

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules of the State THE Health Department Governing Health MAINTENANCE ORGANIZATION QUALITY EVALUATION AND COMPLAINT SYSTEMS, MINNESOTA RULES CHAPTER 4685.

REPORT OF ADMINISTRATIVE LAW-JUDGE

A public hearing in this matter was held before Administrative Law Judge Allan W. Klein on Friday, May 26, 1989, in Minneapolis. This Report is part of a rule hearing proceeding held pursuant to Minn. Stat. §§ 14.131 - 14.20 to determine whether the Department has fulfilled all relevant substantive and procedural requirements of law, whether the proposed rules are needed and reasonable, and whether or not the rules, if modified, are substantially different from those originally proposed.

John A. Breviu, Assistant Attorney General, 136 University Park Plaza, 2829 University Avenue Southeast, Minneapolis, Minnesota 55414, appeared on behalf of the Minnesota Department of Health (hereinafter the "Department"). Also appearing in support of the proposed rules were Dawna L. Tierney, Robin P. Lackner, and Kent E. Peterson. The hearing continued until all interested groups and persons had an opportunity to testify concerning the adoption of the proposed rules.

The Department must wait at least five working days before taking any final action on the rules; during that period, this Report must be made available to all interested persons upon request.

Pursuant to the provisions of Minn. Stat. § 14.15, subd. 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings

of this Report, he will advise the Department of actions which will correct the defects and the Department may not adopt the rule until the Chief Administrative Law Judge determines that the defects have been corrected. However, in those instances where the Chief Administrative Law Judge identifies defects which relate to the issues of need or reasonableness, the Department may either adopt the Chief Administrative Law Judge's suggested actions to cure the defects or, in the alternative, if the Department does not elect to adopt the suggested actions, it must submit the proposed rule to the Legislative Commission to Review Administrative Rules for the Commission's advice and comment.

If the Department elects to adopt the suggested actions of the Chief Administrative Law Judge and makes no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, then the Department may proceed to adopt the rule and submit it to the Revisor of Statutes for a review of the form. If the Department makes changes in the rule other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, then it shall submit the rule, with the complete record, to the Chief Administrative Law Judge for a review of the changes before adopting it and submitting it to the Revisor of Statutes.

When the Department files the rule with the Secretary of State, it shall give notice on the day of filing to all persons who requested that they be informed of the filing.

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

FINDINGS Of FACT

Procedural Requirements

1. On March 31, 1989, the Department filed the following documents with the Chief Administrative Law Judge:

- (a) A copy of the proposed rules certified by the Revisor of Statutes.
- (b) The Order for Hearing.
- (c) The Notice of Hearing proposed to be issued.
- (d) A Statement of the number of persons expected to attend the hearing and estimated length of the Agency's presentation.
- (e) The Statement of Need and Reasonableness.

2. On April 17, 1989, a Notice of Hearing and a copy of the proposed rules were published at 13 State Register 2495.

3. On April 18, 1989, 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 such notice.

4. On April 25, 1989, the Department filed the following documents with the Administrative Law Judge:

- (a) The Notice of Hearing as mailed.
- (b) The Agency's certification that its mailing list was accurate and complete.
- (c) The Affidavit of Mailing the Notice to all persons on the Agency's list.
- (d) An Affidavit of Additional Notice.
- (e) The names of Department personnel who will represent the Agency at the hearing together with the name of one witness solicited by the Agency to appear on its behalf.

- (f) A copy of the State Register containing the proposed rules.
- (g) All materials received following a Notice of Intent to Solicit Outside Opinion published at 12 State Register 1109, published

on

November 23, 1987, and a copy of the Notice.

The documents were available for inspection at the Office of Administrative Hearings from the date of filing to the date of the hearing.

5. The record remained open for the submission of initial written comment and statements until June 15, 1989. The record finally closed on June 20, 1989, at the end of the response period.

Statutory Authority

6. The Department has cited Minn. Stat. §§ 62D.20; 62D.03, subd. 4; 62D.04, subd. 1; and 62D.11 as authority for adopting these rules. Only one of these, however, authorizes the adoption of rules -- the rest authorize the Commissioner to impose certain requirements or require the HMOs to follow certain procedures. The one provision that directly authorizes rules, however, is very broad. Minn. Stat. § 62D.20, subd. 1 provides, in pertinent part:

The Commissioner of Health may, pursuant to Chapter 14, promulgate such reasonable rules as are necessary or proper to carry out the provisions of Sections 62D.01 to 62D.30. Included among such rules shall be those which provide minimum requirements for the provision of comprehensive health maintenance services . . . and reasonable exclusions therefrom

Except where specifically noted below, it is found that Minn. Stat. § 62D.20, subd. 1 provides the Commissioner with authority to adopt the proposed rules.

Small Business Consideration

7. The Minnesota Medical Association is concerned about the impact of these rules on smaller physician clinics. It is particularly concerned about a situation where a physician clinic contracts with three or four HMOs, and each of the HMOs wants to do focused studies in three or four areas. The Association is concerned that having to provide input into a minimum of three focused studies annually from each HMO could completely monopolize the time of the professional and administrative staff, and disrupt the provision of patient care. The Association argues that the Statement of Need and Reasonableness fails to address the impact of these studies on physician clinics which serve as HMO providers, and the Department has, therefore, failed to comply with Minn. Stat. § 14.115.

