STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

Agency Exh. No. 8
File No. HLTH-81-020-JC
Date 6-9-81

In the Matter of the Adoption of Proposed Rules Implementing, Enforcing, and Administering the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845 and Repealing State Planning Agency Certificate of Need Rules, 10 MCAR §§ 1.201 to 1.210

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Commissioner of Health (hereinafter "Commissioner"), pursuant to Minn. Stat. § 15.0412, subd. 4c (1980), and Office of Administrative Hearings rule 9 MCAR § 2.104, hereby affirmatively presents facts establishing the need for and reasonableness of the above-captioned rule adoption and repeal. Words, terms, and phrases used herein which are defined in Minn. Stat. § 145.833 and 7 MCAR § 1.661 B of the proposed rules will have the same meaning as given in the statute and rule unless the language or context clearly indicate that a different meaning is intended.

In order to adopt the proposed rules, the Commissioner must demonstrate that he has complied with all the procedural and substantive requirements of rulemaking. Those requirements are that (1) there is statutory authority to adopt the rules; (2) all necessary procedural requirements have been taken; (3) the rules are needed; (4) the rules are reasonable; and (5) any additional requirements imposed by law have been satisfied. This statement demonstrates and establishes that the Commissioner has met these requirements.

This Statement is organized in the following manner:

A. Statutory Authority

Minn. Stat. § 145.834 grants broad, sweeping rulemaking authority to the Commissioner to adopt such rules as are necessary to "implement, enforce and administer" the Certificate of Need Act (hereinafter "Act"). In exercising this authority, it is clear that the Commissioner could address in rules only those subject areas which he felt were necessary. Therefore, the legislature went a step further and also directed the Commissioner to promulgate rules in several specific areas. These specific additional areas and the statutory authority for promulgation of relevant rules are as follows:

1. Minn. Stat. § 145.834—define commencement of a construction or modification or predevelopment activities;

2. Minn. Stat. § 145.835, subd. 4---provide for the granting of waivers for situations other than listed in this subdivision as the commissioner deems appropriate and not inconsistent with the Act or the National Health Planning and Resource Development Act of 1974, 42 U.S.C., Section 300 k, et seq.

3. Minn. Stat. § 145.835, subd. 5---establish procedures for issuance of emergency waivers;

4. Minn. Stat. § 145.836, subd. 6---prescribe the format for the certificate of need application;

5. Minn. Stat. § 145.837, subd. 1---specify rules to govern the health systems agencies (hereinafter "HSAs") in their determinations whether certificates of need are required and in their review of applications which rules shall at a minimum cover the criteria to be used in analyzing certificate of need applications;

6. Minn. Stat. § 145.837, subd. 2(5)---specify the required findings of fact which shall address the criteria listed in Minn. Stat. § 145.837, subd. 1 and the provisions of 42 U.S.C. § 300 k, et seq.;

7. Minn. Stat. § 145.84---require health care facilities, upon completion of a project for which a certificate of need was issued, to furnish financial information which compares actual costs with the costs estimated in the certificate of need application.

8. Minn. Stat. § 145.845---address membership in HSAs.

In addition to the grants of rulemaking authority in the Act itself, Minn. Stat. § 15.0412, subd. 3 delegates authority to promulgate procedural rules. Furthermore, it is a well-established legal principle that an administrative agency may exercise not only those powers expressly delegated to it by the legislature but also those which arise by fair implication from the express powers. Wisconsin's Environmental Decade, Inc. v. Public Service Commission of Wisconsin, 69 Wis.2d 1,

230 N.W.2d 243, 251 (1975); Welsand v. State of Minnesota Railroad & Warehouse Commission, 251 Minn. 504, 88 N.W.2d 834 (1958).

These proposed rules are based on specific statutory authority and fulfill the requirements imposed by statute for promulgation of rules relating to the Act. Each section of proposed rules is either directly authorized as cited above or is a necessary function to implement, enforce, and administer specific statutory requirements.

B. Statement of Need

In 1971 the Minnesota Legislature adopted the Minnesota Certificate of Need Act, Minn. Stat. § 145.71 et seq. (hereinafter "Old Act"). It was one of several steps taken by governmental institutions to attempt to control skyrocketing health care costs. Its basic means of fulfilling that purpose was to control development of health care facilities and services so that only those which were needed would become operational.

The Old Act directed the State Planning Agency (hereinafter "SPA") to promulgate implementation rules. SPA did so with the adoption in 1971 of 10 MCAR §§ 1.201 to 1.210 (formerly SPA 201 to 210).

In 1979 the Minnesota Legislature repealed the Old Act primarily because changes were necessary to bring state law into compliance with existing federal certificate of need legislation. At the same time, the new Act, Minn. Stat. §§ 145.832 to 145.845, became law. The changes between the Old Act and new are primarily in detail and not in basic design and purpose. Minn. Stat. § 145.834 transferred rulemaking authority to the Commissioner of Health but kept the SPA rules in effect until modified by the rules of the Commissioner.

The Act mandates promulgation of a new set of rules. In the general grant of rulemaking authority and in the seven of eight of the specific grants

of authority, the legislature used the word "shall." Only in Minn. Stat. § 145.835, subd. 4, relating to the granting of waivers, did the legislature give the Commissioner an option to promulgating rules. Otherwise, the Commissioner has no choice. Rules must be adopted. The legislature has already decided that there is a need for the rules.

Need is essentially a policy decision. To argue that the Commissioner has the option to decide, in the face of legislative mandate, that there is no need for rules is to say that he has authority to reverse legislative policy decisions. The Commissioner, as a matter of basic constitutional law, lacks such power. In 1980 the legislature made clear by enacting Minn. Stat. § 15.0412, subd. 8, that it wants its policy decisions with respect to the need for rules carried out. This subdivision requires, unless otherwise specified by law, notices of hearing or notices of intent to adopt a rule without a public hearing to be published within six months of the effective date of the enabling legislation. If the agency fails to meet this deadline, it must so notify the appropriate committees of the legislature and the governor and explain why.

In this situation it is clear why the legislature mandated the adoption of new rules. The SPA rules dealt with basic processes for consideration of projects under the Act. Because the Old Act introduced an entirely new concept and procedure, it was not possible to anticipate and address in the SPA rules many of the problems and issues which arose over the years of actual administration of the Old Act. Ways of dealing with the various issues which arose evolved but were never reduced to rule form. Thus, one reason new rules are needed is to codify existing processes and procedures. Secondly, the Act has new areas not addressed in the Old Act. Implementing rules are needed here. Finally, a review of the Act will review outlines of procedures, processes, review criteria, and similar subjects, but detail

and clarification are needed. In order to adequately address these needs, it became obvious that the easiest way to proceed was to propose repeal of the SPA rules and adoption of an entirely new set of rules to govern the certificate of need process prescribed by the Act.

C. Compliance with Procedural Rulemaking Requirements

Minn. Stat. § 15.0412, rules of the Office of Administrative Hearings, rules of the Attorney General, and the Act, all specify certain procedures which must be followed when an agency adopts rules. All prehearing requirements have been complied with by the Commissioner. The most significant ones are addressed below.

1. Procedural Rulemaking Requirements of the Administrative Procedure Act.

Minn. Stat. § 15.0412, subd. 6, requires agencies which seek information or opinions in preparation for adoption of rules from sources outside the agency to publish a notice of its action in the State Register and to afford all interested persons an opportunity to submit data or views on the subject. Any written material, as well as the Notice itself, must be made part of the hearing record. In the State Register issue of Monday, October 15, 1979, the Commissioner published a "Notice of Intent to Solicit Outside Opinion Concerning Rules Governing Certificates of Need for Health Care Facilities" (hereinafter "Notice of Intent"). 4 S.R. 585. A copy of the Notice as well as any written material submitted in response to the Notice of Intent will be made a part of the record at the hearing.

It should be noted that these rules were in the development and drafting stage for over a year. This long time was mainly attributable to two facts. First, the proposed rules constitute a major undertaking. They are comprehensive in nature which accordingly accounts for their length. A second and more noteworthy factor was the attempt of staff of the Minnesota Department of Health (hereinafter "Department") responsible for drafting the rules to involve just about all of the

interested parties. It is probably because the Department initiated contact with these parties that there were very few direct responses to the Notice of Intent.

In 1979 and 1980, meetings were held with various groups including representatives of th following: Minnesota Hospital Association; Minnesota Association of Health Care Facilities; Association of Residences for the Retarded in Minnesota, the State Planning Agency, Health Systems Agencies, Mayo Clinic, Minnesota Department of Public Welfare, United States Department of Health and Human Services, and the Nursing Home Advisory Council established pursuant to Minn. Stat. § 144A.17. In addition to the meetings, many of these groups submitted written comments. Copies of various drafts were also circulated to these and other groups and persons who also submitted written comments. While perhaps not all disagreements between the interested parties and the Commissioner have been resolved because of these contacts, this give-and-take process has resulted in proposed rules which have already had the benefit of much review and, accordingly, have been improved over a number of drafts.

Minn. Stat. § 15.0412, subd. 1 prohibits an agency from adopting a rule which repeats language from Minnesota Statutes unless the hearing examiner determines that "duplication of the language is crucial to the ability of a person affected by a rule to comprehend its meaning and effect." The proposed rules do repeat language from the Act in several places. An attempt has been made to identify each place and comment upon it in section E of this Statement. However, there is in reality one justification which applies in each instance and will be noted here for convenience of interested parties as well as to cover any instance of duplication not specifically addressed in Section E.

The rules should have a hand-in-glove fit with the Act. This is in part because the rules implement the Act. But in this instance the connection is even closer because the Act also contains a fair amount of detail with respect to process,

procedures, and substantive material. The rules have to pick up on what is already in the Act and either clarify it or, as authorized, provide further detail. For example, Minn. Stat. § 145.835, subd. 1 directs the HSA to "promptly notify" the Commissioner and SPA when a notice of intent to embark upon a certificate of need project is received. "Promptly notify" needs to be given meaning as has been done in 7 MCAR § 1.662 A.3. In yet other instances, the Act specifically directs the Commissioner to include certain statutory items in the rules. See, e.g., Minn. Stat. § 145.837, subd. 1(a) to (m).

With such a close connection between the Act and the rules, repetition of statutory language is virtually mandated. The repetition makes the rules more readable and more easily understood. The connection between the Act and the rules is clearer. One does not have to wonder exactly what part of the Act is being addressed in the rule when the starting point is language from the Act. The rules then build upon that.

Duplication of language from the Act has been held to a minimum and only done where necessary to aid those reading the rules to understand them. Even convenience to the reader should be a sufficient ground to justify the repetition. In this case, however, because of the close interplay between the Act and the rules, repetition of language from the Act becomes "crucial to the ability of a person affected by . . . [the proposed rules] to comprehend . . . [their] meaning and effect." Minn. Stat. § 15.0412, subd. 1.

