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11-0900-7032-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Rules of the Minnesota Department of Health Relating to Health Maintenance Organization Availability and Accessibility of Services and Quality Assurance, Minn. Rules Chapter 4685.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Barbara L. Neilson on December 9, 1992, at 9:00 a.m. in Room D of the Veterans Service Building, 20 West 12th Street, St. Paul, Minnesota.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. §§ 14.131 to 14.20 (1990), to hear public comment, determine whether the Minnesota Department of Health ("the Department") has fulfilled all relevant substantive and procedural requirements of law applicable to the adoption of the rules, evaluate whether the proposed rules are needed and reasonable, and determine whether or not modifications to the rules proposed by the Department after initial publication are substantially different from those originally proposed.

Paul G. Zerby, Special Assistant Attorney General, 525 Park, Suite 500, St. Paul, Minnesota 55103, appeared on behalf of the Department at the hearing. The Department's hearing panel consisted of Irene Goldman, Health Services Analyst, Health Care Delivery Systems Division; Kent Peterson, Director, Alternative Delivery Systems Section; Arnie Rosenthal, Manager of Enforcement, Health Care Delivery Systems Division; and Andrea Mitchell Walsh, J.D., Assistant Commissioner. Twenty-four persons signed the hearing register. The Administrative Law Judge received fourteen agency exhibits and seven public exhibits as evidence during the hearing. The hearing was conducted until all interested persons, groups, or associations had an opportunity to be heard concerning the adoption of these rules.

The record remained open for the submission of written comments until December 29, 1992, twenty calendar days following the date of the hearing. Pursuant to Minn. Stat. § 14.15, subd. 1, five business days were allowed for the filing of responsive comments. At the close of business on January 6, 1993, the rulemaking record closed for all purposes. The Administrative Law Judge received numerous written comments from interested persons during the comment period. The Department submitted written comments responding to matters discussed at the hearing and comments filed during the twenty-day period. In its written comments, the Department proposed further amendments to the rules.

This Report must be available for review by all affected individuals upon request for at least five working days before the Department takes any further action on the rules. The Department may then adopt final rules or modify or withdraw its proposed rules. If the Department makes changes in the rules other than those recommended in this report, it must submit the rules with the complete hearing record to the Chief Administrative Law Judge for a review of the changes prior to final adoption. Upon adoption of final rules, the agency must submit the rules to the Revisor of Statutes for a review of the form of the rules. The agency must also give notice to all persons who requested to be informed when the rules are adopted and filed with the Secretary of State.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Procedural Requirements

1. On October 2, 1992, the Department filed the following documents with the Chief Administrative Law Judge:

(a) a copy of the proposed rules as certified by the Revisor of Statutes;

(b) a copy of the Department's proposed Order for Hearing;

(c) a copy of the proposed Notice of Hearing;

(d) the Statement of Need and Reasonableness (SONAR); and

(e) an estimate of the number of persons expected to attend the hearing and the expected length of the Department's presentation at the hearing.

2. On October 7, 1992, the Department filed a statement indicating that it intended to provide additional discretionary public notice of the proposed rules and the hearing.

3. On October 26, 1992, the Department mailed the Notice of Hearing to all persons and associations who had registered their names with the Department for the purpose of receiving notice of the proposed adoption of rules by the agency. On that date, the Department also mailed the Notice of Hearing to those persons who received additional discretionary notice.

4. On October 26, 1992, a copy of the proposed rules and the Notice of Hearing were published at 17 State Register 888.

5. On October 28, 1992, the Department filed the following documents with the Administrative Law Judge:

(a) the Notice of Hearing as mailed;

(b) a copy of the State Register pages containing the Notice of Hearing and the proposed rules;

(c) an affidavit stating that the Notice of Hearing was mailed on October 26, 1992, to all persons on the Department's mailing list and a certificate that the Department's mailing list was accurate and complete as of October 21, 1992;

(d) an affidavit stating that additional discretionary notice of the hearing was mailed on October 26, 1992, to all persons on a list maintained by the Department's Alternative Delivery Systems Section, Health Care Delivery Systems Division and a certificate that the Section's mailing list was accurate and complete as of October 21, 1992;

(e) all materials received by the Department in response to four separate solicitations of opinion from interested persons;

(f) copies of the Notices of Intent to Solicit Outside Information published in 12 State Reg. 1109 (Nov. 23, 1987) and 16 State Reg. 2060 (March 16, 1992); and

(g) an identification of the Department's hearing panel.

Nature of the Proposed Rules

6. The proposed rules would amend current rules defining terminology used in the Department's regulations pertaining to Health Maintenance Organizations ("HMOs"), repeal existing rules governing the availability and accessibility of care by HMOs, specify new availability and accessibility requirements, and amend existing quality assurance rules to conform citations and correct a grammatical error. The proposed rules include provisions which establish requirements for the provision of primary and specialty physician services, hospital services, and ancillary health services and set forth standards relating to geographic accessibility, coordination of care, timely access to health care services, and access to emergency health care services.

Statutory Authority

7. In its Notice of Hearing and its Statement of Need and Reasonableness, the Department asserted that Minn. Stat. § 62D.20 provides authority for the promulgation of the proposed rules. Minn. Stat. § 62D.20 (1992) generally authorizes the Commissioner of Health to "promulgate such reasonable rules as are necessary or proper to carry out the provisions of sections 62D.01 to 62D.30." Sections 62D.01 to 62D.30 govern HMOs in Minnesota and encompass such matters as required coverages, powers, minimum benefits, prohibited practices, and provider contracts. Section 62D.04, subd. 1(a), (c), and (d) (1992), specifically requires the Commissioner of Health in considering an application for a certificate of authority to determine whether the applicant has "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," has a "procedure to develop, compile, evaluate, and report statistics relating to the . . . availability and accessibility of its services . . .," and has "reasonable provisions for emergency and out of area health care services." Moreover, section 62D.04, subd. 4 (1992), requires that HMOs who have been granted a certificate of authority "continue to operate in compliance with the standards set forth in subdivision 1." The

Administrative Law Judge concludes that the Board has general statutory authority under Minn. Stat. § 62D.20 (1990) to adopt these rules.

Small Business Considerations in Rulemaking

8. Minn. Stat. § 14.115, subd. 2 (1990), requires state agencies proposing rules which may affect small businesses to consider methods for reducing adverse impact on those businesses. The small business statute does not apply to "service businesses regulated by government bodies, for standards and costs, such as . . . providers of medical care." Minn. Stat. § 14.115, subd. 7 (3) (1990). In its Notice of Hearing and Statement of Need and Reasonableness, the Department contends that the HMOs fall within this category and that the proposed rules thus are exempt from the small business consideration provisions. The application of the above exemption has been previously determined to be applicable to rules relating to HMOs. See, e.g., In the Matter of the Proposed Adoption of Rules of the State Health Department Governing Health Maintenance Organizations (Parts 4685.0100; 4685.2800; 4685.1910 to 4685.1970; 4685.2150), OAH Docket No. 8-0900-0247-1 (Report issued Feb. 18, 1986); In the Matter of the Proposed Amendments to Rules Relating to Health Maintenance Organization Enrollee Copayment, Termination, and Supplemental Benefits Provisions, Minnesota Rules Chapter 4685, OAH Docket No. 11-0900--6030-1 (Report issued March 16, 1992). The Administrative Law Judge finds that the exemption properly applies in this instance and that the Department thus need not consider the factors set forth in the statute for reducing the impact of rules on small businesses.