8. The Department has relied on the exception contained in Minn. Stat. § 14.115, subd. 7(b). It takes the position that its rules do not affect

physician clinics directly, but instead they are affected only indirectly. The Department argues that the degree of effort required by an HMO from a provider clinic can be negotiated between them.

9. The Administrative Law Judge agrees with the Department. The rules require that focused studies be completed by the HMO. Part 4685.1125, subp. I and Part 4685.1130, subp. 26. While an HMO may delegate certain quality assurance activities to providers, review organizations, or other entities, there is nothing that requires those entities to assume responsibility for the activities if they do not want to. It is concluded that they are not directly affected by these rules, and thus the agency did not have to consider methods for reducing the impact of the rules on them.

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10. The proposed rules are divided into two distinct parts. The first part establishes an outline of requirements for Quality Assurance (QA) programs. The second part modifies existing rules for complaint systems. The QA rules consist of Parts 4685.1100 - .1130, while the complaint rules consist of Parts 4685.0100, and Parts 4685.1700 - .2100.

11. There are many rules which received little or no negative comment, or where the negative comment received suggested that the rule was just an example of a broader problem (such as inflexibility). Such rules will not be discussed here. Instead, discussion will be reserved for rules where there was a serious question raised with regard to the Department's statutory authority to adopt a proposed rule, its reasonableness, or some other matter which cast out upon the Department's legal ability to adopt it. All of the comments have been read and cataloged, but except as expressly noted below, it is found that the Department has justified the need for and reasonableness of its proposals, that the proposals are statutorily authorized, and that there is no other problem preventing their adoption.

QUALITY-ASSURANCE RULES

General Concern: Too Much Bureaucracy?

12. A number of commentators found the proposed Quality Assurance rules to be too specific, too rigid and too negative. They felt that quality assurance was still in its infancy, was still an "art" rather than a "science", and that these rules sacrificed creativity and flexibility in favor of an audit trail of superficial paperwork.

The Minnesota Medical Association admitted that the proposed rules represent policy decisions and that they need not necessarily be the "right" or "best" choice -- merely a reasonable one. In this particular area, however, they argued that inflexible rules may have an overall negative impact, in spite of their "statutory reasonableness".

Blue Plus, for example, described the development of a recent program to review ambulatory care prior to hospitalization. Blue Plus joined the Department of Health, SHARE Health Plan and Group Health, Inc. in a three-year project. The project was heralded nationally as a "breakthrough" in health plan approaches. Blue Plus fears that if these rules are adopted, the paperwork and effort required by the rules will severely restrict its ability to participate in creative and novel experiments. Ex. 43.

A similar comment was expressed by Quality Assurance Professionals of Minnesota (QAPM), who attached to their comments a letter published in the New England Journal of Medicine. Ex. 34. The letter described two assembly lines, monitored by two foremen. One of the foremen followed the "Theory of Bad Apples", threatening the workers with discipline and firing once he discovered which of them were the "bad apples". The other foreman, in contrast, told the workers he was there to help them, that they were in this job together for the long haul, and that they would all benefit if they could come up with new ways to improve performance. His method was called the "Theory of Continuous

Improvement". The thrust of the letter in the Journal was that federal and state regulators who chose to regulate by the first theory were doing a tremendous disservice to providers and patients, and that regulators who had the courage to follow the second theory would end up with a far better health care system.

13. Which of the two systems to use, and how much "audit trail" record-keeping will be required, is a fundamental policy choice which is appropriately made by the Commissioner. So long as there is a rational basis for an administrator's choice from reasonable alternatives, it is inappropriate for a judge to reject it just because there may be a "better" alternative. So long as the approach chosen is a reasonable one, the Commissioner is free to exercise her discretion. *Manufactured Housing Institute v. Petersen* 347 N.W.2d 238 (Minn. 1984); *Broen Memorial Home-v. Minnesota Department of Human Services*, 364 N.W.2d 436, 440 (Minn. App. 1985).

Quality Evaluation

14. The Minnesota Chiropractic Association (MCA) suggests that proposed Part 4685.1100, which says that the Commissioner or HMOs may conduct enrollee surveys, should require surveys to be mandatory, conducted at least once every three years, and developed and approved by a consumer committee.

15. The Department agrees that enrollee surveys are an important tool, but does not support making them mandatory because that would be contrary to the Department's desire to make the rules as flexible as possible. It is concluded that the Department's position is reasonable. Moreover, there is no problem with the use of the word "may" in this circumstance because it does not result in illegal discretion for the Commissioner. The provision merely allows the Commissioner to conduct surveys herself if she desires to. It does not require the HMO to conduct them.

it Assurance Program

16. NWNL raised a concern about whether subpart 2 of Part 4685.1110 would require disclosure of proprietary or other "inappropriate" information in public documents. MMA joined with that concern, pointing out that Minn. Stat. §§ 145.61 to 145.67 (the so-called "peer review" statute) might be violated by subpart 8 of this rule and subpart 7B of Part 4685.1700. PHP had similar concerns. A number of HMOs suggested the word "appropriately" be inserted in front of the word "delineated".