Minn. Stat. § 15.0412, subd. 4 (1978) as amended by Minn. Laws 1980, ch. 615, § 6, authorizes agencies to incorporate by reference provisions of federal law when the provisions would be "less than 3000 words in length or which would require less than five pages of publication in the state register." The Commissioner is incorporating by reference several federal laws. First, "category" of bed is

defined in 7 MCAR § 1.661 B5 to include the "classification of beds within a health care facility according to certification status under the provisions of Title XVIII and XIX of the Social Security Act." A second instance is found in 7 MCAR § 1.663 A.4.b. (2)(i) and (ii). These provisions deal with the type of information an applicant must submit relating to estimated operating costs of the proposed project. The rule requires that the information must conform with cost centers as described in one of four sources. Two of those sources, both of which are being adopted by incorporation by reference, are the cost allocation requirements under Title XVIII of the Social Security Act, 42 U.S.C. § 1395, et seq., and under Title XIX of the Social Security Act, 42 U.S.C. § 1396, et seq. The last provision of federal law which is being adopted through incorporation by reference are the requirements for an HMO to become "qualified" under Title XIII of the Public Health Services Act, 42 U.S.C. § 300 e.

In order to incorporate federal law by reference, the Commissioner must have first obtained the approval of the chief hearing examiner. His approval for the three above-referenced provisions will be sought prior to the hearing. However, it should be noted that on July 1, 1981, Minn. Stat. § 15.0412, subd. 4a goes into effect. This is 21 days after the public hearing and well before the proposed rule could ever be adopted by the Commissioner. This section gives the Commissioner authority to "incorporate by reference into . . . [his] rules text from . . . the United States Code." There is no limit with respect to the number of words or length of publication in the "State Register" as presently exists.

A final prehearing procedural requirement of the Administrative Procedure Act is that at least 30 days before the hearing a Notice of Hearing and the full text of the proposed rules must be published in the State Register and the Notice must be mailed to all persons who have registered their names with the Commissioner

for the purpose of receiving notice of rules hearings. Minn. Stat. § 15.0412, subd. 4. Both of these requirements have been met. The Notice and rules were published in the State Register on May 4, 1981, 36 days before the hearing. (5 S.R. 1729.) The Notice was mailed to people who had requested the Department to so notify them on May 6, 1981, 34 days before the hearing.

2. Procedural Rulemaking Requirements of the Act.

Minn. Stat. §§ 145.835, subd. 4, and 145.837, subd. 1, direct the Commissioner to promulgate rules regarding the granting of waivers and governing HSAs in their determinations as to whether certificates of need should be issued respectively but only after consulting with the SPA and the HSAs. Minn. Stat. § 145.845 specifies that rules regarding membership in HSAs shall be adopted by the Commissioner after consultation with the SPA. The Commissioner has complied with these requirements. Not only has the Commissioner consulted with the SPA and HSA during the last two years regarding these specific rules but he has consulted with them regarding all the proposed rules. (The specific facts regarding the consultations will be contained in affidavits which will be submitted at the hearing for including in the hearing record.) These discussions have been fruitful as well as fulfilling the technical requirements regarding consultation.

3. Non-Mandatory Actions by the Commissioner

While no other statute establishes requirements with which the Commissioner must comply as a condition of promulgating these rules, there are three additional actions taken by the Commissioner which should be addressed.

First, Minn. Stat. § 15.0412, subd. 4, states that an agency may, but only if it decides to do so, inform persons who had not registered with the agency for the purpose of receiving notice of rulemaking hearings of the scheduled hearing on a specific set of rules. The Commissioner has done so in this instance. On April 29, 1981, Department staff sent copies of the Notice of Hearing as well as

of the proposed rules to 46 persons, groups, or associations which the Department believed had an interest in the rules. Included in this mailing were the SPA, the HSAs, the Minnesota Association of Health Care Facilities, the Minnesota Hospital Association, the Minnesota Medical Association, each of the ten HMOs operating in Minnesota, and attorneys representing various interested persons. Each Senator and Representative also received a copy of the Notice of Hearing on May 1, 1981. The Department also mailed a news release to over 650 newspapers, radio and television stations, public health nursing services, and other interested parties around the state.

Second, Minn. Stat. § 145.834 speaks of an agreement between the Commissioner and SPA. It provides:

> The state planning agency, as the administrative authority for the National Health Planning and Resource Development Act of 1974, 42 U.S.C., Section 300k, et seq., shall enter into an agreement with the commissioner of health under which the commissioner shall promulgate rules governing the administration of sections 145.832 to 145.845. The commissioner of health shall promulgate rules to define the commencement of a construction or a modification or predevelopment activities and other rules necessary to implement, enforce and administer sections 145.832 to 145.845.

As is implied by this provision, there is no need for an agreement between SPA and the Commissioner to promulgate rules for purposes of the state certificate of need program. The Act gives the Commissioner authority independent of SPA to implement, enforce, and administer the state Act. However, for purposes of complying with the requirements of the National Health Planning and Development Act, SPA, as the designated State Health Planning and Development Agency under the federal act* and in compliance with Minn. Stat. § 145.834, has entered an agreement with the Commissioner. A copy of the current agreement is attached hereto as Exhibit A and made a part hereof.

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*Executive Order No. 79-26, May 31, 1979 (3 S.R. 2210).

Finally, the Commissioner has voluntarily submitted a draft of these rules to the Nursing Home Advisory Council. This council must be appointed by the Commissioner pursuant to Minn. Stat. § 144A.17. It is available to the Commissioner to assist him with proposed rules and other matters relating to nursing homes. The council's actions have no binding force. Its recommendations, to the extent it makes any, are advisory only. These rules were submitted to the council on April 17, 1980.

D. General Statement of Reasonableness

In order to adopt rules, an administrative agency must demonstrate that the rules are reasonable. To be reasonable does not necessarily mean to be right. Rulemaking is a quasi-legislative process which primarily involves policy decisions. Thus, there is no inherently right or wrong approach. In addition, the rules do not have to be the best possible rules. Because policy decisions are involved, determining what is best would be practically impossible. What is the best approach to one person is the worst approach to another because of their differing policy perspectives and biases. Thus, in examining a rule, the standard is not whether the rule is right or best but only whether it is reasonable—and in most cases there are many reasonable ways to address a subject covered by a rule. As long as the approach taken by the agency falls within the wide range of reasonableness, the agency has the right to adopt it.

What is reasonable? A rule is reasonable if there is a rational basis for it, or, to express it negatively, if the rule is not arbitrary or capricious. The Office of Administrative Hearings has provided a detailed explanation of reasonableness and the basis for establishing it in the Report of Hearing Examiner in the proceeding, "In the Matter of the Proposed Adoption of Rules Governing the Identification, Labeling, Classification, Storage, Collection, Transportation and Disposal of Hazardous Wastes and Amendments to Minnesota Regulations SW 1,

2, 3, 4, 6 and 7, No. PCA-78-003-WS," at pp. 6-11, a copy of which is attached hereto as Exhibit B and made a part hereof.

The proposed rules under consideration deal primarily with procedures, processes, and criteria for making judgments regarding the issuance of certificates of need and related matters. They specify what persons subject to the rules must submit to the HSA and Commissioner, within what time frames, how the submissions will be analyzed, and the bases on which decisions will be made. The specific approach taken with each subject represents a policy decision. As long as the items which are required to be submitted and the criteria by which the submitted information will be judged address the concerns expressed by the legislature in passing the Act and the time frames provide at least a minimum period needed to perform the designated acts, the rules have a rational basis and can be adopted.

It is, of course, the position of the Commissioner that the proposed rules are reasonable. This assertion is based upon a three-point foundation. First, the proposed rules are consistent with the technical provisions of the Act and facilitate meeting its purposes and objectives. Second, many of the procedural and substantive requirements in these rules have been in effect under the Old Act. And, lastly, the new rules are based on the Commissioner's nine years of experience with the certificate of need process, on research and review of related literature and legislation, review and comment by HSAs and the SPA, and review and comment from interested providers, consumer groups, and the Subcommittee on Health of the House Health and Welfare Committee.

It must be noted, however, that merely because the Commissioner asserts that the rules as proposed are reasonable and a result of a drafting process that included consultation with interested persons does not mean that he will

not take into consideration further suggestions and comments made at the hearing. The rulemaking (quasi-legislative) hearing process provides an excellent opportunity to continue a give-and-take process begun almost two years ago with the aim of improving the rules so that the final product is as useful, workable, and understandable as possible. However, it is clear that the rules as proposed are reasonable and meet every procedural and substantive requirement for adoption.

E. Rule-by-Rule Justification

7 MCAR § 1.661 General Provision.

A. Purpose

A purpose section is included to provide a clear introduction to these rules. Persons directly regulated by the rules need to understand that the rules do not repeat provisions of the Act, which are clear and complete without rules, and that they, therefore, need to read the rules together with the Act. While this is a requirement of the Minnesota Administrative Procedures Act for all rules, it is not commonly understood, and a purpose section is, therefore, needed and reasonable.

The purpose section also describes the Commissioner's intent to develop and enforce minimum review procedures and criteria as necessary to further the purposes of the Act. This statement of intent is needed to give the public advance notification of the Commissioner's approach and to promote cooperation between health care facilities and health systems agencies before the certificate of need review is conducted. This introduction is also reasonable because it is consistent with the intent of rulemaking prescribed in the Administative Procedures Act. No rule is proposed herein unless it constitutes the least restrictive manner in which the Act can be fairly administered.

B. Definitions.

Definitions clarify the meaning of specific words and phrases and thereby facilitate the understanding and application of the rules. Justification

for each term defined is as follows.

1. "Act" and "AIP," 7 MCAR § 1.661 B, 1 and 2. These terms simplify references to the Minnesota Certificate of Need Act and to the annual implementation plan, both of which are terms used in the Act and the rules.
2. "Application," 7 MCAR § 1.661 B.3. Because the Act and rules refer to many different requests for determinations that can be submitted to HSAs and the Commissioner, it is necessary to specify that the term "application" refers only to that submission which is made to request issuance of a certificate of need.
3. "Capital expenditure" 7 MCAR § 1.661 B.4. This definition is needed to clarify the meaning of "capital expenditure" as used in the definition of "construction or modification" in Minn. Stat. § 145.833, Subd. 5. The term "capital expenditure" is defined in the current Certificate of Need rules, SPA 201 (e). The language in the SPA rule is similar to that which is included in this proposed rule. This definition is reasonable because it is consistent with the Act and that which has been used by health care facilities and health planners in Minnesota for the past seven years.

The Act does not limit the sources or types of capital financing. The supply of health care facilities and the concomitant price of services are directly influenced by any type of capital financing (e.g., through the depreciation component in any health care facility pricing structure). It is therefore necessary and reasonable that all potential types of

financing resulting in a project reviewable under the Act be included within the definition of "capital expenditure."

For clarification examples of purchase agreement situations, such as a lease or rental agreement, have been included in the definition as capital expenditures. Minn. Stat. § 145.833, Subd. 5 (a) specifically includes the leases and other similar acquisitions within the scope of construction or modification. Therefore, it is necessary to include leases for acquisition of items which fall within the meaning of construction or modification as capital expenditures. Consistent with the Act [§ 145.833, Subd. 5 (a)(1)], however, and in keeping with general principles of finance, expenditures considered to be operating expenses under generally accepted accounting principles are excluded from the definition.