Fiscal Notice

9. Minn. Stat. § 14.11, subd. 1 (1990), requires agencies proposing rules that will require the expenditure of public funds in excess of $100,000 per year by local public bodies to publish an estimate of the total cost to local public bodies for the two-year period immediately following adoption of the rules. The Department stated in its Notice of Hearing that promulgation of the proposed rules will not result in the expenditure of public monies by local public bodies. No one disputed the Department's contention. The fiscal notice requirements of Minn. Stat. § 14.11, subd. 1 (1990), thus are not applicable to this proceeding.

Impact on Agricultural Land

10. Minn. Stat. § 14.11, subd. 2 (1990), requires that agencies proposing rules that have a "direct and substantial adverse impact on agricultural land in the state" comply with the requirements set forth in Minn. Stat. §§ 17.80 to 17.84 (1990). Because the proposed rules will not have an impact on agricultural land, these statutory provisions do not apply.

Outside Information Solicited

11. In formulating these proposed rules, the Department originally published a Notice of Intent to Solicit Outside Information in November of 1987. See 12 State Reg. 1109 (Nov. 23, 1987). No comments were received by the Board in response to the Notice. The Department circulated drafts of the proposed rules governing accessibility of services and utilization review in April and September of 1991 and met with representatives of several Minnesota HMOs in May of 1991. On March 16, 1992, an additional Notice of Intent to

Solicit Outside Information and Opinions was published in the State Register. See 16 State Reg. 2060 (March 16, 1992). Eight written comments were received in response. Prior to the hearing in this matter, the Department met with interested persons to discuss the definition of "medically necessary care" in the proposed rules and invited participants to submit written comments and suggestions.

Discussion of the Proposed Rules

Need For and Reasonableness of the Proposed Rules in General

12. The Administrative Law Judge must determine, *inter alia*, whether the need for and reasonableness of the proposed rules has been established by the Department by an affirmative presentation of fact. The Department prepared a Statement of Need and Reasonableness ("SONAR") in support of the adoption of the proposed rules. At the hearing, the Department primarily relied upon its SONAR as its affirmative presentation of need and reasonableness. The SONAR was supplemented by the comments made by the Department at the public hearing and in its written post-hearing comments.

13. The question of whether a rule is reasonable focuses on whether it has a rational basis. The Minnesota Court of Appeals has held a rule to be reasonable if it is rationally related to the end sought to be achieved by the statute. *Broen Memorial Home v. Minnesota Department of Human Services*, 364 N.W.2d 436, 440 (Minn.App. 1985); *Blocker Outdoor Advertising Company v. Minnesota Department of Transportation*, 347 N.W.2d 88, 91 (Minn.App. 1984). The Supreme Court of Minnesota has further defined the burden by requiring that the agency "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken." *Manufactured Housing Institute v. Pettersen*, 347 N.W.2d 238, 244 (Minn. 1984).

14. This Report is generally limited to the discussion of the portions of the proposed rules that received significant critical comment or otherwise need to be examined. Because some sections of the proposed rules received little or no negative comment and were adequately supported by the SONAR, a detailed discussion of each section of the proposed rules is unnecessary. The Administrative Law Judge specifically finds that the need for and reasonableness of the provisions that are not discussed in this Report have been demonstrated by an affirmative presentation of facts, that such provisions are authorized by statute, and that there is no other problem preventing their adoption.

Part 4685.0100 - Definitions

15. The proposed rules add several subparts defining new terms to the definitional section of the existing rules. The definitions that received significant critical comment will be discussed below.

16. Subpart 5.A. Emergency Care: Subpart 5 of the Department's current rules includes emergency care among the types of services which must be included in a comprehensive health maintenance services. The proposed rules amend the definition of "emergency care" to encompass "medically necessary care which is immediately necessary to preserve life, prevent serious impairment to bodily functions, organs or parts, or prevent placing the physical or mental health of the enrollee in serious jeopardy."

17. Several commentators proposed revisions to the definition contained in the proposed rules. The Minnesota Medical Association ("MMA") recommended in the interest of uniformity that the proposed rules track the definition used by the federal Health Care Financing Agency ("HCFA"), which requires coverage of services provided in hospital emergency departments after "sudden onset of a medical condition that is manifested by symptoms of sufficient severity (including severe pain) that, in the absence of immediate medical attention, could reasonably be expected to result in placing health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part." NWNL Health Network, Inc. ("NWNL"), proposed the following alternative definition: "medical care which is immediately necessary to prevent serious impairment to an individual's physiological functions, organs or parts, or for the purpose of preserving an individual's life." NWNL did not explain why this definition would be preferable to that proposed by the Department. Metropolitan Health Plan ("MHP") suggested that the rules define emergency care as "medical care which is immediately necessary to preserve an individual's life; or, to prevent serious impairment to an individual's physiological functions, organs, and parts" because it believed that such a definition would be more precise and would avoid the "subjective" references in the proposed rules to placing health in "serious jeopardy." Finally, the MMA and several other commentators suggested that the definition include a reference to "severe pain."

18. The Department declined to modify the proposed rules as suggested. The Department determined that the HCFA definition was too restrictive in its requirement that there be a sudden onset of a condition, given that some medical emergencies develop over time and get progrssively worse. The Department also indicated that the proposed definition was not written in terms of symptoms and asserted that severe pain, where symptomatic of a medical emergency, would be included within the references contained in the proposed definition to care necessary to preserve life, prevent serious impairment to bodily functions, organs, or parts, or prevent placing the enrollee's physical or mental health in serious jeopardy. The Department further responded that the terminology used in the proposed rules was understandable and not unduly subjective, and found that the commentators had not provided any reasonable basis for deleting the reference to mental health emergencies from the definition.

19. O.J. Doyle, EMS Consultant, Doyle Consulting, suggested that emergency ambulance service be included in the definition of "emergency care." Mr. Doyle also asked that the Department amend Minn. Rules pt. 4685.0700 (relating to Comprehensive Health Maintenance Services) by deleting subpart 3, item E (which renders it permissible to exclude or limit ambulance transportation from comprehensive health maintenance services) and adding a provision to subpart 2 mandating the provision of emergency ambulance services, and specify in the rules that HMOs must cover at least 80 percent of the usual and customary charges. In its post-hearing comments, the Department indicated that it felt that it was unnecessary and inappropriate to include emergency ambulance services within the definition of emergency care. The Department noted that the proposed rules do not attempt to identify specific services which may be included within the definition of "emergency care" and pointed out that ambulance services are not excluded from the definition where they otherwise meet the criteria set forth in the proposed rules. The Department indicated that it would be outside the scope of the proposed rules

to consider any amendments to chapter 4685.0700 or the appropriate reimbursement level for ambulance services.

20. The proposed rules define "emergency care" with greater precision than the current rules and in a manner that is consistent with other state and federal regulations. The Department has presented facts justifying the need for and reasonableness of the proposed definition. The Administrative Law Judge finds that the proposed rules are not rendered unreasonable by their failure to specifically mention ambulance services, and that the other modifications suggested by Mr. Doyle would, if included in the proposed rules, result in a rule fundamentally different in effect from that originally proposed. The Notice of Hearing issued by the Department did not propose to amend part 4685.0700 of the Department's existing rules, and any attempt to do so at this point would result in a substantial change from the rules as originally proposed.

21. Subpart 9b. Medically Necessary Care: The Minnesota Medical Association pointed out that each HMO currently implements its own definition of "medically necessary care" and agreed with the need to define the term in the regulations so that consumers and providers may predict when there will be coverage. The Minnesota Hospital Association also expressed its view that it would be wise to have a consistent definition of the term. Group Health, MedCenters, Group Care Inc., and Central Minnesota Group Health Plan (hereinafter referred to as "Group Health and MedCenters") jointly submitted comments in which they questioned the need for a definition of "medically necessary care."