17. The Department responded that there is no inconsistency between the peer review statutes and any of the proposed rules. The proposed rules require documentation to show that the HMOs' board, being ultimately responsible for the management of the HMO, has reviewed and approved the QA activities. The Department assumes that the concern arises from Minn. Stat. § 145.64, which requires information acquired by a review organization to be held in confidence "except to the extent necessary to carry out one or more of the purposes of the review organization". The Department reasons that under Minn. Stat. § 62D.04, subd. 1(b) and (c), HMOs are required to provide for ongoing evaluation of quality of care and reporting of the results. Thus, it concludes, the QA

function of an HMO is intended to benefit the HMO and its enrollees through dissemination of the findings and conclusions of the QA program and that the program "may not be cloaked with a shroud of secrecy within the HMO." The Department concludes that nothing in Minnesota law suggests that the board of an HMO must be treated like an outsider and prevented from having access to its own Quality Assurance information.

18. MedCenters raised concerns regarding the Department's post-hearing comments on the peer review statute protections, including the possibility that a complainant is entitled to know the results of any peer review of the care delivered to the complainant. They believe that the Department's stance could have grave effects on an HMO's ability to conduct peer review. MedCenters' QA committee is structured as a review organization defined in Minn. Stat. 145.61, subd. 5. As such, it expects to benefit from the protection of 145.64, which says that the proceedings and records of a review organization shall not be subject to discovery. MedCenters agrees that it is important to keep the board of directors informed about QA activities, but still believes that the statute limits who can be on a QA committee (because it is a review committee) and who can have access to the committee's confidential information. They believe that these rules should clearly state that QA information is confidential and that HMOs cannot be required to disclose it to enrollees. MMA and MHA are also concerned that the protection of the review organization statute would be lost or otherwise reduced as a result of these rules.

19. The Administrative Law Judge finds that the purposes of Minn. Stat. 145.64 would indeed be frustrated if QA committees or complaint review committees that qualified as review organizations were required to disclose their data and information. The Department is correct that the statute allows disclosure to the extent necessary to carry out the organization's purposes; but they have not demonstrated why such disclosure is necessary or should be

made necessary by these rules. For example, why should it be necessary that any member of an HMO's board of directors know the details of a particular review of a provider's provision of care? Any implication that such disclosure is required has not been demonstrated to be needed or reasonable. On the other hand, the HMO's want to extend the protection of the review organization statute to organizational matters such as authority, function and responsibility. The review organization statute does not apply to such information. The Administrative Law Judge recommends that a provision be added to the Quality Assurance rules (and to the complaint process rules as well) to the effect that nothing therein requires the disclosure of data and information acquired by a review organization in violation of Minn. Stat. § 145.64. In summary, it is found that the rule, as proposed, does not conflict with the statute but that confusion and wasted effort could be avoided by the insertion of a qualifying statement to the effect that the rule does not require the statute to be violated.

20. MCA suggested that in areas where health care professionals other than physicians are responsible for treatment, a member of that discipline should be designated to oversee that segment of the QA program, rather than a physician, as required by subpart 4 of Part 4685.1110. The Department disagrees, explaining that the physician is the "gate keeper" of an HMO's health care system. The Department acknowledges that most persons conducting QA activities have a nursing background, and that trained evaluators are able to evaluate activities even though not trained (or licensed) to conduct the

activities themselves. Requiring all segments of the QA program to be overseen by professionals in each segment would be unmanageable, and could result in line-drawing disputes that would serve no useful function. The Administrative Law Judge finds the Department has justified its position of requiring a physician to oversee the QA program.

21. Subpart 9 of the proposed rules deals with evaluation of enrollee complaints. NWNL, SHARE and MedCenters suggest a language change that would improve some awkward phraseology in the existing language. They propose that subpart 9 be revised to read as follows:

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

The Department should consider this suggestion, but is not required to adopt it in order to have the rule found to be reasonable.

22. Subpart 11 of the proposed rule relates to provider credentials and selection. It generated a fair amount of comment because it attempts to deal with a broad range of providers, from those which are highly regulated and "credentialed", to those who are not. As proposed, it requires an HMO to have policies and procedures for "provider selection and credentials". QAPM suggests that "qualifications" should be substituted for "credentials" in this rule because that would more clearly convey the intent of the rule. MMA thought that the use of the word "credentials" implied that physicians must be board certified or board eligible. The Department thinks that the rule is clear in describing its intent -- that the HMO have a system for contracting with acceptable providers. The Administrative Law Judge finds that the rule, as written, is reasonable but that the QAPM suggestion would improve the clarity of the rule and avoid some of the confusion reflected in the comments. The Department should consider it for adoption.

23. Subpart 12 of the rule, relating to qualifications of HMO staff or contractees involved in QA activities, was criticized as being vague and standardless. The Department responded that it was attempting to be flexible, yet draw attention to the need for qualified personnel. The Administrative Law Judge concludes that given the broad variety of people who are involved in QA activities, the Department is justified in not setting specific, detailed standards. The Department has justified its approach as reasonable under the circumstances.

24. Subpart 13 appears to have a typographical error in paragraph A. That paragraph current requires an HMO to implement a system "to assess that medical records are maintained" appropriately. A number of commentators suggested that the word "assess" was intended to be either "assure" or "ascertain whether". PHP points out that HMOs are not capable of implementing

medical record systems, but that they can contractually require changes by their providers when they determine that medical records are not being maintained properly. The Administrative Law Judge assumes that this is a typographical error, and that "assess" was intended to be "assure". Simply assessing or ascertaining doesn't sufficiently imply any duty to be sure that the records are maintained properly.