In order to reasonably assess the expenditure associated with leases or rentals, we have chosen to use the fair market value of the equipment or property leased, on the date which the agreement was entered, will be used. [This same method of determining value was used in rule SPA 201 (e).] For planning purposes, the fair market value of property or equipment leased or rented is equivalent to the capital expenditure which would have been made if the facility had chosen to purchase rather than to acquire through lease.

In addition, this approach allows the Department to more adequately deal with a situation where a lease may be initially for a relatively short term but prior to expiration renewed, perhaps more than once. This, in effect,

would turn the lease into a long term one. If the fair market value of the item covered by the lease were not the determining factor with respect to application of the Act, the Act could be evaded by keeping its initial financial terms under the jurisdictional monetary limits set by the Act and then, at a later date, to renew the lease.

This definition has in its final sentence clarification of how to interpret a project involving several components. While this concept is explained in greater detail in 7 MCAR § 1.661 H. involving evasions, it is included in this definition so as to make clear the impact of possible separation into components of the capital expenditures involved in a single undertaking.

4. "Category," 7 MCAR § 1.661 B. 5. This term is defined to clarify its use in Minn. Stat. § 145.833, Subd. 5 (a) (2). State licensure and federal reimbursement rules establish various classifications or categories for beds in health care facilities. These classes or categories of beds have general usage in the health care facility industry. These classification systems are applicable to health planning as the need for the various types of beds will vary. State licensure and federal certification categories are used in the State Health Plan, health systems plans and annual implementation plans. It is not possible to adequately examine the need for health care facility beds without knowing its specific category.

Federal reimbursement changes critically affect a health facility's financial considerations. For example, in the most recent six certificate of need applications involving changes in long term care bed categories which the Commissioner acted upon, the average patient charges per day were $39.82 for skilled nursing care compared to $35.17 for intermediate nursing care. The average difference was $4.65 per day or 13.2%. The specific charges were:

Date of Decision	Skilled Nursing Charge per Day	Intermediate Nursing Charge per Day
4-20-81	$34.00	$31.00
3-30-81	$38.34	$30.87
12-31-80	$40.43	$35.16
12-17-80	$43.67	$39.00
7-18-80	$46.00	$43.00
6-10-80	$36.50	$32.00

5. "Commissioner," 7 MCAR § 1.661 B.6. The definition is provided for convenience and to simplify the references to the Commissioner of Health throughout the rules. The definitions need and reasonableness is justified by this purpose.

6. "Construction or modification," 7 MCAR § 1.661 B.7. This term is defined in the Act, Minn. Stat. § 145.833, Subd. 5 (1980). However, there are terms or phrases within the statutory definition which themselves need definition or clarification. Thus, this definition specifies the meaning and usage of this term in cases where the statute by itself is vague or incomplete or would benefit through definitional clarification.

This is the key operative term in both the Act and the rules. Determinations of applicability of projects to the Act frequently depend upon an interpretation of the meaning of "construction or modification." The proposed definition is reasonable because it is consistent with commonly accepted meanings and usages for health planning purposes and cost implications of construction and modification.

For convenience and clarity of the users of this rule and, as well, to avoid misunderstandings and confusion, the language of the Act has been combined with the language of the rule to create a completely self-contained definition. This approach is necessary because of the complexity of the term as defined in statute and clarified in rule. If a series of separate clarifying definitions were used, the comprehensibility of the Act would suffer, especially in view of the rather central role the term "construction or modification" has in the statutory scheme.

Clause a (1) is the basic dollar threshold for determination of applicability and is simply a reiteration of the minimum specified in Minn. Stat. § 145.833, Subd. 5 (a) (1). Clause a (2) is the basic statutory bed change threshold for determination of applicability which has been somewhat reorganized to more clearly indicate the types of changes intended. This latter clause is also needed and reasonable because of its effect of clarifying the meaning of Minn. Stat. § 145.833, Subd. 5 (a) (2).

Clause b of this definition is needed to describe acquisition of diagnostic and therapeutic equipment. This separate treatment is consistent with the statutory approach [§ 145.833, Subd. 5 (a)]. As this matter was administered under the old Certificate of Need Act, the issue of updating

but not totally replacing equipment raised many questions. The clause is therefore needed and reasonable to clarify Minn. Stat. § 145.833, Subd. 5 (a) (1).

The language in this clause recognizes that when a manufacturer installs equipment, in some circumstances generally accepted accounting principles treat the expense of labor and installation as a capital expense to the health care facility. In many other circumstances, such labor is not viewed as a capitalized expense but is instead charged as a normal expense of operation and is thus not included in the definition as being a capital expenditure.

Clause c clarifies the definition of expansion and extension of the scope or type of existing health services with specific reference to Minn. Stat. § 145.833, Subd. 5 (b). The clarifying language is intended to recognize, consistent with the Act's cost control purposes, the desirability of increased efficiency in operations, while at the same time making explicit the content of the controlling term.

The list of five factors is needed to guide the public in determining whether the scope or type of service has been expanded. An increase in volume of services is a plain indication of an extension of the scope of services. The ability to perform different or additional treatments or procedures is an indication of expansion of scope or type of service. When there is an increase in the work force associated

a capital expenditure, a larger operational cost occurs and, very likely, more service is provided to patients of the health facility. This would constitute an expansion and extension of the scope or type of services. Patient mix is an accepted term of art in the health care field and references to the type of patient services performed such as, in hospitals, medical, surgical, maternity, psychiatric, pediatric, and other specialized health services. When the proportion of patients who use these services changes as a direct result of a capital expenditure, it is an extension of the scope of services within the service area being increased. Finally, the geographic source of referrals to the facility may change as a result of a capital expenditure. For example, the replacement of one technology of equipment for another type of technology may cause physicians to initiate referrals to that facility. This change in referrals would result in an extension of the scope of services.

Clauses d and e are required by Minn. Stat. § 145.833, Subd. 5 (c). The two provisions (establishment of a new facility and reviewable predevelopment) are divided in the rule to more clearly present them to the public. Clause f is from Minn. Stat. § 145.833, Subd. 5 (d). The inclusion of these three provisions makes the definition fully consistent with the statutory definition and make the rule complete. The term "construction or modification" is therefore fully understandable to any reader making reference to the rule; tedious cross-references to the Act are prevented.

7. "Direct patient care services," (7 MCAR § 1.661 B.8). The purpose of this definition is to provide a common meaning and usage to the term as used in Minn. Stat. § 145.833, Subd. 4 (b) and in these rules. The definition

is designed to include those commonly accepted direct care components of health care services and does not include general support services such as food service, building maintenance, telephone systems or similar services.

8. "Exemption," 7 MCAR §§ 1.661 B.9. This defined a decision which may occur solely for the purposes of HMO related applications. The inclusion of this definition is needed to provide clear notification that this decision option by the Commissioner is available to HMO projects only and to differentiate it from other types of decision.

9. "Evidence," 7 MCAR § 1.661 B.10. This term is used in 7 MCAR §§ 1.663 G. This term was previously defined in the State Planning Agency rules. These proposed rules make no substantive change in the State Planning Agency rule SPA 201 (i). Because formal rules of evidence are not used at the public certificate of need hearing held by HSAs and because the hearings are more open and legislative in nature than trial type proceedings, it is necessary to define the term. The key elements are that only information submitted to the HSA prior to the hearing may be considered and that "evidence," for the purposes of the HSA making a recommendation, is the same "evidence" used by the Commissioner for making the final certificate of need decision.

10. "Health maintenance organization," or "HMO," 7 MCAR § 1.661 B.11. The term has the definition given to it by the Minnesota Statute which regulates the formation and operation of HMOs and is supported by common reference in this State.

11. "Hearing body," 7 MCAR § 1.661 B.12. Because many different groups could conduct a public hearing pursuant to the Act, the rules are made more readable by developing a generic term rather than to repeatedly list all of the groups whenever reference is made to the entity which conducts the hearing. The definition assists in the readability of 7 MCAR § 1.663 G.

12. "HSA" and "HSP," 7 MCAR § 1.661 B, 13 and 14. These terms are needed and reasonable to simplify references to "Health Systems Agency" and "Health Systems Plan" as used throughout the rules.

13. "Institutional health service," 7 MCAR § 1.661 B. 15. This term is used throughout the Act and these rules but is not defined in the Act. The term "health services" is defined in Minn. Stat. § 145.833, Subd. 3. In the context of the health services industry, the term "institutional" refers to organized health services provided through buildings or organizations recognized for a particular health care purpose. Webster's Third New International Dictionary, 1971, p. 1171, supports this common reference when it defines "institution" as "something or someone well established in some customary relationship" or " a building or the buildings occupied or used by such organizations." This is also consistent with the Act's focus on "health care facilities." (§ 145.833, Subd. 2)

For these reasons and for consistency with common usage, this definition is identical to the definition in the Act of "health services." Accordingly, the term is used synonymously with "health service" as it is defined in the Act.

14. "Long range development plan," 7 MCAR § 1.661 B. 16. This is needed to specify the document which should be considered by the HSA and the Commissioner in reviewing certificate of need applications as described in Minn. Stat. § 145.837, Subd. 1 (b). Minnesota laws do not define this term; however, over the years, such a document has developed in the health planning process through common practices by individual health facilities, Section 1532 of the National Health Planning and Resources Development Act (42 U.S.C. 3001-1) and Section 234 of the Social Security Amendments of 1972 (42 U.S.C. 1395x (2)).

A great deal has been written in recent years about the importance of interaction between the areawide health planning process, as performed by HSAs and State Agencies, and corporate planning activities, including the "long range development plan." For example, Reeves, Bergwall and Woodside[1] wrote that institutional planners should make every reasonable effort to see that institutional survival is compatible with community well-being. These authors state that there needs to be understanding and participation of institutional planning efforts in the development and ongoing implementation of health systems plans in order to assure the most productive results.

Tucker[2] wrote of the results of failure of some health care facilities to establish health planning processes of their own. He described the

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[1]Philip Reeves, David Bergwall, Nina Woodside, Introduction to Health Planning, Washington, D.C., Information Resources Press, 1979, p. 63-64.

[2]Stephen L. Tucker, "Introducting Marketing as a Planning and Management Tool," Hospitals and Health Services Administration, 22 (1): 37-44, Winter 1977.

result that institutions which do not establish long range plans react only to internal pressures rather than to operate to the mutual benefit of the institution and the community it purports to serve.

As noted above, two federal laws have imposed institutional planning. Section 234 of P.L. 92-603, the Social Security Amendments of 1972, requires each hospital participating in Medicare or Medicaid to have an operating budget and a capital expenditure plan for at least a three-year period. These documents are to be reviewed and updated annually and their preparation supervised by a committee of the board, administration and medical staff. Section 1532 of P.L. 93-641 established long range plans as a consideration in the review of certificate of need requests as implemented by states.