22. In the SONAR, the Department pointed out that there are substantial differences in the manner in which various Minnesota HMOs interpret "medically necessary care" and that these differences, coupled with the lack of common standards and criteria, have resulted in a great deal of uncertainty for HMO enrollees regarding which services will be covered. The Department indicated in its post-hearing comments that the phrase is used throughout the HMO Act and asserted that the definition of the term in its regulations is a reasonable method to implement the Act. In addition, several portions of part 4685 of the rules refer to "medically necessary care" or "medical necessity" without definition, and the phrase is used in the definition of "emergency care." Because HMOs deny coverage for services deemed not to be medically necesary, the Department has determined that it is important for HMOs to use a fair, reasonable and objective definition. The definition will also permit the Department to use a consistent definition in evaluating complaints by enrollees and auditing HMOs for compliance with the requirement that reasonably necessary medical services be provided to enrollees.

23. The Department has demonstrated that it is necessary and reasonable to include a definition of the phrase "medically necessary care" in the proposed rules in order to reduce uncertainty regarding the meaning of the phrase and ensure that consistent criteria are employed by HMOs and the Department.

24. The proposed definition of "medically necessary care" was supported by several commentators, including the Office of Ombudsman for Older Minnesotans, the Minnesota Nurses Association, the Director of the Center for Public Policy of Hazelden Institute, and Rehab Services. The Minnesota Occupational Therapists Association, the MMA, the Minnesota Hospital

Association, NWNL, MHP, Group Health, MedCenters, and other commentators did, however, recommend several revisions in the language of the proposed rules.

25. The reference to "generally accepted principles of practice" contained in the rules as originally proposed was the subject of the most critical commentary. Group Health, MedCenters, NWNL, and the MMA suggested that this phrase be deleted because it may be construed to require that HMO providers meet a standard of care which is higher than the current legal standard used in malpractice cases. In its post-hearing comments, the MMA suggested that the rules be revised to refer to "generally accepted practice" or "generally accepted community practice," and opposed any use of the term "standards." NWNL recommended that the rules refer to "the type and level of care that is commonly provided in the community" rather than "principles of practice." Preferred One recommended that the phrase "standards of practice" or language referring to "generally accepted practice" be used. Group Health and MedCenters urged the Department to refer to "commonly accepted standards of medical practice" and include a further definition defining this phrase to mean "the type and level of care that is commonly provided in the community for a specific diagnosis or condition. A standard may be general, rather than specific, in nature and may include a broad range of appropriate approaches."

26. Several other suggestions were made with respect to other aspects of the proposed definition of "medically necessary care." MHP suggested that the definition be modified to provide that "'medically necessary' care must be consistent with generally prevailing medical practice as determined by health care providers in the same or general specialty and should manage the condition, injury, or illness in a manner that takes into consideration what is appropriate in terms of frequency, level of intensity, duration and setting." A similar definition was offered by UCare Minnesota. The Minnesota Hospital Association ("MHA") supported the reference in the proposed rules to the prevention of deterioration of the enrollee's physical or mental health, but suggested that the definition of "medically necessary care" otherwise should be similar to the definition used in the medical assistance rules promulgated by the Minnesota Department of Human Services. The MHA contended that such an approach would ensure consistency in interpretation, utilize a definition that is already understood by the medical provider community, and incorporate within the definition references to "pain" and specific conditions which must be treated by medical providers. The MMA recommended that the proposed rules recognize treatment for pain as "medically necessary care," as did the Minnesota Chapter of the American Physical Therapy Association, the Minnesota Occupational Therapy Association, Minnesota Valley Rehabilitation, and several individual commentators.

27. The MMA further suggested that the Department clarify the statement in item A. that "medically necessary care must be consistent with generally accepted principles of practice as determined by health care providers in the same or similar general specialty as typically manages the condition, procedure, or treatment at issue." NWNL, Group Health, and MedCenters suggested that the Department omit the reference in item B. to "maintaining" the enrollee's health because such a requirement would conflict with language in many HMO contracts excluding such services and it is unclear how the Department would construe such a requirement. UCare proposed deleting item B. of the proposed rules in its entirety. In contrast, Dr. Crimmins of the MMA, the MOTA, the Minnesota Nurses Association, and several occupational and physical therapists expressed support for the inclusion of maintenance care in

the definition of "medically necessary care." The MMA, the Minnesota Occupational Therapy Association, Minnesota Valley Rehabilitation, Preferred One, and other commentators recommended that the rules refer to the restoration or maintenance of the enrollee's "functional state" or "functional status." UCare suggested that item C. (which refers to preventing deterioration of the enrollee's condition) be deleted. Preferred One also found item C. to be problematic, asserting that it may be unreasonable to try to prevent such deterioration if a patient is terminal or in a persistent vegetative state. With respect to item D., the MMA suggested that the reference to the "possible" onset of a health problem was overbroad and should be revised; the term "health condition" should be used instead of "health problem"; and the rules should be modified to clearly indicate that the prevention of a possible onset of a health condition would include reasonable screening tests. Preferred One expressed similar concerns and suggested that the language of item D. be revised to state, "prevent the reasonably likely onset of a health problem or condition, detect an incipient condition or evaluate a patient complaint/concern." UCare supported the language of item D. as originally proposed.

28. Group Health and MedCenters suggested that the phrase "prudent use of resources" be integrated into the definition of "medically necessary care" because cost is a relevant consideration in determining what services are medically necessary. Several other commentators, including the MMA, Molly O'Dea, an occupational therapist, and Becky Stone, a physical therapist and representative of NovaCare, objected to the inclusion of cost as a factor in the determination of medical necessity.

29. The Department disagreed with the suggestions of commentators that it should revise or eliminate references in the rules as originally proposed to care which helps maintain the enrollee's health or prevent deterioration of the enrollee's condition. The Department emphasized that the maintenance of health requirement in the proposed rules is consistent with the statement in the statute governing HMOs that comprehensive health maintenance services are "a set of comprehensive health services which the enrollees might reasonably require to be maintained in good health." Minn. Stat. § 62D.02, subd. 7 (1992) (emphasis added). The Department further stressed that coverage for these services must be made on a case-by-case basis, and that the proposed rules simply ensure that HMOs cannot exclude all care necessary to help maintain the enrollee's health or prevent deterioration of the enrollee's condition on the basis that it is never medically necessary. The Department also declined to modify the proposed rules to refer to "functional status" rather than "health" because "health" is used in the governing statute and would appear in any event to encompass "functional status," found it unnecessary to refer to care necessary "to evaluate a patient's complaint/concern" because that would be subsumed within care necessary to detect an incipient problem or restore health, and noted that, as in the definition of "emergency care," it would be inappropriate to include "severe pain" within the definition because the rules do not attempt to describe symptoms that might render medical care necessary. The Department did not explicitly respond to the recommendation that the definition incorporate a reference to "prudent use of resources."

30. In its post-hearing comments, the Department modified items A., B., and D. of the definition of "medically necessary care" contained in the proposed rules to refer in item A. to "practice parameters" rather than

"principles of practice," include the word "or" at the end of item B. (as a grammatical correction), and refer to the "reasonably likely" rather than "possible" onset of a health problem in item D. (in accordance with the suggestion of Preferred One). As modified, subpart 9b. would provide as follows:

> **Medically necessary care.** "Medically necessary care" means health care services appropriate, in terms of type, frequency, level, setting, and duration, to the enrollee's diagnosis or condition, and diagnostic testing and preventive services. Medically necessary care must:
>
> A. be consistent with generally accepted practice parameters as determined by health care providers in the same or similar general specialty as typically manages the condition, procedure, or treatment at issue; and
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> B. help restore or maintain the enrollee's health; or
>
> C. prevent deterioration of the enrollee's condition; or
>
> D. prevent the reasonably likely onset of a health problem or detect an incipient problem.