Quality Evaluation Activities

25. Subpart 1 of proposed Part 4685.1115 requires an HMO to conduct quality evaluation activities according to the steps set forth in another rule. The quality evaluation activities must address "each of the components" of the HMO described in another rule (which sets forth 11 clinical components, eight organizational components, and three consumer components, for a total of 22 components). Blue Plus suggests that this subpart should be modified to require the QA activities to "consider", rather than "address", each of the components listed, and then the HMO should be required to "decide on the priority components to be addressed in any given year's plan". The Administrative Law Judge finds that this proposal would resolve many of the concerns discussed earlier about rigidity, and also discussed below under Part 4685.1130, subp. 2.A., and recommends that the Department consider it for adoption. However, to the extent that the Department has made a policy choice to require that each of the components be addressed, it has justified that as a reasonable alternative. The Department may maintain the rule in its current form, or it may consider the suggestion of Blue Plus. Either is reasonable, and it is within the Department's discretion to choose either.

26. Subpart 2 of the rule defines the scope of the evaluation by listing the 22 components referred to above. A number of commentators made recommendations for additions or deletions. The Chiropractic Association urged that a component relating to services requested, but not provided, be added to

the list. The Medical Association responded that this would essentially call for HMO policy to be set on the basis of enrollee desires as opposed to deliberative efforts by the HMO to ascertain enrollee health needs. The Medical Association suggested that it would allow a concerted effort by a small group of enrollees to drive HMO decision-making. The Administrative Law Judge finds that the rule is reasonable without the addition proposed by MCA.

27. Another proposal for an expansion of the scope relates to residential treatment for emotionally handicapped children. St. Joseph's Home for Children noted that it has been difficult and time consuming to coordinate services for children with HMO providers regarding residential treatment for emotionally handicapped children. The facility pointed out that Minn. Stat. § 62A.151 (the health insurance statute) requires HMOs to cover treatment of emotionally handicapped children in residential treatment facilities, under certain conditions. The facility believes that including the component in the quality evaluation list will remind HMOs of their responsibilities, and avoid the difficulties which the facility has encountered to date. The Administrative Law Judge finds that the rule is reasonable without this addition. While he is sympathetic to the difficulties faced by the facility, the rule cannot be said to be unreasonable without the proposed addition. There would be no reason why the Department could not add it, if it saw fit, but it cannot be required to do so.

28. The Senior Law Project of Southern Minnesota Regional Legal Services urged that a component be added to require evaluation of "appropriate medical training of individuals making or communicating decisions involving coverage and medical necessity". The Project noted that it had received many pieces of anecdotal information from providers who felt that medically necessary services were being denied by HMOs, and that the medical training of some HMO staff members who make or communicate prior authorization decisions has been suspected of being inadequate. Ex. 41. The Administrative Law Judge notes that one of the components requiring study is "prior authorizations, as applicable". The Department indicated that this suggestion was a new issue to it, and was willing to consider it for future rule revision. Ex. 53. The Administrative Law Judge concludes that the rule is not unreasonable without it.

Quality Evaluation Steps

29. Part 4685.1120 sets forth a series of steps which an HMO should follow to identify, prioritize, correct, and evaluate problems or areas for improvement. There were a number of changes proposed for it. The first change came from the Chiropractic Association, which noted that the problem identification procedures omitted the consumer components which are required to be evaluated. They note that the consumer components appear to be left out of this rule. The Department, in post-hearing comments (Ex. 46), agreed with the Association, stating that it had intended to include consumer components as part of the evaluation step. The Department proposes to modify subpart 1.A. of this rule as follows:

- A. Ongoing monitoring of process, structure, and outcomes of patient care of clinical performance- including the consumer components listed-under [part] 4685.1115, Subp. 2.C.; and

The Administrative Law Judge finds that it is reasonable to include consumer components, and that it is not a substantial change.

30. Another point raised by the Chiropractic Association was that the number of complaints was not a factor listed among those to be used in determining priorities. It recommended that if there are 15 or more complaints received on an item within one year, then a problem must be selected for study. The Department believes that it would be too specific and inflexible to set a number such as that for all HMOs, and believes that the proposed addition to the previous subpart would assure that attention is paid to consumer components. The Administrative Law Judge concludes that the rule is reasonable without the addition proposed by the Association.

31. The rule relating to evaluating corrective action drew some comments from HMOs who were concerned about potential violations of the peer review statutes discussed above. As discussed more fully above, it is appropriate to add a proviso to these rules that they do not require the disclosure of data and information acquired by a review organization in violation of Minn. Stat. § 145.64. So long as that is worded to apply to all of the rules (which is recommended), then there is no need to repeat it here again.

32. The Chiropractic Association again points out that complaints are not listed as a factor for selecting topics for focused studies, and suggests that complaints should be a factor. The Metropolitan Senior Federation, in a similar vein, notes that this subpart (which sets forth a list of considerations to be used in selecting topics for focused studies) does not specifically require HMOs to categorize consumer complaints as a problem area. The Department, in post-hearing comments, agrees and proposes to amend the rule by adding a new subpart 2.F. which would read:

F. areas_where complaints have occurred.

33. That change, however, was set forth in Ex. 46, which is the Department's initial post-hearing comment letter. It drew a response from a number of HMOs because the letter also included a related change which the HMOs opposed. However, this other change was not discussed in the letter, and it appears that it may be a typographical error. The rule as initially published allowed HMOs to select topics for focused studies "based on any of the following considerations", and then went on to list five considerations. In the letter agreeing to add complaints as a consideration, the Department set forth the lead-in sentence as requiring HMOs to select topics for focused studies "based on the following considerations". In other words, the Department omitted the words "any of the". A number of HMOs reacted to that omission, and SHARE (Ex. 52) indicated that their agreement with the addition regarding complaints was contingent upon the understanding that the omission of the words "any of the" would be rectified.