Given this widespread emphasis on long range plans by health care facilities and the existence of the plans in the current process, it is reasonable that the rules define this term in the context of existing practice.

15. "On behalf of" 7 MCAR § 1.661 B. 16. The term is used both in Minn. Stat. 145.833, Subd. 5 (a) and (c) and these rules to broaden the applicability of the regulatory provisions. The Act applies to more than the direct activity by a health care facility. Entities which may have a separate corporate organization but who may be acting in the interest of a health care facility are intended to be covered by and to comply with the Act. Situations based on contract or working relationship which are in the interest of, on the authority or behest of, or for the benefit of a health care facility are reasonably considered to be on the behalf of

a health care facility. The source of the definition of this preposition is in part Webster's Third New International Dictionary, 1971, p. 198, which defines "on behalf of" as "in the interest of, as the representative of, or for the benefit of."

16. "Predevelopment activity," 7 MCAR § 1.661 B. 18. This definition attempts to render consistent two separate uses of the term in the Act. The basic definition "predevelopment activity" is based on Minn. Stat. §§ 145.835, Subd. 1 which broadly applies to any activity in preparation for a project.

While all "predevelopment activity" requires submission of a letter of intent pursuant to Minn. Stat. § 145.835, Subd. 1, only those predevelopment activities specified in Minn. Stat. § 145.833, Subd. 4, can be considered to be themselves reviewable. The definition of "reviewable predevelopment activity" clarifies the meaning of Minn. Stat. § 145.833, Subd. 4, to clearly show that reviewable predevelopment activity is a limited class of predevelopment activity.

17. "Patient," 7 MCAR § 1.661 B.19. This is defined to simplify references to this term in the Act. The definition is intended to include persons receiving long-term care in institutions referred to in other state laws as "residents." The definition's need and reasonableness is therefore justified for this purpose.

18. "Project," 7 MCAR § 1.661 B. 20. is defined to simplify the multiple references to "project," "proposal," and "construction or modification" in the Act. Since there is no substantive difference among the Act's uses of these terms, the common definition of "project" was chosen.

19. "Provider," 7 MCAR § 1.661 B. 21. This definition is needed to clarify its meaning and distinguish it from the term "consumer" as defined in the Act. By defining "provider" in this section, a distinction is clearly made between a "consumer" and "provider." In addition, the definition complies with the National Health Planning and Resources Development Act and regulations promulgated thereunder. [42 U.S.C. § 300L-1 (b)(3)(A) and 42 CFR § 122.09 (a)(1) and (2)(1978).]

20. "Recommendation of the HSA," 7 MCAR §§ 1.661 B.22. The term needs to be defined to clarify its meaning as used in Minn. Stat. §§ 145.836 and 145.837, as well as in these rules. For simplification, this term has been defined to mean the action of the HSA, the supporting rationale developed by the HSA and all information provided by the applicant.

21. "Region," 7 MCAR § 1.661 B. 23. This term is defined in a way similar to the previous State Planning Agency Rule SPA 201 (o) and conforms to the designation process described in the National Health Planning and Resources Development Act [42 U.S.C. § 300L-1 (b)(3)(D)(ii)(1978)] and regulations promulgated thereunder.

22. "Requestor," 7 MCAR § 1.661 B. 24. The term designates the licensed medical doctor or doctors who submit a notice of the proposed acquisition or purchase of equipment pursuant to Minn. Stat. § 145.835, Subd. 3. For reasons of clarity "requestor" is distinguished from "applicant" which is used elsewhere in the Act and rules to describe the person who submits a certificate of need application or waiver request.

23. "State Health Plan," 7 MCAR § 1.661 B. 25. The definition is needed to specify a document referred to in these rules and which has been used in the existing certificate of need review process when HSPs are less complete or raise other concerns. The "State Health Plan" is required by the National Health Planning and Resources Development Act and the definition provided in these rules is based upon that federal law. (Section 1524 (c)(2)(A and B), 42 U.S.C. 300k.)

24. "SPA," 7 MCAR § 1.661 B. 26. The term simplifies reference to "State Planning Agency."

C. Membership of health systems agencies and their governing bodies.

The next major section, 7 MCAR § 1.661 C, sets forth the requirements for membership of HSAs pursuant to Minn. Stat. § 145.845. There is considerable confusion about the scope of application of the word "membership" in Minn. Stat. § 145.845. Since the operating procedures of HSAs are closely tied to the National Health Planning and Development Act and the Department of Health and Human Services (HHS) regulations, the interpretation of the word "membership" should consider the federal certificate of need scheme.

The Act and HSS regulations specifies criteria for "membership" in the "governing body" of corporate HSAs. 42 USCA § 300L-1(b)(2)(C); 42 CFR § 122.109(b). The specified requirements correspond closely to the "membership" criteria set forth in Minn. Stat. § 145.845.

Neither the Act nor HHS regulations deal with "membership" in any context other than the "governing body." The "governing body" may delegate certain of its functions to an executive committee or advisory committee. "Membership" on committees, however, is controlled by the same standards as "membership" on the "governing body." 42 USCA § 300L-1(b)(3)(A); 42 CFR § 122.09(c) and (f). The Act does require, however, that each HSA establish a process for selecting "members" to its "governing body" which assures "the opportunity for broad participation in such process by the residents of the health service area...." 42 USCA § 300L-1(b)(3)(D)(ii) (1978). This congressional concern with encouraging participation by area "residents" in the selection of the "governing body" clearly implies participation in or a type of "membership" in HSAs for nongoverning body members. At the same time, the total absence, aside from residence, of any prerequisites to participation in HSA "governing body" selection indicates that the Minnesota "membership" requirements refer to "membership" in the "governing body," not participation in other HSA activities. To interpret Minn. Stat. § 145.845 as referring to "residents" who wish to participate in HSA governing board selection ignores the federal scheme and dramatically complicates the HSA structure. In addition, the absence of any express authority to regulate HSA participation, other than at the "governing body" level, may be interpreted as precluding the Minnesota Legislature from establishing additional prerequisites to participation in the "governing body" selection process.

HSAs have developed operating procedures with respect to participation of area residents. In all situations, a resident is eligible to join the area HSA corporate "membership" simply by completing an application form. The number of corporate "members," however, is limited by the corporation's bylaws. In addition, HSAs have various categories of "members," e.g., "consumer" and "provider." Each category is entitled to a certain number of corporate "members" (an amount proportionate to that category's "membership" in the "governing body"). In practice, the "consumer" allotment never fills up while plenty of "providers" apply to fill their allotment. Participation in the governing board selection process depends on an individual's classification. For example, "consumer" members may participate only in selecting consumer representatives to the governing board. Similarly, "provider" members select the provider "members" of the "governing body." Corporate "members" generally meet annually to select the "governing body," and that is the extent of their involvement in the HSA. The system apparently functions well, and is based on a reasonable and practical interpretation of the certificate of need scheme.

In conclusion, several reasons exist to interpret Minn. Stat. § 145.845 as referring primarily to "membership" in the "governing body" of an HSA. First, the Minnesota requirements for "membership" conform very closely to the federal criteria for"membership" in an HSA "governing body." Second, the federal Act specifically states that any "resident" of a health systems area may participate in the selection process for "governing body""members." To interpret the Minnesota "membership" criteria as applying to any person who wishes to become a corporate "member" could hinder participation by area residents. Third, provisions (6) and (7) of Minn. Stat. § 145.845 seem inapplicable to corporate "members" and clearly applicable to "members" of the "governing

body." Fourth, no provisions of the federal Act or HHS regulations authorize a State to promulgate rules respecting corporate "membership." Finally, the existing system apparently works satisfactorily. No obvious reason exists to promulgate rules restricting or complicating HSA corporate "membership" significantly.

Therefore, 7 MCAR §§ 1.661 C. 1. references the corporate HSA bylaws as the basic source of corporate membership standards and 7 MCAR §§ 1.661 C. 2. prescribes needed details, as required by Minnesota law, with regard to the governing body.

It is the responsibility of the governing body to conduct business and carry out duties and functions except when it delegates to staff or committee the responsibilities for making recommendations. To expediate operation of HSAs, it is reasonable that procedures be established for delegation of certain functions to staff.

The term of office prescribed in these rules is consistent with the federal law and complies with the requirement in Minn. Stat. § 145.845 (6) that a fixed term of membership be prescribed.

While Minn. Stat. §§ 145.845 requires representation by specific groups which may not be required by federal law, the federal law does not prohibit states from adding such additional minimums for membership of governing bodies.

Reference is made in this rule to the Metropolitan Council and its health board, called the Metropolitan Health Board, in order to clarify its role. In metropolitan areas, the federal Act permits a public regional planning body to serve as the HSA, with the aid of a "governing body" for health planning appointed by the existing regional planning body. 42 U.S.C. § 300L-1(b)(1)(B). Minn. Stat. § 145.833, Subd. 6 designated the metropolitan council as the HSA for the Twin Cities area.

Finally, 7 MCAR § 1.661 C.2.c. is needed to assure that committees or sub-committees delegated responsibility for recommendations on certificate of need shall maintain consumer interests and control similar to the entire HSA. This rule is also consistent with the federal law and regulation for delegation of functions to committees. [42 U.S.C. § 300L-1 (b)(3)(A); 42 CFR § 122.09 (c) and (f).]

D. Conflicts of Interest

7 MCAR § 1.661 D. defines and provides a method for handling conflicts of interest. The necessity for the rule is obvious. Generally accepted legal principles prohibit persons with conflicts of interest from being involved in decisions in which they have a material interest in the outcome. This accomplishes preservation of objectivity and avoidance of bias or prejudice.

This rule provides a commonly accepted procedure for dealing with a conflict of interest by prohibiting formal or informal participation in the discussion of or vote on proposed projects when a conflict of interest exists.

7 MCAR § 1.661 D.2 lists circumstances when a conflict of interest exists. These circumstances are analygous to the standards in Minn. Stat. § 145.833, Subd. 8 and 7 MCAR § 1.661 B.21, definition of provider compared to consumer. In both § 1.661 B.21 and this rule particular emphasis on clarifying what is meant by material financial interests. The rules require that a conflict of interest be declared in writing to the HSA before review starts on an application. Additionally, any person shall have a right to question orally or in writing whether or not a conflict of interest exists.

When a conflict of interest exists, there will be fewer board members available to vote on the matter in question. To prevent the HSA vote from being based upon less than a reasonable number of affirmative votes, persons having a conflict of interest should be excluded from the count of board members needed for a quorum. For example, without this rule, if an HSA board of directors had 30 members and 10 were found to have a conflict of interest, it would be possible for only a quorum to be declared present with only six remaining board members and four affirmative votes could adopt a motion regarding a project. With the rule, it would take at least 16 board members to be present besides the 10 persons with a conflict of interest and a majority of the members voting shall be necessary to adopt a motion regarding the project. Considering the statutory purpose to base decisions upon maximum possible participation on the local level by HSA directors (Minn. Stat. § 145.832, Subd. 1), this rule is reasonable and necessary.