31. The most significant modification made by the Department is its substitution of the phrase "practice parameters" for "principles of practice." The language utilized by the Department was not specifically suggested by any of the commentators. Unfortunately, because the Department's modifications were submitted on the day the record closed in this rulemaking proceeding, the Administrative Law Judge does not have the benefit of public comment concerning the new language. In its post-hearing comments, the Department explained that the American Medical Association has described practice parameters as strategies for patient management developed to assist physicians in clinical decision making. Such parameters identify a range of appropriate strategies for the management of specific clinical conditions or specify a range of appropriate uses of specific diagnostic or therapeutic interventions. The AMA publishes an annual directory of practice parameters that in 1992 listed over 1300 practice parameters developed by more than three dozen physician organizations. More than 200 additional practice parameters are in the process of being developed. The AMA has indicated that, "[a]lthough relevant practice parameters will likely be admissible into evidence in a malpractice lawsuit, they will in general serve only as evidence of the standard of care and not as an absolute or inflexible standard that must be followed in all circumstances."

32. The Department has fully explained the rationale for the proposed use of "parameters of practice" and has justified its choice of this terminology as reasonable. The other modifications proposed by the Department were grammatical in nature or in response to comments received during the rulemaking proceeding. The substantive modifications were the subject of public comment and do not result in a rule that is substantially different from that originally proposed. The Department has shown that the definition of "medically necessary care" contained in the proposed rules, as modified, is needed and reasonable. While the Department may choose to consider making additional changes in this definition in accordance with the suggestions of

interested parties, the proposed rules are not rendered unreasonable by their failure to include all of the recommended revisions. The modified rules are not a substantial change from those originally proposed.

33. Subpart 12a. Primary Care Physician: As originally proposed, subpart 5 of part 4685.1010 of the rules required HMOs to provide the services of "primary care physicians" to provide initial and basic care to enrollees, and subpart 12a of part 4685.0100 defined the term to include only licensed physicians. The Minnesota Medical Association supported the use of the phrase "primary care physician" in the proposed rules as being reasonable and consistent with state policy, but recommended that the rules refer to certification "approved" by the American Board of Medical Specialists or the American Board of Osteopathy. Preferred One also urged that the rules refer to certification "in a board approved by" the American Board of Medical Specialists or the American Board of Osteopathy. Group Health and MedCenters recommended that the definition be narrowed in order to exclude obstetricians and gynecologists because they do not have broad-based practices and cannot treat the full range of patient problems.

34. The Minnesota Chiropractic Association, the Minnesota Optometric Association, and the Minnesota Nurses Association opposed the use of the phrase "primary care physician" and suggested that the term "primary care provider" instead be utilized. These associations asserted that the revision is necessary because restricting coordination of care provided to HMO enrollees to medical doctors is contrary to the recognition in current law and practice that there are many providers other than medical doctors who can, and do, furnish initial care to patients. They pointed out that doctors of chiropractic, optometrists, nurse practitioners, and nurse midwives are frequently utilized as primary care providers and coordinators of care and that such an approach is supported by various state and federal statutes. They also contended that restricting the coordination of care to medical doctors would be inconsistent with current trends in health care planning and could reduce the access of HMO enrollees to basic services. They suggested that the definition of "primary care physician" be deleted and that the following definition of "primary care provider" be substituted: "'Primary care provider' means a licensed practitioner, either employed by or under contract with a health maintenance organization, who, within the practitioner's legal scope of practice, furnishes initial and ongoing basic care." MHP supported changing the terminology to "primary care provider" to include nurses, nurse practitioners, and midwives, but opposed inclusion of optometrists and chiropractors. It proposed an alternative definition which would limit the meaning of the term "primary care provider" to "an individual who, by virtue of special education, training and licensure is able to perform invasive procedures and to prescribe medication in the course of evaluating, diagnosing, treating and/or referring patients for other treatment." NWNL objected to the inclusion of chiropractors and optometrists within the definition of primary care providers because they cannot provide the full scope of primary care services or write prescriptions. Group Health and MedCenters recommended that all non-physicians such as chiropractors, optometrists, nurse practitioners, and nurse midwives be excluded from the category of primary care provider.

35. The Department decided to retain a definition of "primary care physician" in the proposed rules but revised the definition to specify that the term encompasses, inter alia, a licensed physician "who is board-certified

or board-eligible and working toward certification in a board approved by the American Board of Medical Specialists or the American Board of Osteopathy in family practice, pediatrics, internal medicine, or obstetrics and gynecology." This modification was suggested by the MMA and Preferred One and is consistent with language used in subpart 13b. of the proposed rules. In response to the comments made by the Minnesota Chiropractic Association, the Minnesota Optometric Association, and the Minnesota Nurses Association, the Department proposed adding a new definition of "primary care provider" to the definitional section and making further revisions to other parts of the proposed rules specifying that "primary care providers" deliver initial and basic care to enrollees. The new provision set forth in subpart 12b. of the definitional section would read as follows:

> **Primary care provider**. "Primary care provider" means a primary care physician as defined in Subp. 12a. or a licensed practitioner such as a licensed nurse, optometrist or chiropractor who, within that practitioner's scope of practice, as defined under the relevant state licensing law, provides primary care services.

In support of this revision, the Department noted that HMOs should be allowed (but not required) to utilize nurses and other licensed non-physicians in providing primary care services to enrollees, in accordance with current HMO practice. The Department's definitions of "primary care physician" and "primary care provider," as modified, have been shown to be needed and reasonable to identify physicians and other providers who are expected to provide primary care functions for HMO enrollees. These issues were the subject of substantial discussion during the rulemaking proceeding. The modifications made by the Department are responsive to comments received during and following the public hearing in this matter and do not constitute a substantial change from the rules as originally proposed.

36. Subpart 13a. Referral: In its post-hearing comments, the Department proposed modifying this portion of the proposed rules to replace the word "directs" with "allows." The rule, as modified, would define "referral" to mean "a prior written authorization from the health maintenance organization or an authorized provider that allows an enrollee to have one or more appointments with a health care provider, for consultation, diagnosis, or treatment of a medical condition, to be covered as a benefit under the enrollee's health maintenance organization contract." The modification was made in response to a suggestion by Preferred One and recognizes that enrollees are not "directed" to obtain referral services but instead are "allowed" to do so. The Department has shown that the proposed rules, as modified, are needed and reasonable to avoid confusion and misunderstanding between enrollees, providers, and HMO administrators regarding what sorts of referrals have been authorized. The modification made by the Department serves to clarify the proposed rules, was made in response to a suggestion by an interested party, and does not constitute a substantial change from the rules as originally proposed.

37. Subpart 13b. Specialty Physician: As originally proposed, this rule part defined "specialty physician" to include physicians "other than a primary care physician" who are board-certified or board-eligible and working toward certification in a specialty board approved by the American Board of

Medical Specialists or the American Board of Osteopathy "from the major areas of clinical services." The MMA and Preferred One recommended that the Department modify the proposed definition by deleting the phrase "from the major areas of clinical service" because the phrase is not defined and many specialists come from "non-major" areas of clinical service. The MMA also suggested deleting the phrase "other than a primary care physician" because all physicians except those in general practice are specialty physicians. The Department accepted these suggestions and modified the proposed rules in the requested manner. As revised, subpart 13b. would read as follows:

> **Specialty physician**. "Specialty physician" means a licensed physician, either employed by or under contract with the health maintenance organization, who has specialized education, training, or experience, or who is board-certified or board-eligible and working toward certification in a specialty board approved by the American Board of Medical Specialists or the American Board of Osteopathy.