34. The Administrative Law Judge finds that the omission of the words from the post-hearing comment is a serious matter. If it was intentional, and if the Department intended to remove the flexibility that was present in the version of the rule as published, then that removal must be viewed as a substantial change. Moreover, the Department has failed to justify the reasonableness of requiring all of the considerations to be present. It would dramatically restrict the areas which could be considered for focused studies. In light of the controversy surrounding focused studies, such a change deserves justification and an opportunity for affected persons to comment on it.

However, the Administrative Law Judge thinks it is more likely that the omission of the words "any of the" was an oversight or typographical error.

Assuming that to be the case, then the question is whether there is any problem with the Department's adoption of the recommendation that complaints be added as a consideration. So long as it is only one of a number of alternative bases, there is no problem with it. It would not be a substantial change, and is a legitimate response to public input.

Filed Written Plan and-Work-Plan

35. This rule, the last of the rules relating to the Quality Assurance program, requires a initial written plan prior to the Commissioner's certification of an HMO, and then annual work plans thereafter. One of the requirements in the subpart relating to the annual work plan is that each HMO

must complete a minimum of three focused studies annually. However, that was not the only provision that drew criticism.

36. The subpart relating to the annual work plan has two separate components. The first component, set forth in paragraph A., requires a detailed description of the proposed quality evaluation activities that will be conducted in the following year. The activities must address all of the 22 components defined in an earlier rule. The second part of the subpart is the part relating to focused studies. It requires that the plan describe the focused studies to be conducted in the following year, and sets forth seven items that are to be included in the description. The subpart ends with the requirement that each HMO complete three focused studies annually. It is important to keep the two parts separate, and not confuse one with the other.

37. With regard to the first part, which requires that the HMO address all 22 components of the health care delivery system, and describe in its annual plan how it is going to do so, virtually all of the HMOs commented said this was just too much. The most common proposal was that each of the components be reviewed at least once every three years, rather than instead of once every year. The Department's post-hearing response clarifies its idea of how this annual review will be accomplished:

If the HMO were permitted to address an area only once every three years, potential problems within major health services such as hospital care, mental health care, and pharmacy services could go undetected for an inordinate amount of time.

It is important to note that the rules do not require the HMO to conduct major initiatives in each of the areas listed. The HMOs must simply have monitoring activities in place which provide data about each of these areas. The quality assurance committee must evaluate the data to be certain there are no problems or deficiencies. If there are no problems, then the HMO need not take corrective actions or conduct focused studies. The basic requirement is that the quality assurance program address in some fashion, each of these major areas of health care services delivered by the HMO.

(Ex. 46, p. 2.) The Administrative Law Judge accepts the Department's explanation of the level of activities which will satisfy the rule. With that explanation, the first part of the annual work plan portion of the rule is found to be justified as both needed and reasonable.

38. The second part of the rule, the one relating to focused studies, also drew criticisms. They will not be repeated here, because they are essentially the same criticisms as were mentioned in an early Finding relating to "too much bureaucracy". The Department has presented facts justifying its selection of three plans per year. The Department has elected to require three each year, rather than two or one. That is a choice which the Department is

entitled to make, without second-guessing from a Judge, so long as it has justified the reasonableness of its choice. I conclude that it has done so.

39. One of the criticisms raised against the Department's proposal on focused studies was that, as originally written, the rule required that the focused study sample "be representative of the total health maintenance organization population". A number of HMOs pointed out that many valid studies would address a problem that only involves a segment of the enrollees, e.g., immunizations of infants. The Department agreed that the rule should be clarified because its initial intent (at page 65 of the Statement of Need and Reasonableness) was to allow studies affecting limited segments of the population. The Department has proposed to amend the sentence to require that the study sample be representative of all HMO enrollees "who exhibit characteristics of the issue being studied". The modified rule is reasonable, and is not a substantial change.

Effectiye DAte

40. MedCenters urged that the effective date of the rules be delayed to allow time for implementation. The Department disagrees with the request. If the rule is adopted in August, HMOs will be required to submit a work plan by November 1 and implement it by January 1, 1990. The Department believes that it can reasonably be done, and if the effective date of the rules were delayed until January 1990, then no work plans would be filed until the following November, and implementation would not begin until January 1991. The Department also notes that HMOs have had drafts of the rules since July of 1988.

41. PHP points out that even if implementation is delayed, HMOs will still be required to continue with Quality Assurance programs which they have in place. SHARE argues that, while the HMOs have had drafts of the rules, they were just drafts and they have been noting the same objections throughout the process. They think that three months to file an annual plan and less than five months to hire additional staff to implement it is too short.

42. The Administrative Law Judge finds that the Department's proposal is reasonable, but suggests that the Department add a provision allowing the Commissioner to grant extensions of the November 1, 1989 filing date for some reasonable period, such as 90 day, upon a showing of good faith efforts to meet the deadlines. This extension provision would only be for this first year.