E. Ex parte communications.

The term "ex parte communication" (7 MCAR § 1.661 E.) is needed to advise the public that the HSA, the SPA, and Commissioner, as well as their staffs, are restricted in their communications during the review process. Such restrictions preserve the objectivity of the process, as well as the due process rights of the applicant. They also assure all parties of an equal opportunity to submit factual information for consideration. Black's Law Dictionary, Revised Fourth Edition, 1968, p. 661-2, contains a definition of "ex parte" which is the basis for this rule. As applied to a judicial proceeding, Black's explanation is that ex parte means an application (or communication) is made by one party to a proceeding in the absence of the other. It would not be ex parte if both parties had notice of it.

This prohibition against ex parte communication does not apply to attempts by government officials to investigate possible misrepresentation, inaccuracy, or omission of relevant information. This is similar to court appeal of a contested case proceeding under Minn. Stat. §§ 15.0424 to 15.0426. The review is based upon the record except when irregularities in procedure are alleged. Minn. Stat. § 15.0424, Subd. 6. Thus, here, the government may look beyond the record to determine if there are irregularities.

F. Extension of review period.

7 MCAR § 1.661 F. describes the process for obtaining an extension of time for review. Minn. Stat. § 145.837, Subd. 3, specifies that the review period may be extended for any length of time upon mutual agreement of all three parties referenced in this rule. In order to obtain verification of this agreement and to process requests in an orderly manner, it is reasonable

that the agreement be reached through written notification and that each of the parties be required to promptly respond to requests for an extension of the review period as specified in the rule.

7 MCAR § 1.661 F.4. is based upon the Minnesota Supreme Court case, Benedictive Sisters Benevolent Association v. Pettersen, 299 NW 2d 738 (Minnesota 1980). The decision established that the time periods are directory and that the merits of the HSA and Commissioner review should be the key to the process. The time period should be and, as a practical matter, have been strictly maintained; however, there may be minor variations in time which would not, for example, grant grounds to the applicant to consider the pending certificate of need or waiver approved.

G. Time computation.

The Act and these rules are replete with numerous references to acts which must be done within specified time periods. To avoid confusion over when the time periods begin and end, 7 MCAR § 1.661 G was added to the rules. It is based upon Rule 6.01 of the Rules of Civil Procedure for the District Courts. This method was chosen because a process for computing time that has worked well in another setting would be inherently reasonable. In other words, it has been proven effective.

The only variation from the system used by the State's district courts relates to the start of time periods upon the receipt of a document. Under the court system a document is considered served when it is placed in the mail. Time periods begin to rule when the item is mailed. In those situations the court rules expand the time period by three days to allow for the time it takes to be delivered. The Commissioner has instead opted for time periods to begin when the document is actually received (although the proposed rules are consistent with the court rules in holding that the act of mailing tolls the running of a time period). This approach seems more consistent with the less

formalistic process established by the Act and rules. Applicants generally become involved in certificate of need matters on relatively infrequent occasions and might assume that a time period begins when they receive an item. Thus, this one change from the court system seemed desireable.

H. Evasions.

7 MCAR §§ 1.661 H. defines conditions which are "evasions," pursuant to Minn. Stat. § 145.841. The planning concepts of interdependent or interrelated review are fundamental to comprehensive health planning and are among the purposes of the Act. Relationship among the various services is studied within the certificate of need review process. Possible combined financing arrangements are key considerations in determining whether a project is a "single proposed construction or modification." Financing arrangements are critical to the question of evasions because of the interdependent nature of numerous services in a health care facility even though they may not be physically connected to one another. Since combined financing generally must go through a comprehensive review by financial specialists associated with lending institutions, there is an interdependent relationship. The costs of combined financing, as well as temporal considerations, are interrelated. It is reasonable that these matters be considered a single undertaking.

7 MCAR §§ 1.661 H.2. is needed to clarify that the mere existence of a long-range planning effort by the institution, as described in the statement of need for 7 MCAR §§ 1.661 B.16., does not constitute a reviewable "project." This is consistent with the previously described health planning concept for encouragement of institutional planning.

I. Interpretation of rules.

Interpretation of the Act is governed by Minn. Stat. ch. 645. Chapter 645 contains the canons of construction and definitions of terms which apply to all laws enacted by the Legislature. Similar interpretation guidelines have not been established for rules. Since rules have the force and effect of law, Minn. Stat. § 15.1413, Subd. 1, it is appropriate that the same canons of construction apply to them. This is what 7 MCAR § 1.661 I does. (A bill pending before the Legislature, S.F. 1043, and H.F. 1159, would make most of chapter 645 applicable to rules. If enacted, 7 MCAR § 1.661 I. could either be deleted or substantially changed, depending upon the actual wording of the bill.)

7 MCAR § 1.662 Determination of Applicability and Waivers.

A. Submission of notice.

Minn. Stat. § 145.835, Subd. 1, require that a notice of intent be submitted to the HSA before an applicant starts any significant planning with respect to a project. The purpose of the notice of intent is to create basic regimenting and ordering of the review process. Accordingly, it is necessary for the notice of intent to be submitted a reasonable period of time in advance of submission of an application to achieve the purposes of a notice of intent. Since the Act only applies to construction and modification projects of a significant nature (projects of a less significant nature are not subject to the Act or may be waived from review), it is reasonable that the applicant would have started planning at least 60 days before submission of an application. Furthermore, the 60 day notice period is consistent with the 60 days given the HSA and Commissioner to act upon a request to determine whether the Act is applicable to a project as specified in Minn. Stat. § 145.835, Subd. 2. The request for determination must be accompanied by a letter of intent.

This time period would not, therefore, be a hardship to the applicant. On the contrary, a great deal can be accomplished to advance comprehensive health planning during the 60 days between submission of the notice of intent and the application. For example, the HSA staff could consult with the applicant regarding the contents of the application and the method for submission of the application. Finally, such advance notice of intent prepares the HSA staff and board for future review process and enables advance planning for a thorough, orderly, and otherwise competent review.

7 MCAR § 1.662 A.3. directs the HSA to forward a copy of the notice of intent to the Commissioner and SPA within ten days of receiving it. This provision

is needed to clarify the phrase "promptly notify" the Commissioner and the SPA in Minn. Stat. § 145.835, Subd. 1. This rule also assures the applicant of prompt notification of the schedule for submission of an application. Such notification is reasonable to simplify and clarify the application process for the applicant.

7 MCAR §§ 1.662 A.4 is necesaary to provide a list of the contents of a notice of intent. Only absolutely necessary items are to be provided in this earliest submission, and care has been taken to exclude information which may not be available at this early time. Furthermore, at the point a person is ready to engage architectural, consulting or fund raising services, the project should have progressed beyond the initial stages and have taken suffucient form so as to enable the person to provide general information requested in this rule.

It should also be noted that the notice of intent is the document from which the Commissioner must determine whether the activity is subject to the Act. It is, therefore, necessary that the proposed construction or modification be thoroughly summarized and that the estimate of capital expenditures be projected at this time.

A statement has been made in 7 MCAR § 1.662 A.5. to inform the public that a notice of intent does not establish an assumed restrictive right to sponsor a project. In the past, some persons have questioned this point.

As an administrative procedure consistent with the purposes of the Act, it is critical that the time period between the submission of the notice of intent and the application be limited. Periods of time less than one year were considered, but rejected, because it was felt that complications in dealing with architectural and other consultants and internal facility reviews frequently

take many months even when the same basic project is being considered. In the other hand, a period of time more than one year indicates extended delays, extended consultation for modifications and, frequently major changes in capital expenditures. Therefore, if applications have not been submitted within one year after the submission of the notice of intent, it must be assumed that the project has been either cancelled or significantly modified. It is, therefore, reasonable to require submission of a new notice of intent after this one year delay.

To allow for situation when a notice of intent could not have been submitted 60 days in advance, the Commissioner should be permitted to waive or reduce this time requirement. Since the 60 day requirement is for administrative purposes, a waiver or reduction of this requirement in special circumstances would not be inconsistent with the Act or these Rules. This rule recognizes that when special circumstances arise, it is fair to the applicant to proceed with the review process in a expedited fashion.

B. Determination of Applicability.

Minn. Stat. § 145.835, Subd. 2 allows a potential applicant or any person directly affected to request a determination as to whether the Act applies to a proposed project. While the Act allows a request for a determination of applicability at the time of submission of the notice of intent, there is also a need to allow a request for determination of applicability regardless of whether a notice of intent has been submitted.

The request for determination of applicability either before or after submission of the notice of intent would as a practical matter be necessary for persons other than the applicant. Since the Act allows any person (not just the applicant) directly affected to request a determination of applicability,

the timing of the request must logically include an earlier or later request.

Similarly, it needs to be clarified that the Commissioner may, without specific request by an outside party, make a determination regarding applicability of the Act. To not have such authority would be a severe limitation in enforcement powers.

The Commissioner needs specific ability in rule to ask for additional clarifying information if the notice of intent is insufficient to determine applicability. If the applicant does not supply such additional information upon request, the only recourse available to the Commissioner is to assume that the unavailable information would make the project subject to review. The type of additional information which could be requested by the Commissioner in such cases would be clearly limited to Minn. Stat. §§ 145.833, Subd. 5 and to 7 MCAR §§ 1.661 B.7.

In order to encourage response to the Commissioner's information request and to permit prompt action by the Commissioner, the rule cites failure to supply information as grounds for determination of applicability. Obviously, the Commissioner's determination could be changed at a later date if a new request for a determination were submitted containing information which established that the project did not fall within the jurisdiction of the Act.

7 MCAR §§ 1.662 B.3. describes the procedure which the HSA and the Commissioner shall follow in determining whether a certificate of need is required. This

procedure, which is set out in Minn. Stat. 145.835, Subd. 2, is included in the Rules to clarify the provisions to the public and follows in logical sequence after the steps specified in 7 MCAR § 1.662 B.1. and 2. Placing statutory provisions in the rules as part of a sequence set out in the rules is crucial to the ability of persons affected by the Act to comprehend its meaning and effect.

C. Acquisition of Equipment by Physicians.

This rule is necessary to assure that adequate information is submitted by physicians who propose to acquire diagnostic or therapeutic equipment which require a capital expenditure in excess of $150,000. All of the information items listed in 7 MCAR § 1.662 C.1 are related to the criteria specified in 7 MCAR § 1.662 C.5. for making the decision on this matter.

Since only certain types of non-health care facility, organizational structures are covered by this section, it is necessary for the legal structure or organization to be identified in the notice. With respect to the other items which a requestor must submit under 7 MCAR § 1.662 C.1. a to k, they are factors which can shed light on whether there is such a connection between the doctors acquiring the equipment and a health care facility so as to lead to a conclusion that the proposed acquisition is designed to circumvent the Act.