The modifications in the rule language were made by the Department in response to comments received during and following the hearing, are reasonable to clarify the definition of specialty physician, and do not constitute a substantial change from the rules as originally proposed.

38. Subpart 16. Urgently Needed Care: The proposed rules define "urgently needed care" as "medically necessary care which does not meet the definition of emergency care but is needed as soon as possible, usually within 24 hours." Preferred One commented that the definition was vague and urged the Department to try to improve it. Preferred One did not suggest any alternative language. The Department declined to modify the definition in response to this comment. The Department has shown that the proposed rules are needed and reasonable to distinguish care which is needed as soon as possible (urgent care) from that which is immediately necessary (emergency care). The manner in which the term is defined in the proposed rules is consistent with common usage in the health care community and has not been shown to be unduly vague.

Part 4685.1010 - Availability and Accessibility

Subpart 1.A. - Centers of Excellence

39. As originally proposed, subpart 1.A. referred to medical facilities that provide specialized medical care such as organ transplants and coronary artery bypass surgery as "centers of excellence." Many commentators, including the MMA, Preferred One, and Medical Alley, objected to the use of this term because it may improperly imply that other facilities do not provide excellent services. Medical Alley did not suggest replacement language but indicated that others have recommended such terms as "referral centers, "tertiary care centers," or "specialty centers." The MMA and Preferred One supported use of the term "referral centers." They pointed out that the use of this term has been recommended in a report issued by the Health Planning Advisory Committee to the Minnesota Health Care Commission. The Department has determined that the term "referral centers" more accurately describes the facilities encompassed within this rule provision and agreed in its post-hearing comments that the proposed rules should be modified to refer to

"referral centers" rather than "centers of excellence." The use of the term "centers of excellence" was the subject of extensive discussion at the public hearing. The Department revised the rules in response to suggestions by interested persons. The modification clarifies the proposed rules and does not constitute a substantial change from the rules as originally proposed. 1/

40. The proposed rules provide examples of criteria that HMOs may use in designating a facility as a referral center. As originally proposed, the rules indicated that such criteria included "volume of services provided annually and the mortality and morbidity rates." The MMA pointed out that neither volume nor mortality and morbidity rates are necessarily effective measurements of excellence and that mortality and morbidity can be influenced by many outside variables. Medical Alley and Preferred One also objected to this language. They agreed that the volume of services provided is not necessarily a good measure and asserted that mortality and morbidity rates should be adjusted for case mix and severity. The Department adopted language suggested by Preferred One and modified the rules in its post-hearing comments to refer to "the case mix and severity adjusted mortality and morbidity rates." The proposed rules continue to include the reference to "volume of services provided annually." The Department has justified the need for and reasonableness of this portion of the proposed rules. Although volume of services provided annually may not be a reliable measure of quality, the proposed rules do not require HMOs to use volume of services in determining which facilities to designate as referral centers but merely identify volume of services as an example of a criterion that an HMO may use.

Subpart 2 - Basic Services

41. The proposed rules require, *inter alia*, that HMOs "develop and implement written standards or guidelines which address the assessment of provider capacity to provide timely access to health care services in accordance with subpart 6" of the rules. The Minnesota Occupational Therapy Association recommended that language be added to subpart 2 requiring that HMOs provide responses to telephone prior authorization requests for rehabilitation services within two working days and prohibiting HMOs from asking physicians to rescind orders for cost containment reasons. The MOTA indicated that such language would ensure that enrollees gain timely access to essential treatment. The comments of MOTA were supported by Minnesota Valley Rehabilitation. The Department indicated that this area may be addressed by Minnesota's new utilization review statute and was reluctant to incorporate the standard in the proposed rules. NWNL indicated that this portion of the proposed rules implies that each HMO must have written standards applicable to each provider regarding accessibility to care and stated that this approach is impractical because some providers contract with several HMOs, each of which may have different accessibility requirements. The Department discussed NWNL's concerns in its post-hearing comments. The Department indicated that

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1/ The Administrative Law Judge notes that the revised version of the proposed rules submitted by the Department with its January 6, 1993, final comments neglected to change the term "centers of excellence" to "referral centers" on page 3, line 21 and page 8, line 11 of the proposed rules. The Department should make these revisions prior to adopting the proposed rules. Such revisions would not constitute substantial changes.

access to care standards are generally similar among HMOs and that accessibility standards would involve a range of acceptable time limits. The Department also stated that providers who contract with more than one HMO typically adopt one set of written standards that are acceptable to all of the HMOs with which it contracts. The Department thus declined to modify the proposed rules.

42. The rules have been shown to be needed and reasonable to establish basic staffing requirements that all HMOs must meet based upon the projected needs of its enrollees for covered health care services. While the Department may consider revising the rules based upon the suggestions of interested persons, the proposed rules are not rendered unreasonable by their failure to incorporate the comments summarized above.

Subpart 2.A. - Primary Care Physician Services

43. This subpart of the proposed rules was modified by the Department following the hearing in order to be consistent with the addition of the term "primary care provider" in Subpart 12b. of the definitional portion of the proposed rules. As modified, subpart 2.A. would be headed "Primary Care Services" instead of "Primary Care Physician Services." In addition, a new item (4) would be added under subpart 2.A. which would provide as follows:

> (4) To the extent that primary care services are provided through primary care providers other than physicians, and to the extent permitted under applicable scope of practice in state licensing laws for a given provider, these services shall be available and accessible as required by Subparts 2.A.(1) through (3).

Subpart 2.A.(3) has also been modified to refer to "practice parameters" rather than "principles of practice" to be consistent with the definition of "medically necessary care" (as discussed in Findings 30-32 above). These changes have been shown to be needed and reasonable. As discussed in Findings 33-35 above (relating to the definition of "primary care physician"), these modifications were made in response to comments made at the hearing and in post-hearing comments, were the subject of substantial discussion, and do not constitute a substantial change from the rules as originally proposed.

44. UCare suggested that subpart 2.A.(1) be revised to state that HMOs shall fulfill the availability and accessibility requirements through written standards "which may include" those set forth in subitems (a) through (e), rather than the present language which requires written standards encompassing subitems (a) through (e). The Department indicated in its post-hearing comments that the proposed rules clearly require HMOs to meet their obligations by making primary care physician services available through the listed options and declined to make the recommended modification. In the SONAR, the Department emphasized that people sustain injuries or become ill at all hours of the day and night, and that it thus is important to ensure that HMOs are equipped to provide primary care services during all of these hours. The Department has justified its position that HMOs should be required to develop written standards for regularly scheduled appointments during normal business hours, after-hours clinics, 24-hour answering services, back-up coverage, and referrals to urgent care centers and hospital emergency centers as set forth in subitems (a) through (e).

Subpart 2.B. - Specialty Physician Services

45. Preferred One suggested that the term "specialty physician services" be changed to "non-primary care physicians" or "referral physicians" since primary care physicians are also "specialists" in their own right. The Department did not adopt this recommendation and did not explain its position in its post-hearing comments. The proposed rules are not rendered unreasonable by their failure to incorporate this suggested change.

46. Group Health and MedCenters suggested that subpart 2.B.(1) be revised to recognize the existence of "staff model" HMOs in which the HMO employs specialty physicians and to encompass situations in which HMOs do not employ or contract with specialty physicians but do enter into other types of arrangements with them. The Department accordingly has modified the first sentence of item (1) to state, "The health maintenance organization shall provide directly, contract for or otherwise arrange for specialty physician services which are covered benefits and to which enrollees have continued access in the health maintenance organization's service area." This portion of the proposed rules, as revised in post-hearing comments, has been shown to be needed and reasonable. The modification adopted by the Department is not a substantial change from the rules as originally proposed.