COMPLAINT_RULES

Requirements for a complaint system

43. The Department has proposed to define a "complainant" as an enrollee, a former enrollee, or "anyone acting on behalf of" an enrollee or former enrollee. Group Health, NWNL, and MedCenters stated that the rule ought to require more specificity regarding who may act on behalf of an enrollee. Group Health suggested that the following be added:

To act on behalf of an enrollee or former enrollee, the complainant's representative must have written authorization from the enrollee or former enrollee, or in the case of a deceased enrollee, must have written authorization from the [personal representative] of the decedent's estate. A parent or legal guardian may act on behalf of a minor without written authorization from the minor.

The Department thinks such a degree of detail is not needed within the rule.

SHARE and Blue Plus suggests the following language:

. . . or anyone [acting] whom the health maintenance organization has determined to be legally empowered to act on behalf of the enrollee

44. The Administrative Law Judge is sympathetic to the legitimate concerns of the HMOs regarding invoking the complaint process too easily. On the other hand, the public interest would be frustrated by imposing too many restrictions on who could file a complaint. Particularly in cases involving broad public interest and publicity, it would be unfair to put the HMO in a position of invoking the process whenever it received "complaints" from persons who had read a newspaper story about a particular case. The Department indicated it would not object if an HMO inserted more stringent requirements in its contract, but that flexibility must be recognized in the rule. It is concluded that the Department's rule is not unreasonable or too vague as written, but that the Department should consider adding language such as "anyone whom the HMO reasonably believes to be acting on behalf of . ." or similar language. The language prepared by SHARE and Blue Plus is another option.

45. Subpart 1.A. of Rule 4685.1700 provides that if a complainant orally notifies an HMO that the complainant wishes to register a complaint, the HMO must make a complaint form available. The Board on Aging believes that the complaint form should be more than "made available" to persons who indicate that they wish to register a complaint. They suggest that it should be mailed within three days. The Department intended this rule to meet the requirements of Minn. Stat. § 62D.11, subd. 3, which requires the HMO to provide a description of the complaint process to an enrollee who communicates to the HMO

about a lack of services or poor quality of services. The Department has included, as one of the requirements for a suitable form, that it include a description of the HMO's internal complaint system and time limits. Whether to include the description of the system on the form or not is really immaterial. The more material question is whether or not the Department's rule, which only requires that the HMO "make available" a form, is unreasonable without a requirement that it be mailed within a certain number of days. While mailing is certainly one way of delivery, there is no reason why other forms ought not to be allowed. The rule is not unreasonable as proposed, and it does offer the HMO some flexibility. However, the Department might want to consider the option of changing the phrase "make available a complaint form" to "promptly provide a complaint form".

46. The Ombudsman for Older Minnesotans pointed out that the elderly population must have the ability to have complaints investigated, whether verbal or written. The rule ought to recognize that many times there are impairments, language barriers, inability to read or write, mentation difficulties, or physical disabilities which can interfere with a person's ability to register a complaint if the rule is too strict. It urged the Department to consider a different method for handling oral complaints than is presently in the rule. An alternative might be to require an HMO receiving an oral inquiry about a complaint to advise the person that they will be providing the written information required by the rule as presently proposed, but also to make inquiry as to whether the person may need help completing a written complaint. If so, the HMO should then give that person the telephone number of the Department staff or, if the HMO is willing to do so, the telephone number of an HMO staff person who would assist the person in putting the complaint in writing. However, for now it is concluded that the rule is reasonable without any change.

47. Subdivision 1.B. relates to time limits for an HMO to issue an initial decision on a complaint. Many HMOs urge that the proposed rule be modified to provide that the HMO must have all the information reasonably necessary to process a complaint before the 30-day time limit begins to run. Also, they urge that the HMO ought to have an additional 30 days (not just 14, as proposed) if it is unable to make a decision within the 30-day period, so long as it informs the complainant of the extension and the reasons for the delay. MedCenters states that they typically have to wait two weeks for receipt of medical records from participating providers, and at least four weeks for receipt from non-participating providers. PHP points out that the only way to meet the proposed timelines will be with additional staff, which can only be funded by passing on additional costs to the employers and

individuals who pay the cost of care.

48. The Department of Human Services, on the other hand, believes that the reduced timelines help to rectify the imbalance between the large HMO and the consumer. Long timelines discourage the consumer from pursuing legitimate issues, they assert. The Board of Aging states that the time limits are not unreasonably burdensome to HMOs and are absolutely necessary in order for enrollees' complaint rights to be meaningful. The Ombudsman believes the 30-day response time is crucial for risk-based Medicare patients because they must have time to request a Medicare appeal. The Metropolitan Senior Federation feels the proposed time periods are appropriate because consumers are held to similar time constraints in filing complaints. Ex. 32, 42, 40 and 45.

49. The Department agrees that the time period should not start until the HMO receives a "complete" complaint, but feels the HMOs suggested language is too vague and gives the HMOs too much discretion. The Department offers to add the following at the end of subpart 1.B.:

If a complaint unreasonably withholds information essential to the investigation of the complaint, the timeframes referenced in this paragraph may be extended until the information is received by the health maintenance organization.

This proposed change was submitted to the Administrative Law Judge on the last day of the response period, and so he does not have the benefit of the input from the affected HMOs and advocates. He is concerned about the idea that the timeframe may be extended only if a complainant "unreasonably" withholds information. It is not clear whether that limitation will create problems or not. Nonetheless, it is found that the proposed rule, as suggested for amendment by the Department, is reasonable. Affected persons are urged to keep track of any problems created by the word "unreasonably", and if it creates difficulties, they can ask the Department to amend the rule at a later time. But for now, the rule may be adopted (with the proposed amendment).