The information to be submitted recognizes a tremendous potential variety of facts which could impact the nature and significance of the relationship

between a facility and a physician's office. For example, circumvention of the Act may occur when a health care facility is involved in funding or support of the equipment to be acquired or when a reasonably large volume of patients from a health care facility are expected to use the equipment. Or as another example, there may be no direct financial relationship, but the nature of the relationship benefits the health care facility materially because the facility does not need to purchase the equipment itself.

7 MCAR § 1.662 C.2. sets up a reasonable process for the determination of whether a notice is complete. It is reasonable that the Commissioner make a decision within a short period of time relative to completeness of the notice. Twenty days is comparable to the total time for completeness review of applications specified in Minn. Stat. § 145.836, Subd. 1. If the Commissioner finds the information to be incomplete, it is reasonable that immediate steps be taken to inform the requestor and to indicate what will cure the defect sufficiently to allow the Commissioner to make his determination.

If the Commissioner finds the notice to be complete, the prescribed 60 day period for the Commissioner to make his decision relative to circumvention should immediately commence. Not to require submission of complete information before the 60 day period begins to run would result in many meaningless reviews.

Consistent with the policy of the Act which calls for input from the local level on health planning decisions, the proposed rules permit the HSA to comment on the proposed acquisition or purchase and request a public hearing. A 20 day time period is reasonable for HSA comment since a longer

period would make it almost impossible for the Commissioner to hold a public hearing and render a decision before the end of the 60 day review period.

If a hearing is held, it will be conducted by a hearing examiner from the Office of Administrative Hearings. As 7 MCAR § 1.662 C.4. indicates, the hearing examiner's report shall be considered advisory to the Commissioner and not final. This is consistent with the contested case provisions of the Administrators Procedures Act as found by the Minnesota Supreme Court [Independent School District No. 277 v. Pautz , 295 NW 2d 635 (Minn. 1980); and People for Environmental Enlightenment (PEER) v. Minnesota Environmental Quality Council, 266 NW 2d 858 (Minn. 1978)] and Minn. Stat. § 145.835, Subd. 3, which requires that the Commissioner make the final decision.

7 MCAR §§ 1.662 C.5 prescribes certain factors which the Commissioner must consider in determining whether a proposed acquisition or purchase is of a design which would circumvent the Act. The first four factors are ways in which the health care facility could materially benefit by the proposed acquisition or purchase.

In some situations a significant proportion of patients of the health care facility may use the equipment to be acquired by a physician. This situation would materially benefit the health care facility because the health care facility would be less likely to need to purchase the equipment. Such a purchase would be subject to the Act. Other relationships between physicians and health care facilities related to the equipment purchase which might potentially benefit the facility include rental space from the health care

facility, billing arrangement through the health care facility, transportation relationships between the two entities, various types of shared staffing arrangements, physical connections between a physician clinic and a health care facility or assistance in financing.

It is also reasonable to consider, as a factor in circumvention, the necessity of a health care facility to purchase such equipment if the acquisition were not made by the physician's office involved. Such equipment acquisition by the health care facility would be reviewable under the Act and therefore, based upon equal treatment, a review should be performed for a comparable purchase by a physician's office.

The fifth factor is needed to enable the Commissioner to consider other information germane to this decision and consistent with the Act. This is inherently fair as well as logical as any such information would have been submitted by the requestor or would have been introduced as evidence at a hearing and subject to rebuttal by the requestor. Not to permit the Commissioner to consider a relevant category of information which was not thought of during the promulgation of these rules, but which becomes apparent through an orderly fact-finding process, would be an absurd result and not required by any principle of law.

The final sections of this proposed rule (7 MCAR §§ 1.662 C.6. and 7.) describe the process the Commissioner will use to make his decision and to notify the applicant and HSA of the result. The process is a reasonable administrative method for granting written notice of the decision as required by Minn. Stat. § 145.835, Subd. 3. and if consistent with the

time frames for determination of applicability in Minn. Stat. § 145.835, Subd. 2.

D. Waivers.

Minn. Stat. § 145.835, Subd. 4, cites two situations where a waiver for a Certificate of Need may be granted to a proposed project. The law also gives the Commissioner authority to promulgate rules for granting a waiver in other situations. These situations must not be inconsistent with the Act or the National Health Planning and Resources Development Act. This rule is needed to enumerate these additional situations and to identify the details of the process under which waivers may be granted.

7 MCAR § 1.662 D.1.a. describes the situations covered by the Act and provides additional examples of items which are eligible for waivers under Minn. Stat. § 145.835, Subd. 4. It is necessary and reasonable to provide these additional examples so that the public can better understand the types of services which will not be considered direct patient care services.

7 MCAR § 1.662 D.1.b. is a reasonable use of the Commissioner's authority to add waiver situations because it applies to acquisition of equipment which will have an insignificant impact on health planning. Acquisition of diagnostic and therapeutic equipment which simply replaces existing equipment and which has approximately the same capability should not

require an extensive application and review for approval. Subject to the waiver limitations as listed in 7 MCAR § 1.662 D.2, this rule allows routine approval of replacement of equipment because such replacement does not change patient referral patterns, utilization patterns, or other health planning considerations.

7 MCAR §§ 1.662 D.1.c. allows waivers for changes in beds between categories when the changes have no appreciable impact on health planning or health services within the area, when the project is not reviewable under other provisions of the Act or these rules and when the criteria of 7 MCAR §§ 1.662 D.2 are met. This waiver is reasonable because it screens those projects which may effect health planning in contrast with those which are merely routine changes in bed categories. Changes in bed categories which affect health care considerations are subject to a Certificate of Need review.

7 MCAR §§ 1.662 D.1.d. provides for a waiver for reviewable predevelopment activity. While a waiver would not be granted when a significant increase in patient charges would result or when the predevelopment activity would be inconsistent with existing health planning documents, a full certificate of need review of other predevelopment activity would be pointless. In these latter situations, predevelopment activity must be pursued before the information would be available to the applicant to submit a complete certificate of need application and for the HSA to review the criteria specified in the Act. Unless the proposal is abandoned, these projects will result in a reviewable project at a later point.

When an existing health care facility is acquired by another health care facility, (7 MCAR § 1.662 D.1.e.) the project may frequently also not have appreciable impact on health planning or the other health services within the area. However, this category of project is subject to the Act and the considerations for waiver must be applied to these projects.

The criteria for reviewal of waiver requests are listed in 7 MCAR § 1.662 D.2. These criteria are clear and concise and the Commissioner will be able to apply them without an extensive application or a detailed review involving an HSA hearing. The criteria are intended to separate the insignificant projects from projects with significant financial or health planning implications.

The three criteria enumerated in this rule are derived from and based upon the review criteria of Minn. Stat. § 145.837, Subd. 1. Since these criteria form the basis for determination of whether or not certificate of need should be issued, it logically follows that they should be the touchstone for waiver determinations. However, they have been carved down and made more specific to more easily advise applicants, HSA planners and the general public of the precise matters which should be focused upon in a waiver review. When a potential project is eligible for waiver consideration, the applicant and planners can save time and money by considering limited, specific criteria instead of the complete list of review criteria in the Act.

7 MCAR §§ 1.662 D.2.a. establishes the criterion relating to significant increases in patient charges. This criterion is an elaboration of Minn. Stat. §§ 145.837, Subd. 1 (g), which requires consideration of the probable impact on the health care facility's operating costs and charges. It is reasonable that a project which would result in a "significant increase" in patient charges be ineligible for a waiver of certificate of need review because of the cost control purposes listed in Minn. Stat. §§ 145.832, Subd. 1. The relative costs and benefits of a proposed project involving a significant increase in patient charges should be analyzed by the HSA and the Commissioner through a full review process. It would be inconsistent with the purposes of the Act to grant waivers to projects which involve significant increase in patient charges.

A 5% increase in patient charges was selected on the basis of experience by the Department in these matters and is a reasonable threshold for when to investigate the rising cost more thoroughly by certificate of need review. The 5% standard will be applied after including projected inflation increases. These inflation increases would affect the calculation of adjustments in patient charges in ways not related to the proposed project. Allowing an inflation increase also is reasonable since it is based upon the allowable hospital charge increase limit established for the Hospital Rate Review program and comparable inflation indicators for other health care facilities. The Department of Public Welfare is currently developing an inflation indicator for long term care facilities and, for the small number of other types of facilities, the industry norms can be considered. These inflation indicators are distributed to facilities well in advance of the affected period and are therefore a commonly available, consistent, simplified reference point for inflation.

7 MCAR § 1.662 D.2.b. is based upon Minn. Stat. §§ 145.837, Subd. 1, (b), (c) (d), and (e). To ascertain the relative importance of certain projects which would be granted waivers, it is necessary to consider the items listed in this rule. These items generally referred to the health planning purposes of avoiding unnecessary duplication, maintaining appropriately high utilization rates and maintaining optimum effectiveness and efficiency of operations as cited in Minn. Stat. §§ 145.832, Subd. 1.

A third criterion in 7 MCAR §§ 1.662 D.2.c.is based upon Minn. Stat. § 145.837, Subd. 1 (a) and (b) which require analysis of a project in view of health planning documents. It is necessary to add the State Health Plan to be list of documents contained in the statute because the State Health Plan combines and clarifies the statutorily specified health systems plans and establishes statewide policy in situations of overlap, omissions in the health systems plans or statewide needs. However, the weight given the State Health Plan shall be as specified in 7 MCAR § 1.663 C.6. The inclusion of the State Health Plan is further justified as a part of review criteria, 7 MCAR § 1.663 E.1. In that section of the Statement of Need and Reasonableness, there is a considerable discussion of how health systems plans are incorporated into a State Health Plan and the detailed collaboration between the health systems plans and State Health Plan.

7 MCAR § 1.662 D.3 is needed to provide the potential waiver applicant with advance notice of the necessary information to submit with a waiver request. 7 MCAR § 1.662 D.3. a,b, and c are necessary to judge the eligibility of a waiver proposal, according to Minn. Stat. §§ 145.835, Subd. 4, (a) and (b), and 7 MCAR §§ 1.662 D.1. 7 MCAR §§ 1.662 D.3 d and e are needed to enable the Commissioner to evaluate the request in light of the criteria for a waiver listed in 7 MCAR §§ 1.662 D.2.

7 MCAR § 1.662 D.4. prohibits the HSA from making a recommendation until the project's sponsor submits a request that contains all necessary information. The requirement is reasonable on its face. Decisions simply should not be made without having all the relevant data. The rule also contains a necessary corollary to the requirement of acting only after receipt of complete information. That corollary is the authority to ask for additional information. This is not an unilateral authority, however, because whatever is requested must relate to and allow for full review of the waiver request in light of the eligibility standards and review criteria.

To understand the basis for the HSA recommendation, 7 MCAR 1.662 D.4 requires the HSA to submit a rationale in support of its recommendation as well as all information submitted by the applicant. It is necessary that the information which the applicant submitted be sent to the Commissioner. This is because the action of the HSA is a recommendation only. The Commissioner alone makes the final decision. This final decision would not be possible without having access to all of the underlying information which bears on the request.