47. The proposed rules provide that specialty physician services which are covered benefits and to which enrollees have continued access in the HMO's service area "shall be available and accessible 24 hours per day, seven days per week." Medica and NWNL suggested that the Department add the phrase "as necessary" or "as is medically necessary" to this sentence of the proposed rules. Although the Department noted in its post-hearing comments that it agrees that not all specialty services may be required 24 hours per day or seven days per week and that the need to provide a service would depend upon the circumstances of each particular case, it has determined that it is necessary for an HMO to have all services potentially available when needed. The Department thus refused to make the suggested change in the language of the second sentence of subpart 2.B.(1). The proposed rules have been shown to be needed and reasonable to ensure that the services of specialty physicians are available when necessary.

48. Subpart 2.B.(2) requires that specialty physician services to which enrollees do not have continued access, such as referrals for consultation or second opinions, shall be provided by the HMO through contracts or other arrangements. Group Health and MedCenters were critical of the distinction made in the rules between specialists to which enrollees have continued access and other specialists. They pointed out that some specialists choose not to enter into contracts with HMOs and suggested that the rules specify that all specialist services be made available through contracts, employment relationships or other arrangements. The Department has addressed this concern by revising the language of subpart 2.B.(1) to recognize that an HMO need not enter into formal contracts with all possible specialists (see paragraph 46 above). Subpart 2.B.(2), as originally proposed, already refers to the provision of specialty services to which enrollees do not have continued access through contracts "or other arrangements."

49. In order to be consistent with the modification made in the definition of "medically necessary care," the Department has substituted the phrase "practice parameters" for "principles of practice" in subpart 2.B.(3).

Subparts 2.C. and 2.D. - Hospital Services and Ancillary Services

50. In its post-hearing comments, the Department revised the proposed rules to substitute the phrase "practice parameters" for "principles of practice."

Subpart 2.E. - Outpatient Mental Health and Chemical Dependency Services

51. This subpart of the proposed rules requires, *inter alia*, that HMOs contract with or employ sufficient numbers of qualified providers of outpatient mental health and chemical dependency services to meet the projected needs of their enrollees consistent with generally accepted principles of practice. 2/ Subpart 2.E.(1) of the proposed rules indicates that services for persons with chemical dependency problems "shall be provided by outpatient treatment programs licensed by the Minnesota Department of Human Services ("DHS") under parts 9530.5000 to 9530.6500 [relating to outpatient alcohol and drug treatment programs] or by hospitals licensed under chapter 4640." Several persons, including the Director of Eden Programs and the Director of the Center for Public Policy of the Hazelden Institute, commented that this provision of the proposed rules may be read to imply that HMOs need not cover services provided at licensed residential treatment programs such as Hazelden. These individuals noted that other rule provisions promulgated by the DHS authorize the licensure of chemical dependency rehabilitation programs provided in residential facilities and emphasized that the use of such facilities is cost-effective in many situations and appropriate for people with certain presenting conditions. The Department clarified during the hearing and in its post-hearing comments that it was not its intent to imply that HMOs were precluded from covering licensed residential treatment services when such programs are the most appropriate placement for HMO enrollees. To clarify its intent, the Department modified the proposed rules to add a new subpart following subpart 2.E. addressing residential treatment programs:

> F. The health maintenance organization shall contract with residential treatment programs licensed by the Department of Human Services under parts 9530.4100 through 9530.4450 to provide services to people with alcohol and other chemical dependency problems.

This issue was the subject of substantial discussion at the hearing. The Department made it clear at the hearing that it did not intend to preclude coverage of services provided by residential treatment programs. No one present at the hearing or submitting comments following the hearing raised any objection to the coverage of services provided by residential treatment programs or to the Department's proposed revision. The proposed rules, as modified, are needed and reasonable to clarify the coverage of chemical

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2/ In drafting its post-hearing revisions, the Department apparently overlooked the reference in subpart 2.F. to "principles of practice." This phrase should be changed to "practice parameters."

dependency services. The modification does not constitute a substantial change from the rules as originally proposed. 3/

52. As originally proposed, subparts 2.E.(1) and (3) of the rules required that services for people with alcohol and other chemical dependency problems be provided by DHS-licensed hospitals or outpatient treatment programs, and that outpatient mental health services be provided by licensed psychiatrists, psychologists, social workers, marriage and family therapists, and psychiatric nurses and by DHS-licensed mental health centers and clinics. Medica, NWNL, and several other commentators objected to these provisions on the grounds that HMOs may thereby be prevented from contracting with non-licensed providers who are otherwise qualified. While the Department indicated in its post-hearing comments that it continues to believe that it is preferable to use licensed counselors or programs, it revised the proposed rules to permit exceptions if necessary to make certain services available. As revised, subpart 2.E.(4) would provide as follows:

> (4) The health maintenance organization, either directly or through its contracted mental health or chemical dependency provider, shall have available services that are culturally specific or appropriate to a specific age, gender, or sexual preference. If any of these services cannot be provided by licensed providers and programs, the health maintenance organization shall file a request for an exception to the requirements of Subparts (1) through (4). A request for an exception shall be considered a filing under part 4685.3300. The health maintenance organization shall submit specific data in support of its request.

(New language underlined.) The proposed rules, as modified, have been shown to be needed and reasonable to clarify the HMO's responsibility to provide outpatient mental health and chemical dependency services, eliminate confusion regarding the nature and scope of those services, and provide for the filing of exception requests. The modifications serve to clarify the proposed rules, satisfy the concerns of interested persons participating in the rulemaking hearing, and do not result in a rule which is substantially different from that originally proposed.

53. Group Health and MedCenters also expressed concern about the manner in which the requirement in subpart 2.E.(4) that HMOs have available services that are "culturally specific or appropriate to a specific age, gender, or sexual preference" may be applied and suggested adding the phrase, "to the extent reasonably possible and professionally advisable." The Department did not discuss this concern in its post-hearing comments. Although the Department should consider the suggestion, the proposed rules are not rendered

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3/ The Department may wish to consider making a change in the language of subpart 2.F. to incorporate a requirement that the HMO "provide directly, contract for or otherwise arrange for" residential treatment programs. Such a revision would be similar to the modification made by the Department to part 4685.1010, subpart 2.B. discussed in paragraph 46 above, and would not constitute a substantial change.

unreasonable by their failure to incorporate the language recommended by Group Health and MedCenters.

Subpart 2.F. (renumbered 2.G.) - Emergency and Urgently Needed Care

54. As originally proposed, subpart 2.F. required HMOs to contract for emergency care and urgently needed care to be available and accessible within the HMO's service area 24 hours a day, seven days a week. Group Health, MedCenters, and NWNL suggested that the rules be revised to indicate that HMOs may "provide directly or contract for" such services, in recognition that HMOs may provide some urgently needed care through their own clinics. The Department revised the proposed rules accordingly. In addition, the Department renumbered the subpart 2.G. due to the addition of a new subpart 2.F., as discussed in paragraph 51 above. 4/ The Department has shown that the proposed rules, as modified, are needed and reasonable to clarify the obligation of HMOs to provide emergency and urgent care to their enrollees and do not result in a substantial change.