50. Similar concerns about timelines were raised with respect to subpart 1.C., which relates to an internal appeal of the HMO's initial decision. The Department has acquiesced in one of the proposed changes (insertion of the word "key" in front of "findings" in paragraphs (4) and (5)), but otherwise believes that the timelines proposed in the rule are reasonable. The Administrative Law Judge accepts the Department's justification. While adding an extension period (such as 14 days) for unavoidable delays would also be reasonable, the Department has justified its current position on the timeframes and no additional change is necessary.

51. MedCenters pointed out that a requirement in the existing rule, that arbitration is available only after an initial decision has been rendered, was proposed for deletion. MedCenters was opposed to that deletion. The Department responded that the deletion was inadvertent, and agrees that enrollees ought to go through the first step of the internal process before going to arbitration. The Department proposed to reinsert language which limits arbitration to complaints which are "unresolved by the mechanisms set forth in item B.". Such a change is appropriate, and is not a substantial change.

52. The Department has acceded to the request from a number of HMOs that the phrase "within 24 hours" in subpart 1.E. is unreasonable for notifying the Commissioner of an immediately and urgently needed service over a weekend. It

has added the phrase "or by the end of the next business day" in order to cure the problem. However, it may have created some confusion in its wording by stating "within 24 hours or by the end of the next business day" without indicating "whichever is greater". It would avoid confusion if the phrase "within 24 hours or" were deleted, or if the phrase "whichever is greater" were inserted. While the HMOs' concerns are reflected in the Department's additional language, any confusion ought to be remedied for purposes of clarity.

Dispute Resolution by Commissioner

53. Proposed Rule 4865.1700, subp. 2 sets forth procedures that will be followed when a complainant submits a complaint to the Commissioner. In pertinent part, it provides as follows:

A complainant may at any time submit a complaint to the commissioner, who may either independently investigate the complaint or refer it to the health maintenance

organization for further review. . . . After investigating a complaint, or reviewing the health maintenance organization's decision, the commissioner may order a remedy, including one or more of the following:

- A. imposition of a fine according to Minnesota Statutes, section 62D.17;
- B. an order to provide a service; or
- C. an order to reimburse an enrollee for a service already provided that the enrollee has paid for.

54. The Minnesota Council of HMOs takes exception to two of the three remedies proposed above. It has no problem with the administrative fine provision contained in item A., but it raises numerous arguments against the adoption of paragraph B. and paragraph C., which it refers to as "coverage orders". The three most important concerns are:

- (a) that the Department does not have statutory authority to adopt a rule providing for coverage orders;
- (b) that the language chosen by the Department grants the Commissioner unfettered discretion to order a remedy, without any standards to guide her; and
- (c) that the Department has failed to present facts demonstrating the need for or reasonableness of such remedies.

55. The enforcement provisions of the statute are generally contained in Minn. Stat. § 62D.15 to 62D.17. They give the Commissioner three specific remedies against HMOs:

- 1. suspension or revocation of an HMO's certificate of authority (§ 62D.15);
- 2. administrative fines, up to \$10,000 per violation (§ 62D.17, subd. 1); and
- 3. orders to "cease and desist from engaging in any act or practice in violation of the provisions of section 62D.01 to 62D.29." (§ 62D.17, subd. 4).

Nowhere in the statutes is the Commissioner given the authority to order an HMO to provide a service, or to order an HMO to pay for an already-provided service.

56. The Department relies, in part, on Minn. Stat. § 62D.11, subd. 1(a), which states that where a complaint involves a dispute about an HMO's coverage

of an "immediately and urgently needed service", then the Commissioner may review the complaint and "order the appropriate remedy pursuant to section 62D.15 to 62D.17." Those statutes, reviewed immediately above, provide for only three remedies: suspension/revocation of the certificate, administrative fines, and cease and desist orders. More importantly, however, the Department relies on a statute that is explicitly limited to cases of "immediately and urgently needed service" for authority to issue coverage orders in all cases, urgent or not.

57. The Department argues that other statutory sections require an HMO to obtain approval from the Commissioner for any of its enrollee contracts. Other statutes permit the Commissioner to suspend or revoke a certificate if the HMO is unable to fulfill its obligations under its contracts. The Department reasons that if it has the ultimate authority to suspend or revoke an HMO's certificate, it certainly has lesser authority to order an HMO to act when it is not honoring its contract. The Department relies on a series of federal labor cases for the proposition that an agency has broad discretion to adapt its remedies to the needs of a particular situation so long as its remedy is remedial, not punitive, is exercised in support of the agency authority to restrain violations of law and is used as a means of removing the consequences of a violation. Ex. 47, p. 5. While that may be the standard for federal agencies, it is not the standard applicable to state agencies in Minnesota. When the Legislature has granted certain enforcement powers to be applied in certain situations, the agency may not adopt a rule empowering it to use other enforcement powers in other situations. *lei*, for example, *Keefe v. Cargill*, 393 N.W.2d 425 (Minn. App. 1986). In that case, the Legislature authorized a fine to be imposed if an employer violated a posting requirement of the OSHA law. Despite that authority, the Department adopted rules providing that violation of a posting requirement would result in dismissal of an appeal. On

challenge, the court held that the agency acted outside the scope of its authority in adopting the rule, and that the rule was invalid. ito-also, state, by Spannaus v.. Lloyd A.Fry Roofing Co. 246 N.W.2d 696, 699-700 (Minn. 1976).

