtain medically appropriate health services and to avoid services that are unnecessary, duplicative, wasteful or even harmful. It is also in the best interests of enrollees and HMOs to avoid paying for services that are not necessary or appropriate. Obtaining unnecessary and duplicative services adds to the already high cost of health care, both in Minnesota and nationally. It is imperative that HMOs, as well as other health care providers and insurers, take reasonable measures to prevent paying for unnecessary services. This rule provision, by allowing an HMO to control access to health care services for certain enrollees who demonstrate a pattern of inappropriate utilization of services, will help control these costs.

The proposed rule would allow an enrollee who is dissatisfied with his primary care physician to change his primary care physician. This is necessary and reasonable because it would not be fair to force an enrollee to obtain basic and initial care, as well as care coordination and supervision, from a physician with whom he is not satisfied. In their comments on this rule provision, the HMOs wanted assurances that enrollees would be allowed to change primary care physicians by following the HMO's own procedures and rules for change. We agree that this is reasonable and amended the draft rule to reflect this requirement. While an HMO cannot prevent an enrollee from changing primary care physicians, it can require the enrollee to follow the HMO's change procedures.

It is important that an HMO have a process that provides for coordination and continuity of care when an enrollee is referred to specialty care. The proposed rule would require an HMO to provide care coordination and continuity for these enrollees. The proposed rule recognizes that it is generally preferable for the primary care physician to assume the responsibility of coordinating care when referrals are made. However, the rule is flexible in that it allows each HMO to implement its own system of providing care coordination and continuity for its enrollees who are referred to specialty care. In some situations, it may be appropriate for a specialty physician to assume the responsibility of care coordination. For example, an enrollee being treated for cancer may have his care coordinated by an oncologist rather than by a primary care physician. The underlying purpose of this rule provision is to assure that, when an enrollee is referred for specialty services, a health care professional will coordinate his care. The rule

specifies that the HMO is responsible for providing this service, either directly or through arrangements with its participating providers.

The coordination of care provision is similar to rules of other states, namely Ala. Admin. Code 420-5-6.06 (Alabama State Board of Health); Fla. Admin. Code Ann. Ch. 10D-100.006 (Florida Department of Health); Rules of Oklahoma State Department of Health, Ch. 52, Section 802; Title 10 N.Y. Comp. Codes R. & Regs. 98.13 (Rules of New York Department of Health); 28 Pa. Code Ch. 9.75 (Rules of Pennsylvania Department of Health). For a discussion of the role of the primary care physician in care coordination, see "And Who Shall be the Gatekeeper? The Role of the Primary Physician in the Health Care Delivery System", Anne R. Somers, Inquiry, Winter 1983.

Subp. 6. TIMELY ACCESS TO HEALTH CARE SERVICES.

The purpose of this rule provision is to specify the responsibility of the HMO to arrange for necessary health care services to be available and accessible in a timely manner. The rule specifies that the HMO can fulfill this responsibility either directly or through its providers. For example, a staff model HMO would be directly responsible to assure that health care services are available at its facilities in a timely manner. Other HMO models would need to assure timely access by having contracts with a sufficient number of providers.

The proposed rule requires covered health care services to be accessible "in accordance with medically appropriate guidelines consistent with generally accepted principles of practice." It is necessary to indicate to HMOs the

standards they are expected to apply in arranging for services to be timely. This rule provision reasonably requires Minnesota HMOs to follow accepted principles of practice. It would not be feasible nor reasonable for this rule to specify exact time limits within which specific health care services must be provided. Rather, by tying HMOs to medically appropriate guidelines based on accepted principles of practice, the rule indicates the parameters within which these services will be considered timely. As accepted principles of practice evolve over time, HMOs would be held to the most current principles of practice.

The proposed rule requires that appointments for health care services be scheduled according to the type of health care service needed. The rule provides some examples of different types of appointments. The rule requires that these appointments be scheduled according to medically appropriate guidelines consistent with generally accepted principles of practice. Rather than establishing appointment schedules in these rules, we require each HMO, either directly or through its providers, to establish its own scheduling guidelines. This rule allows for some differences between HMOs yet requires that all enrollees have services available and accessible within generally accepted parameters.

These rules are similar to regulations of other states, e.g., Fla. Admin. Code Ann. r. 10D.100.006 (1988). Oklahoma State Board of Health, HMO License Rules, Ch. 52, Section 802.

Subp. 7. ACCESS TO EMERGENCY CARE.

The Department has received many complaints from HMO enrollees regarding denials of coverage for emergency care. In investigating and attempting to resolve these complaints, we have determined that there is much confusion and misunderstanding regarding when coverage should be provided and when coverage can reasonably be denied. This rule section is intended to clarify these issues and reduce future conflicts between HMOs and their enrollees over coverage for emergency care.

It should be noted that these rule provisions apply only to emergency care that is not provided at the direction of the HMO. If the enrollee has first contacted the HMO, or an authorized provider, and emergency care has been authorized, there is no dispute over coverage of the care.