Subpart 2.H. (renumbered 2.I.) - Routine Referrals to Participating Providers

55. This portion of the proposed rules requires that HMOs implement a system that assures that routine referrals are made to participating providers. It further requires that enrollees may not be held liable if the HMO provider erroneously gives a referral to a nonparticipating provider. The Office of Ombudsman for Older Minnesotans supported the language of the proposed rules that specifies that enrollees are not liable when erroneous referrals are made. NWNL suggested that the rules specify that the referral must be in writing. Group Health and MedCenters indicated that the rules should state that the referral must be made to a participating provider "to the greatest extent possible." The Department declined to revise the language of the proposed rule. It emphasized that the definition of "referral" contained in the proposed rules refers to referrals as "prior written authorizations" and requires that referrals be in writing. The SONAR indicates that the proposed rules are intended to "require the HMO to implement a sytem 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." The Department thus may wish to consider adding the language suggested by Group Health and MedCenters in order to clarify this intent. The proposed rules as originally drafted are not, however, rendered unreasonable by their failure to include the suggested language, and have been shown to be needed and reasonable to avoid enrollee confusion and complaints.

4/ As discussed in paragraph 46 and footnote 3 above, the Department may wish to revise the language of the rules to state that the HMO may provide directly, contract for or otherwise arrange for emergency care and urgently needed care. Such a change would not constitute a substantial change from the rules as orginally proposed.

Subpart 3 - Geographic Accessibility

56. Subpart 3 of the proposed rules generally requires that the maximum travel distance or time within the HMO's service area to the nearest primary care provider or general hospital provider be the lesser of 30 miles or 30 minutes, and that the distance or time to the nearest provider of all other health services (including specialty physician services, ancillary services, and specialized hospital services) be the lesser of 60 miles or 60 minutes. These requirements do not apply when enrollees are referred to referral centers. The proposed rules permit an HMO to obtain an exception to the geographic accessibility requirements if it can demonstrate with specific data that the requirements are not feasible in the particular service area.

57. Group Health and MedCenters suggested that the intent of the rules be clarified by referring to "average driving time." The Department pointed out that many enrollees take public transportation to medical appointments and declined to make the suggested change. The Department's refusal to incorporate the proposed modification in the proposed rules has a rational basis and does not render the proposed rules unreasonable.

58. Group Health, MedCenters, and UCare suggested that the 60 mile/60 minute requirement contained in subpart 3.B. be changed to 75 or 100 miles/minutes for outstate Minnesota rather than requiring HMOs to apply for an exception. Although the Department acknowledged in its post-hearing comments that specialty services may not be readily available in outstate Minnesota, it declined to make the suggested change. The Department indicated that the ability to establish a provider network within the service area is a basic requirement for HMOs and stated that HMOs should not be approved for a particular geographic area if a network of specialty physicians and ancillary services cannot be established within a reasonable distance. The Department further noted that, because access to specialty services in outstate Minnesota may be addressed by the "integrated service network" initiative being considered by the Minnesota Health Care Commission, it is reluctant to promulgate rules that might conflict with such standards. The Department emphasized that the standards established in subpart 3 would apply to health plans applying for approval in a new service area and new health plans seeking certificates of authority, and indicated its willingness to add language to the subpart to "grandfather in" all currently approved service areas. It is reasonable and not unduly burdensome to require HMOs to request an exception for specific services that are not available within 60 miles or 60 minutes. The Administrative Law Judge believes that it would be helpful if the proposed rules contained additional language which clearly indicated that currently approved service areas are not subject to the geographic accessibility requirements. The addition of such language would not constitute a substantial change from the language of the rules as originally proposed.

59. Metropolitan Health Plan suggested that subpart 3.C. be modified to allow exceptions when an enrollee selected an HMO with full knowledge that it had no participating providers within 30 miles of the enrollee's residence. In response, the Department proposed modifying the language of subpart 3.C. to indicate that items A and B do not apply when enrollees are referred to referral centers "or when enrollees have chosen a health plan with full knowledge that the health plan has no participating providers within 30 miles or 30 minutes of the enrollee's place of residence." The proposed rules, as modified, are needed and reasonable to clarify that persons who reside outside

the HMO's service area may choose to enroll or to elect their continuation rights. The modifications made do not constitute a substantial change from the rules as originally proposed.

Subpart 4 - Exceptions for Access to Care and Geographic Accessibility

60. Subpart 4 sets out a procedure by which HMOs may request exceptions to the requirements of the proposed rules with respect to access to care and geographic accessibility. Group Health and MedCenters contended that the exception process would be unduly burdensome and that the proposed rules do not provide sufficiently clear direction regarding what data would be sufficient to support a request for an exception. The Department declined to modify the language of the proposed rules. The proposed rules identify several factors which shall be considered by the Commissioner in granting a request for an exception, such as utilization patterns and projections, the HMO's financial ability to pay charges for health care services that are not provided by HMO employees or pursuant to contracts, and the HMO's system of documentation of authorized referrals to nonparticipating providers. By providing guidance regarding the factors to be considered by the Commissioner, the proposed rules provide some indication of the data to be submitted by HMOs in support of their requests for exceptions. Moreover, the proposed rules indicate that exception requests shall be considered filings under part 4685.3300 of the existing rules. That rule part requires the Commissioner to specify the supporting information required in any letter disapproving the filing for failure to supply adequate supporting information and permits the HMO to refile the additional information as an amended filing. The proposed rules thus contain sufficient guidance and safeguards to ensure that HMOs will be made aware of the types of supporting information that will provide a basis for the granting of an exception under the subpart. The proposed rules have been shown to be needed and reasonable as originally drafted.

Subpart 5 - Coordination of Care

61. Subpart 5 of the proposed rules was modified following the hearing to substitute the phrase "primary care providers" wherever the phrase "primary care physicians" appeared, in accordance with the modifications made to subpart 2.A. above. This revision was discussed in Finding 35 above (relating to the definition of "primary care physician"). The modification was made in response to public comment and has been found to be needed and reasonable.

62. UCare suggested that the language of subparts 5.A. and B. be revised to clarify that the health plan itself may provide necessary referrals, and proposed that the phrase "when feasible or appropriate" be added to these subparts. The Department agreed that the rules should permit the health plan itself to make referrals but determined that the language suggested by UCare would not accomplish this goal. The Department thus has proposed to modify the second sentence of subpart 5.A. to state as follows: "In plans in which referrals to specialty physicians and ancillary services are required, the primary care providers or the health maintenance organization shall initiate the referrals." The Department has demonstrated that the proposed rules, as modified, are needed and reasonable to set forth coordination of care standards. The modification clarifies the proposed rules and does not constitute a substantial change.

63. As modified in the Department's post-hearing comments, the fourth sentence of Subpart 5.A. states, "If requested by an enrollee, or if determined necessary because of a pattern of inappropriate utilization of services, an enrollee's health care may be supervised and coordinated by the primary care provider." Group Health and MedCenters suggested that this sentence state, "If a health maintenance organization utilizes a gatekeeper approach for all enrollees, if specifically requested by an enrollee, or if determined necessary . . . ." The Department declined to make the requested revision because the term "gatekeeper" is not defined or used elsewhere in the statute or rules and because it believes that the gatekeeper model is already addressed by virtue of the reference in the second sentence of the subpart to plans "in which referrals to specialty physicians and ancillary services are required." The Administrative Law Judge finds that the proposed rules are not rendered unreasonable by their failure to include the suggested language.

Subpart 6 - Timely Access to Health Care Services

64. In accordance with the revised definition of "medically necessary care," the Department has revised subpart 6.A. to substitute the phrase "practice parameters" for "principles of practice." This revision was discussed in Finding 30-32 above and has been found to be needed and reasonable and not a substantial change from the rules as orginally proposed.