7 MCAR § 1.662 D.6. merely states the time which the Commissioner has to make his decision. The time limit is prescribed in statute. It is important to repeat it in the rule because the rule outlines the entire process. To leave this out merely because it appears in the statute could cause confusion and at a minimum inconvenience to the reader by forcing the person to jump back and forth between the Act and the rules.

The procedures for applying for and being granted an emergency waiver are established in 7 MCAR § 1.662 D.7. The need for this rule was established in Minn. Stat. § 145.835, Subd 5, which requires the Commissioner to establish procedures to expedite waivers under emergency conditions. It is reasonable under such circumstances that the written request require only minimum information and that copies of the emergency waiver request be sent to both the Commissioner and the HSA simultaneously. It is a practical necessity to allow the HSA three working days to forward its recommendation since the HSA must verify the disaster and the HSA may have other emergencies to deal with at the same time. This rule does not preclude the HSA from making a recommendation to the Commissioner in a shorter period of time.

A total of five working days is the maximum time proposed for a review of emergency waiver requests. This recognizes concurrent review by the Commissioner and the HSA and the potential that a review could be completed in less than five working days.

Considering the minimal amount of review that would be possible within this short period of time, the criteria for granting emergency waivers must be extremely straightforward. An emergency waiver shall be granted when the Commissioner finds that the two conditions exist as specified in 7 MCAR § 1.662 D.7.d.(1) and (2). When either of these two conditions is not met, it would indicate that a full certificate of need review would not be detrimental to the health of people in the community. That is, even if a disaster struck a health care facility, an emergency would not exist because the facility's patients can still be adequately cared for and the purposes of the Act would only be met by a routine certificate of need review.

7 MCAR § 1.662 D.6 e clarifies that the nature and scope of an emergency waiver project is limited to replacement or repair necessitated by the disaster. Given the limited circumstances under which an emergency waiver is applicable, it naturally follows that no expansion, extension, or other remodeling shall occur under the auspices of this type of waiver.

For the purposes of enforcement and periodic reports, 7 MCAR § 1.662 D.8. is needed to clarify that granting a waiver shall be considered to have the same effect as issuance of a certificate of need. This is reasonable because the threshold for applicability to the Act was met when the waiver was granted. It should be clear that enforcement under Minn. Stat. § 145.842 would be possible if there are violations related to a waiver.

Similarly, periodic reports are required by the Act and these Rules for all projects of "construction or modification," which by definition includes waiver projects. The periodic reports mechanism enables comparisons of the actual costs of the construction or modification with estimated costs in either an application for a certificate of need or a request for a waiver. In order to have a complete data base of "construction and modification" projects, it is reasonable to have such data on both waiver projects and complete review projects.

7 MCAR § 1.662 D.9. establishes when a waiver will expire. Minn. Stat. § 145.839 establishes a similar standard for fully processed certificates of need. If there were no expiration date for waivers, the authority to construct or modify the waived project would be continued indefinitely. Changes in the health plannning environment or critical changes in the conditions

associated with the project may occur. The purposes of the Act would not be met if these circumstances could never be reviewed.

An 18 month time limit is reasonable for expiration of a waiver because this is the same amount of time used for expiration of a certificate of need and conditions of a similar nature exist for both situations. On the other hand, 90 days is reasonable for commencement of construction based on an emergency waiver because of the expedited nature of the emergency waiver. If an emergency waiver project has not commenced within six months, it can be assumed that immediate repair was not necessary and further review of this matter would not be detrimental to the health of the community.

7 MCAR § 1.662 D.10. is needed to clarify the relationship between a waiver application and the evasion provision of Minn. Stat. §§ 145.841. cited above. This rule is reasonable because waivers are intended for very specific application as defined in the Act and these Rules, frequently with cost limitations associated. Separating projects into portions for waivers and other portions for consideration for review could, in some cases, eliminate the complete project from certificate of need review. On the other hand, to expedite the review process it should not be viewed as an evasion to ask for a waiver for every part of a total project when the remaining component is still subject to certificate of need review. In this case the waiver could be denied if it is inconsistent with the purposes of the Act to not review the project as a whole.

The waiver provisions found in these rules are not inconsistent with the National Health Planning and Resource Development Act. In certain provisions these rules are more stringent than the federal law and regulations, an option available to States. The waiver provisions in these rules are not identical to federal "required approvals" or "expedited review." Substitute procedures from those in federal regulations are anticipated in 42 CFR §§ 122.308 and 123.411.

7 MCAR § 1.663 Review process, procedures and criteria.

A. Submission and contents of application for certificate of need.

7 MCAR § 1.663 A.1. establishes the administrative process for submission of applications. It is needed to assure an orderly process for submission of applications and to permit the staff to establish basic work schedules. Without time periods and schedules for submission, the HSA staff and the Commissioner would have difficulty predicting workloads and the quality of work may suffer.

In addition, by controlling the submission of applications, HSA committee meetings and hearings can be scheduled on a long-term, regular basis. This is important because HSA members who serve on committees and at hearings are volunteers. Scheduling meetings and hearings on a regular basis allows members to plan their own schedules and the chance that they will be able to attend. This can have a beneficial effect on the system because failure to have a quorum would result in rescheduled meetings and hearings, which translates into delay for the applicant.

Applicants are protected in the rule from long intervals between submission dates by the requirement that applications may be submitted at least every 30 days. They are further protected from surprise changes in the submission schedule by the requirement that any changes be announced in the State Register 60 days in advance. Thus, applicants will always have advanced notice of the submission schedule which will allow them to adjust their own internal planning process.

The proof that this process is reasonable rests in experience. The process has been used by HSAs and the state planning agency for several years under the requirements of the Federal Social Security Act, Section 1122. The Federal Social Security Act is a concurrent federal need review process conducted by the HSA, SPA and the federal Department of Health and Human Services. A monthly review schedule has proven to be a workable and reasonable process.

7 MCAR § 1.663 A.2. specifies the number of copies of the application which must be submitted. This is a resonable and necessary administrative requirement for expeditious processing of an application. If the applicant submitted only one copy of the application, the HSA would have to immediately make copies for internal review and distribution to the Commissioner, the SPA and HSA committees. It is quite likely that several days of review time would be lost in this process. For this reason, submitting multiple copies is in the best interest of all parties. In addition, requiring the facility to submit multiple copies does not significantly increase its costs.

Fourteen copies was selected as the required number so as to provide one copy for each of the 11 members of the typical project review committee, one copy for the HSA staff, one copy for the Commissioner, and one copy for the SPA. If the HSA requires additional copies of the application, it can photocopy them within a reasonable period of time without delaying the review process which can start immediately because of the multiple copies. Some HSAs have requested more than 14 copies. While applicants may voluntarily provide such extra

copies, it is our opinion that it would be unduly burdensome to provide more than 14 copies as a general rule.

7 MCAR § 1.663 A.3. requires the Commissioner to develop different application forms for the different types of health care facilities subject to the Act. In order to make the application form specific to each type of facility, it is necessary and reasonable to have four separate application forms. For example, the application information for hospitals will differ from the form for long-term care facilities (nursing homes and boarding care homes). Information in the application which are different in these two types of facilities are operating costs, methods for examining the revenue, methods for describing geographic area served, patient origin, existing similar health care facilities, alternatives which should be considered as a substitute for the project, and the relationship to the health systems plan. Similar differences exist between these two classes of projects and supervised living facilities which are proposed for mentally retarded persons and persons with related conditions.

7 MCAR § 1.663 A.3.c. requires that to the extent practicable the application form allow the applicant to substitute material from other similar, governmental need determination programs. The Minnesota Department of Public Welfare determines the location of and need and programming for certain facilities for mentally retarded persons. (Minn. Stat. § 252.28 and DPW Rule 185.) It is reasonable that, to the extent possible, the material in these applications be used in the state certificate of need application. The applicant would thereby be saved the effort of developing a totally new application.

Other types of entities such as out-patient surgical centers, HMOs, physicians' offices, and other entities acting on behalf of hospitals may be required to apply for a certificate of need. Accordingly these applicants should have a separate application form which allows more flexibility than the other three forms.

7 MCAR § 1.663 A.4. lists the information which shall be included in all application forms. Minn. Stat. § 145.836, Subd. 2, authorizes the commissioner to prescribe the format for the certificate of need application. This statute also describes minimum information to be included in the application. This rule complements the items listed in the Act by clarifying critical items of information and adding certain information items which relate to criteria for review in the Act and these rules.

7 MCAR § 1.663 A.4.a. requires a description of the project. This item is listed first to provide the reader with an immediate description of the project and to promote easier understanding of the application. The information requirements in this Rule is needed so that the review criteria in Minn. Stat. § 145.837, Subd. 1, can be applied to the project and for initial understanding of the project's scope.

7 MCAR § 1.663 A.4.a.(1) simply clarifies Minn. Stat. § 145.837, Subd. 2 (d) by requiring a comparison to the existing building and services. Clause (2) of this rule clarifies the information required by Subd. 2 (d)(2) of the same Section of law as well as 7 MCAR §§ 1.663 E.2.c., 4.a. and 4.d.

Clause (3), relating to a statement by an architect or other construction specialist, is needed to clarify the status of conformance with physical plant requirements. In the past, when this requirement was not present, projects frequently have been delayed or confused during certificate of need review due to lack of sufficient evidence that the projected modifications are in conformance with State and federal requirements. In several past cases, the applications were remanded to the HSA partly due to lack of clarification of physical plant requirements. And, in other cases, certificates of need were issued but after further investigation by the applicant found that the project had to be cancelled or significantly changed due to State and federal requirements for physical plants. It is in the best interest of both the applicant and government to have an understanding of the status of physical plant requirements before certificate of need review.

Clause (4) requires information which will permit review of the cost and methods of energy provision, a criterion for review in Minn. Stat. § 145.837, Subd. 1 (k) and 7 MCAR § 1.663 E.4.e. Complete information relating to this important criterion is necessary in order for the HSA and Commissioner to adequately consider it in the certificate of need decision.

Finally, clause (5) of 7 MCAR § 1.663 A.4.a. requires anticipated dates of commencement and completion of the project, as required in Minn. Stat. § 145.836, Subd. 2.

Since the purposes of the Act are largely related to financial aspects of the project, 7 MCAR § 1.663 A.4.b. requires more extensive informational than other sections of the application forms.

As authorized by Minn. Stat. § 145.836, Subd. 2 (d)(1), the rules require the applicant to submit information regarding the capital budget or estimated total capital expenditures of the project. The list of major component expenditures in 7 MCAR § 1.663 A.4.b.(1)(a) is taken from commonly accepted construction procedures including forms used by the federal Department of Health and Human Services for federal construction programs and the past experience of HSAs and the Department of Health in review of certificate of need applications.

7 MCAR § 1.663 A.4.b.(1)(b) requires a description of the effect of the project on the applicant's solvency. Such information is specifically required in Minn. Stat. § 145.836, Subd. 2, (d)(3). Furthermore, this information is needed so that the project can be evaluated based upon the review criterion in Minn. Stat. § 145.837, Subd. 1, (g).