A. This is intended to implement the statutory requirement of Minn. Stat. 62D.07, Subd. 3. to inform enrollees of the HMO's procedures to secure access to emergency care. Well informed enrollees will be more likely to follow the HMO's procedures for obtaining emergency care. This will reduce the number of incidents of unauthorized emergency care. Therefore, it is very important that HMOs periodically remind enrollees how to access emergency care.

B. This rule provision is intended to allow a reasonable period for enrollees to inform their HMO that emergency care has been provided without a prior referral from the HMO. The 48 hour time period is contained in several HMO contracts and seems to be generally accepted as reasonable. It is important

that enrollees provide timely notice so that the HMO can assume responsibility for any continuing care including transferring the enrollee to a participating hospital if inpatient care is necessary. The two exceptions to the 48 hour time limit are logical and necessary. There are times when it is just not possible to give timely notice. There are other instances when the need for emergency care is clear and the only problem is that the enrollee did not give notice within 48 hours. Under this proposed rule, an HMO could not deny coverage solely because the enrollee did not give notice within 48 hours. This is consistent with 62D.11, Subd. 4 which prohibits an HMO from denying coverage solely for failure to obtain prior authorization.

C. and D. These provisions specify that coverage of emergency care cannot be limited to participating providers nor to care received within the HMO's service area. Coverage of emergency care is dependent on the need for immediate care, not on the status of the provider as participating or within the service area. This is consistent with Minn. R. 4685.0700, Subp.2 which requires coverage for all emergency care regardless of the status of the provider.

E. The purpose of this rule provision is to provide guidelines for the HMO to use in processing claims for coverage of emergency care that was not authorized according to the HMO's procedures. We have found, through our investigations of these many complaints, that often an HMO will deny coverage of these claims without making any attempt to determine if it was reasonable for the enrollee to have obtained emergency care without first contacting the HMO. Often the denial is made on the basis of the enrollee's diagnosis and

does not even consider the symptoms that prompted the enrollee to seek emergency care in the first place. This rule provision requires an HMO to look at each claim to determine if emergency care was reasonable under the circumstances.

The rule provides factors to consider in determining whether it was reasonable to have obtained emergency care. The standard is that of the reasonable person, considering contributing factors such as time of day, day of week, symptoms and special circumstances. These are all reasonable and necessary factors for an HMO to take into consideration when processing these claims. For example, on a weekday during normal business hours, care may be available at several locations including urgent care centers and HMO facilities. However, in the middle of the night, care is only available at a hospital emergency room. Care that could reasonably wait for the next morning may not reasonably wait until after the weekend. Therefore, it is important to require the HMO to look at each case to consider what was reasonable under the circumstances.

The rule specifies that the HMO must first obtain enough information, including the presenting symptoms, to allow it to process the claim. This prohibits the HMO from determining coverage based only on the actual diagnosis. This rule recognizes that enrollees are not trained medical professionals. They cannot be expected to diagnose their conditions based on their symptoms. It takes the skills of a trained physician to diagnose. It is unfair to base coverage decisions on the actual diagnosis. Often the same or similar symptoms are present with different diagnoses. Therefore, it is

reasonable and necessary to require the HMO to obtain sufficient information when processing these claims.

Subp. 8 CONTINUITY OF CARE IN THE EVENT OF CONTRACT TERMINATION.

This section is prompted by past problems we have had when a large primary care provider terminates its participation with an HMO. The termination creates the potential for continuity of care issues with at-risk enrollees, as well as uncertainty for all affected enrollees. We have learned from these past problems that an HMO must have a plan immediately available to ensure an orderly transfer of all affected enrollees to other primary care providers. The plan must also enable the HMO or its providers to identify enrollees with special health risks or needs so that they can receive any special services that may be needed to assure continuity of care. The rule calls for a generic written plan that can be used whenever a primary care provider terminates its participation with an HMO. The rule does not tell an HMO how to handle these issues, only that it must have a system to accomplish an orderly transfer and to identify at-risk enrollees so their special needs can be met. The rule does not require an HMO to refer enrollees back to terminating providers but it does allow enrollees to request a referral back. This rule provision is necessary in order to prevent future problems caused by the loss of primary care providers from an HMO network.

GENERAL STATEMENT OF NEED AND REASONABLENESS - QUALITY ASSURANCE

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

PART BY PART STATEMENT OF NEED AND REASONABLENESS - QUALITY ASSURANCE

4685.1115 Activities

Subp. 2. B. (4). This is being amended to correct a minor grammatical error which does not affect the substance or meaning of this provision. The current rule refers to "health care of providers" which is clearly an error. The QA activity at reference is the appointment scheduling and waiting period for services provided by all types of health care providers. We propose amending this section to correct the error and clarify the meaning of this section of the QA rule.

Dated 7/17/92

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

Marlene E. Marschall

Commissioner

REFERENCES

28 PA. Code Ch. 9

Alabama State Board of Health, Chapter 420-5-6

Mich. Admin. Code r.325

Fla. Admin. Code Ann. r. 10D.100

Rhode Island R27-41-HMO

Tex. Admin. Code, Department of Health, HMO Regulations, Ch. 119

Cal. Admin. Code Title 10, Section 1300

N.Y. Comp. Codes R. & Regs, Title 10

Oklahoma State Board of Health, HMO License Rules, Ch. 52

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