65. The Minnesota Chiropractors Association suggested that the Department add language to subpart 6 to clarify that the provision only addresses the issue of timeliness of access. The Department agreed that such a revision would be proper and modified the language of subpart 6.A. in its post-hearing comments to provide that the HMO (directly or through its provider contracts) shall arrange for covered health care services "to be accessible to enrollees on a timely basis in accordance with medically appropriate guidelines . . . ." The Association also suggested that additional language be added to the proposed rules to clarify that the "medically appropriate guidelines" to which the rules refer "may be those adopted for use by a national or state health care society and approved by the commissioner of health or state examining board." No other commentators recommended clarification of the meaning of "medically appropriate guidelines" and the Department did not address the concern in its post-hearing comments. The proposed rule, as modified, has been shown to be needed and reasonable to clarify the accessibility requirements. The revision does not result in a rule that is substantially different from that originally proposed. While the proposed rules cannot be said to be unreasonable without the additional language proposed by the Minnesota Chiropractic Association, the Department should consider the Association's comment and may add clarifying language to the rule if it sees fit.

66. Subpart 6.B. of the proposed rules requires that HMOs or their participating providers have appointment scheduling guidelines based on type of health care service. Metropolitan Health Plan commented that the proposed rules would improperly require the health plan to dictate to providers the type of appointments they should have as part of their practice, and asked that the language be stricken from the proposed rules. The Department declined to modify or delete this provision of the proposed rules. The Department indicated in its post-hearing comments that the proposed rules would not require HMOs to dictate appointment schedules to their providers but

would merely require HMOs to ensure that their providers have their own appointment scheduling guidelines. Based upon statutory provisions governing HMOs, it is reasonable to conclude that HMOs have both the authority and the responsibility to determine that their providers have a reasonable basis for scheduling appointments. See, e.g., Minn. Stat. §§ 62D.04, subd. 1(a) (1992) (requiring HMOs to demonstrate their potential ability to assure the availability and accessibility of adequate personnel and facilities) and 62D.14, subd. 3(a) (1992) (authorizing evaluation by the Commissioner of Health of the appropriateness and timeliness of services performed with respect to the dealings of participating entities with HMOs). The proposed rule is needed and reasonable to provide guidance for the Commissioner's evaluation of the timeliness of services.

67. UCare suggested that alternative language be included in subpart 6.B. which would require that HMOs or their participating providers have a system for review of appointment availability which is based on the type of health care service in order to ascertain access to preventive, primary care, and specialty care for HMO members. The Department declined to modify the language as suggested by UCare because it believes that the language of the proposed rule is more precise. The Department stressed that the rule as originally proposed would require actual appointment scheduling guidelines that the Department could review in an audit rather than the self-monitoring proposed by UCare. The Department has justified the reasonableness of the approach used in subpart 6.B.

Subpart 7 - Access to Emergency Care

68. As written, the proposed rules require coverage of medically necessary emergency care regardless of whether the care is provided by participating or non-participating providers. The Office of Ombudsman for Older Minnesotans expressed support for language of the proposed rules, particularly the provisions which recognize that the enrollee may not be physically or mentally able to provide notice of an emergency situation to an HMO, require that coverage be afforded even where no notice is given if the care would have been covered if notice had in fact been given, and identify factors to be considered in determining whether care is reimbursable as emergency care. Medica suggested at the public hearing that the rule distinguish between emergency care provided by participating providers and that provided by non-participating providers. It did not supply suggested language. The Department indicated in its post-hearing comments that it was unsure what changes Medica would like to see in the proposed rules and declined to modify them under the circumstances.

69. Group Health and MedCenters suggested that language should be added to the proposed rules permitting HMOs to terminate coverage at the point that an enrollee would have been transferred to a participating hospital had notice been provided. The Department declined to modify the proposed rules because it found the suggested language to be confusing and because it felt that the concern has been addressed in subpart 7.B. Pursuant to that subpart, HMOs may require an enrollee to provide notice no later than 48 hours after becoming physically or mentally able to give notice. The Department indicated that the intent of subpart 7.B.(1) and (2) is to permit HMOs to deny coverage to enrollees who fail to give timely notice despite their ability to do so at the point at which the enrollee was stable and could have been transferred to a participating provider.

70. Preferred One suggested that "urgent care" should be covered only in contracting facilities when provided within the plan's service area and should be covered in non-contracted facilities when the enrollee is outside of the service area. The Department indicated that Preferred One's comment was not relevant to this subpart of the proposed rules since it only relates to access to emergency care and not care provided at urgent care facilities.

71. As proposed, the rules provide that, in determining whether care is reimbursable as emergency care, HMOs must consider (among other factors) "a reasonable person's belief that the circumstances required immediate medical care that could not wait until the next working day or next available clinic appointment." NWNL commented that the "reasonable person" standard in the proposed rules is vague and difficult to define with precision. It expressed a concern that most enrollees who use emergency rooms inappropriately could easily state that they reasonably believed they did the right thing. The Department disagreed and declined to modify the proposed rules based upon its view that the reasonable person standard is objective, commonly used, and generally understood.

72. The Department has demonstrated that the proposed rules are needed and reasonable to reduce uncertainties and conflicts between HMOs and enrollees regarding coverage for emergency care. Because the nature of Medica's recommendation was unclear and the comment of Preferred One was not pertinent to this rule provision, the rules cannot be said to be unreasonable by virture of their failure to respond to those concerns. While the Department may wish to consider modifying subpart 7.B. along the lines suggested by Group Health and MedCenters to clarify its intent, the rule is reasonable without the additional language. Finally, the reference in the rules to the "reasonable person" standard is not found to result in an unduly vague or imprecise standard. Although the proposed rules will require a case-by-case consideration of each factor set forth in subpart 7.E., including a consideration of what a reasonable person would have believed under the circumstances, the "reasonable person" standard is a frequently-used legal standard which, by requiring the application of an objective rather than a subjective test, looks beyond the particular sensibilities of the individual involved. Moreover, the proposed rules set forth several other factors which must be examined by the HMO in determining whether care is reimbursable as emergency care.

<u>Subpart 8 - Continuity of Care in the Event of Contract Termination</u>

73. Subpart 8 of the proposed rules requires that HMOs have a written plan that provides for continuity of care where primary care providers or general hospital providers terminate their participation with the HMO. The proposed rules require HMOs to develop a system to notify enrollees of the termination or site closing, accomplish an orderly transfer to new providers, and identify at-risk enrollees to enable their special needs to be met. The Office of Ombudsman for Older Minnesotans indicated that it would support additional language in the rule placing an obligation on the HMO to coordinate discharge planning for the individual enrollee. The Department did not discuss this suggestion in its post-hearing comments. In the SONAR, the Department stated that subpart 8 merely requires that HMOs develop systems to deal with continuity of care issues and was not intended to tell an HMO how to handle these issues. The proposed rules have been shown to be needed and

reasonable as written. While the Department may wish to consider the suggestion of the Office of Ombudsman in future rulemaking, the proposed rules are not rendered unreasonable by failing to incorporate additional continuity of care requirements.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Minnesota Department of Health ("the Department") gave proper notice of this rulemaking hearing.

2. The Department has fulfilled the procedural requirements of Minn. Stat. §§ 14.14, subds. 1, 1a and 2 (1992), and all other procedural requirements of law or rule so as to allow it to adopt the proposed rules.

3. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3, and 14.50 (i) and (ii) (1992).

4. The Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.50 (iii) (1992).

5. The additions and amendments to the proposed rules that were suggested by the Department after publication of the proposed rules in the State Register do not result in rules that are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3 (1990), and Minn. Rules pts. 1400.1000, subp. 1, and 1400.1100 (1992).

6. Any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

7. A finding or conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon an examination of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules be adopted consistent with the Findings and Conclusions made above.

Dated this 5th day of February, 1993.

Barbara L. Neilson

BARBARA L. NEILSON
Administrative Law Judge

Reported: Tape Recorded (No Transcript Made)