Similar restrictions exist upon the Department's attempt to extrapolate its authority for "immediately and urgently needed services" to all complaints. Where a statute clearly limits its application to specifically enumerated subjects, it may not be extended to other subjects by a process of construction. Grisvold v.-Ramsey-County, 242 Minn. 529, 65 N.W.2d 647 (Minn. 1954).

58. The idea of empowering the Commissioner to issue coverage orders is certainly an obvious one that could not have escaped the imagination of legislators, industry lobbyists, and Department officials involved in the drafting and review of HMO legislation. It is not an obscure, ephemeral, or highly sophisticated concept that might have been overlooked. While none of the comments included any legislative history on this point, it is likely that the Legislature, in the give-and-take of crafting a bill, decided that coverage orders were not appropriate powers to grant to the Commissioner. That is not to say that they may not be appropriate powers for the Commissioner to have available. But the decision of whether they should be granted, and under what circumstances they may be exercised, is one which the Legislature must make. In summary, it is concluded that the Department does not have statutory authority to adopt paragraphs B. and C.

59. The Department's justification for the need for these coverage orders was also inadequate. The Statement of Need and Reasonableness reads, in the entirety of its relevant part, as follows:

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

(SONAR, pp. 83-84.) Minn. Rules pt. 1400.0500 requires that a statement of need and reasonableness contain:

a summary of all the evidence and argument which is anticipated to be presented by the agency at the hearing justifying both the need for and reasonableness for the proposed rules

The Department's attempted compliance in the case of these coverage order provisions is inadequate. It has failed to comply with Minn. Stat. § 14.14, subd. 2. For example, the Department has been regulating HMOs and dealing with complaints from enrollees for some time. Has experience demonstrated a gap in the Department's enforcement tools to demonstrate that there is a need for adding these? Has the Department been unable to fulfill its responsibilities to enrollees under the current scheme? While detailed data gathering is not required, some effort It attempting to show that there is a problem requiring the rule is necessary.

60. A third complaint raised against the proposed two provisions is that the Commissioner is granted unbridled discretion to issue a coverage order under any circumstances. The rule merely provides that after investigating a complaint, or reviewing an HMO's decision, the Commissioner "may order a remedy, including one or more of the following". . . . The HMOs complain that rule fails to give notice of any standards which would govern the Commissioner's decision. The Department responded by indicating that a coverage order could be issued only upon the finding of a statutory violation. The Department stated, in post-hearing comments:

The Council appears to contend that the rules give the Commissioner the authority to be arbitrary in the issuance of a remedial order, including the possibility of issuing an order for no reason whatever. Plainly, the rules do not grant the Commissioner any such authority. An order may be issued only upon the finding of a statutory violation. The HMO act requires an HMO to honor its contractual obligations with enrollees. Thus, only upon finding a breach of the HMO's duty to its

enrollee may the Commissioner issue an order under the proposed rule.

Ex. 47, pp. 8-9. The Council responded to this as follows:

In its response, the Department has apparently conceded that the Department must first prove a violation of some section of chapter 62D before issuing a coverage or reimbursement order as proposed. Yet, nothing in the Statement of Need and Reasonableness or the proposed rule reflects such a standard.

Ex. 50, p. 4. The Council is not correct about the Statement of Need (see quotation above), but it is correct about the rule itself. As was stated later on in the Council's argument:

The issue is whether the Department can take action without any standards, whether it can order a remedy without even attempting to define the "wrong" which triggers the remedy. Fundamental principles of due process suggest otherwise.

id., p. 5.

61. It is concluded that the rule's failure to specify when it can be invoked grants to the Commissioner unbridled discretion. Unless some standards are added to the rule, it cannot be adopted in its present form. In order to cure this defect, standards must be added, such as a requirement of a violation of certain statutory sections 2 See, Anderson v. Commissioner-of-Highways, 126 N.W.2d 778, 780 (Minn. 1964).

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

CONCLUSIONS

1. That the Department of Health gave proper notice of the hearing in this matter.

1, 2 In light of the decision reached on statutory authority, these other

rulings may be unnecessary, but they are offered here to avoid any additional repetitive proceedings. In a similar vein, the rule as written contains no appeal provisions. The Department, in Ex. 47, pp. 9-11, suggests that the appeal provisions of section 62D.17, subd. 4 are applicable to coverage orders. If that is the case, then it should be specified in the rule.

2. That the Department has fulfilled the procedural requirements of Minn. Stat. §§ 14.14, subs. 1, 1a and 14.14, subd. 2, and all other procedural requirements of law or rule.

3. That 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) (ii), except as noted at Findings 58 and 60.

4. That the Department has documented the need for and reasonableness of its proposed rules with an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.15, subd. 3, except as noted at Finding 59.

5. That the amendments and additions to the proposed rules which were suggested by the Department after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3, and Minn. Rule 1400.1000, subp. I and 1400.1100.

6. That the Administrative Law Judge has suggested action to correct the defects cited in Conclusions 3 and 4 as noted at Findings 58-60.

7. That due to Conclusion 4, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3.

8. That any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

9. That 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 except where specifically otherwise noted above.

Dated this 20th day of July, 1989.

ALLAN W. KLEIN
Administrative Law Judge