It is reasonable that a solvency determination be based upon standard financial indicators. These indicators are prescribed to elicit commonly formated information for project review purposes. Since the financial indicators are easily calculated from existing financial reports, this requirement will not unduly burden the applicant with additional data collection.

The specific selection of financial indicates in this rule permits comparison of at least five minimum indicators among all applicants. These five indicators were selected on the basis of the Department's experience in hospital rate review since 1975 and thorough research into the appropriate use of indicators in the health care facility industry to demonstrate general financial solvency.

The ratio of debts to total assets is the "debt ratio" in common usage.[3] This indication shows the facility's ability to withstand times of financial hardship and to, in general, meet both its short-term and long-term obligations.

The next three ratios operating revenue to total assets (commonly called "total asset turnover"), operating revenue to fixed assets (commonly called "fixed asset turnover")[4] and total revenue to fixed assets (a variation of "fixed asset turnover") are indicators of funds management or efficiency in dealing with their assets. Turnover relationships reflect upon a facility's long-term solvency. Large investment in fixed assets limits the flexibility of the facility to respond to changes in the marketplace and general solvency could be weakened.

[3]Helfert Erick A., Techniques of Financial Analysis, Homewood, Illinois, Richard D. Irwin, Inc., 1967, p. 61.

[4]Cleverley, William D. and Nielsen, Karen, "Assessing financial position with 29 key ratios," HFM, January, 1980, p. 32.

The final ratio, interest to total expense (which includes interest), is commonly called the "interest expense ratio."[5] This ratio measures the impact of debt financing on facility expenses. In general, this is categorized as a "capital structure" ratio measuring the desirability and realism of additional debt financing. If the health care facility reimbursement system in the future forces more price-competitive relationships among facilities, this ratio, as well as the others described above, would become even more critical indicators of financial feasibility.

Minnesota hospital averages for all of the above ratios are available based upon data back to 1977. Such data was published in the "Report on the Minnesota Hospital Rate Review System" by the Minnesota Department of Health, December 1979, p. 183. Data for recent years will be made available soon by the Department of Health. Similar averages and industry norms can be developed for other health care facilities.

7 MCAR § 1.663 A.4.b.(1)(c) (availability and method of financing) reflects the informational requirement of Minn. Stat. §§ 145.836, Subd. 2 (d)(4). It would not be possible to fully and adequately assess this information without requiring the specific detail of itemization of the financing costs, an estimation of the interest rate, and the projected debt service amount as a percentage of the cost per adjusted patient admission. This information is critical to determine whether the cost of the resulting service is reasonable compared to similar services.

[5] "Financial Ratios of Minnesota Hospitals, 1978 Study," unpublished report to the Minnesota Department of Health by Peat, Marwick, Mitchell and Company, Minneapolis.

7 MCAR § 1.663 A.4.b.(2) requires an estimate of total operating costs based on the requirements of Minn. Stat. § 145.836, Subd. 2 (d)(2). This section is needed to clarify the method for presentation of operating costs. The estimated operating costs must conform to "cost centers" as described in Minn. Stat. § 145.833, Subd. 3. Since almost all health care facilities in Minnesota utilize the cost allocation requirements of Medicare and Medicaid and the Minnesota Hospital Rate Review System, it is reasonable to require the use of these cost allocation requirements in the certificate of need application. Other cost allocation requirements are proposed for less well-known or future cost allocation systems for health care facilities. Since these cost allocation methods constitute the existing procedures in the health care industry, the applicant will incurr no significant additional cost in determining such costs.

7 MCAR § 1.663 A.4.b.(3) is needed to evaluate the anticipated effect the project will have on the facility's revenues. This information is required in Minn. Stat. § 145.836, Subd. 2, (d)(3).

To determine the impact of the project on the facility general financial solvency, it is necessary to know an estimate of the total annual revenue upon completion of the project for at least five years. These figures are then compared with the operating costs estimates obtained in the previous section.

Minn. Stat. § 145.836, Subd. 2 (d)(3) also requires that the application contain a description of the impact of the construction or

modification on the facility's per day and per admission charge or per out-patient visit charge. In order to improve the relavance of the data reviewed, it is reasonable that such information be reported as average patient charges by services affected by the project. Data on aggregate patient charges may indicate relatively small aggregate impact on charges but there may be large changes in the charges to patients of the affected service.

7 MCAR § 1.663 A.4.c. is needed to provide information required by Minn. Stat. § 145.836, Subd. 2 (a) and to clarify the nature of the geographic description in terms of standard political boundaries. This rule is necessary to obtain uniform, comparable identification of the geographic area and it is reasonable to make use of commonly accepted identifications. It is also necessary and reasonable for purposes of verification to identify the sources of data used to develop the proposed geographic service area.

7 MCAR §§ 1.663 A.4.d. is needed to fulfill the requirement of Minn. Stat. §§ 145.836, Subd. 2 (b). To make this material most useful in the review process, clause (1) requires that the population data be reported by demographic categories, i.e. age, sex and any other available individual descriptions. The population changes in a single demographic category may not be evident in aggregate population data. For example, even though total population in an area may be decreasing or remaining constant, population over age 65 may be increasing significantly and thereby germane to a Certificate of Need decision. As a general rule, different population groups have certain predictable differences in health service needs. These commonly form the basis for unique proposals by health care facilities.

7 MCAR § 1.663 A.4.d.(2) requires data which relates to disease in the population to also be submitted. This data is commonly available for mortality from diseases such as cancer and heart disease. In some instances morbidity rates are available which indicate high or lower incidence of certain diseases or conditions among certain populations. When this information is available, it should be submitted in the application for consideration by the HSA and Commissioner.

7 MCAR § 1.663 A.4.d.(3) is needed to supply information to be considered as a review criterion in 7 MCAR § 1.663 E.1.d.(3). The basis for this criterion is described in detail in the section of this Statement relating to review criteria. Receiving information relating to impact on underserved persons permits consideration of this very basic fulfillment of community needs.

More specific indications of the applicant's performance related to access to health services is required in 7 MCAR § 1.663 A.4.d.(4). This clause supplies the information to be used to consider the review criteria 7 MCAR § 1.663 E.1.d.(4), (5) and (6). The time period five years was selected to be consistent with other data requirements in Minn. Stat. § 145.836, Subd. 2, (d)(2) and (g). The information required by this clause would not be available to the HSA for consideration if not submitted in the application. Further explanation of the need and reasonableness of these access criteria are found in the section of this Statement on review criteria.

7 MCAR § 1.663 A.4.e. is needed and reasonable because it is required by Minn. Stat. § 145.836, Subd. 2, (f). The information required

is clarified by reorganizing the statutory language into an outline form and adds the informational requirement related to teaching, research and referral facilities. This latter information requirement is needed to consider its impact as a criterion for review specified in Minn. Stat. § 145.837, Subd. 1 (i) and (j).

Information on consumer choice plans and programs (7 MCAR § 1.663 A.4.f.) must be submitted in order for the HSA and commissioner to evaluate criterion 7 MCAR § 1.663 E.3. relating to competition among similar services. The language used is intentionally general so that the facilities may use as much innovation as possible in exploring new ways to promote price competition. The project number of persons involved is important in order to assess the significance of the competitive plan in terms of number of citizens. The methods of public information on cost and quality is also critical so that the HSA and commissioner can assess the potential impact of the plans or programs as a marketplace controller of cost and indicator of public acceptability.

7 MCAR § 1.663 A.4.g. is needed because it is required by Minn. Stat. § 145.836, Subd. 2 (c). It is important to have data and findings from the facility on <u>each service component</u> of the project so that the complete review responsibilities of the HSA and commissioner can be performed. Since Minn. Stat. § 145.837, Subd. 1 (b) requires the agency to consider the relationship between the proposed project and the long range development plan it is reasonable to include this requirement in the content of the application. Such requirements are needed by the facility for internal planning and do not pose a significant additional cost to the applicant to supply the data in a certificate of need application.

7 MCAR § 1.663 A.4.h. is needed to make more specific the requirements of Minn. Stat. § 145.836, Subd. 2 (g). References cited in the review criteria section of this Statement shown that occupancy rates and utilization rates for specific services are critical health planning factors. This rule therefore requires that specific occupancy rates for licensed beds and beds which are set up and staffed be included in the application form. Both of these calculations of occupancy rates are needed because: (1) licensed beds indicate an institution's potential capacity and; (2) the set-up and staffed rate shows the actual operating history of the facility in terms of the occupancy.

Since Minn. Stat. § 145.836, Subd. 2 (f) requires submission of utilization data for existing facilities in the area, it is reasonable to require the applicant to submit historic utilization data, particularly occupancy data for its own facility. The information is requested for each of the past five years with particular detail on the preceding twelve months. The preceding twelve months provide recent trend information and is important for projection of future impact. The five year total average occupancy is particularly important for estimating projected impact with least variation due to seasonal or other short-term influences.

This rule also requires the applicant to submit projected utilization rates including documentation of assumptions for the first five years after completion of the project. It is critical that the documentation of assumptions be submitted to allow the HSA and the Commissioner to carefully evaluate the accuracy of the proposed utilization information. Occupancy rates do not describe the specific use of equipment or specified

services as well as utilization by service. Both occupancy and service specific utilization are important items of information and are clearly a part of the general authority to obtain projected "utilization" information specified in the Act.

Quality of care is to be considered by the HSA and commissioner as a review criterion specified in 7 MCAR § 1.663 E.4.f. The information on this criterion must therefore be required in 7 MCAR § 1.663 A.4.i. Without such information in the application the facts would not be in the record for consideration.

The survey reports from the Department of Health and voluntary survey groups was selected as the basic information in order to assure that there is basic reliability of facts to be used for quality conclusions. Quality of care is commonly defined differently among different groups depending upon experiences. The Department of Health data as well as voluntary survey groups (i.e. Joint Commission on Accreditation of Hospitals) have accepted standard for quality judgements which have undergone extensive evaluation.

7 MCAR § 1.663 A.4.j. is required by Minn. Stat. § 145.836, Subd. 2 (e). It is reasonable to require delineation of the reasons for rejecting alternatives to allow the HSA and the commissioner to critically analyze the application. It would be difficult or impossible for the HSA and the commissioner to analyze the alternatives considered and rejected unless the reasons for these choices are identified. The reasoning behind rejection of alternatives also assists the HSA and commissioner in their consideration of alternatives. Inclusion of reasons in the application therefore may shorten the review process.

The final component of the application is 7 MCAR § 1.663 A.4.k. This item is required by Minn. Stat. § 145.836, Subd. 2 (h) and is clarified in this rule to identify the types of relationships that should be included in the application. This clarification is needed to uniformly review applications and encourage consistency.

While there are other sections of the HSP, AIP and State Health Plan which may be related to a project, the most critical section of these documents for comparison is the planning objectives. According to the Minnesota State Health Plan Development Policy approved by the Statewide Health Coordinating Council, HSAs and the State Planning Agency must complete objectives if a priority goal has been established for this service. A priority health service component deserves special consideration as it relates to six service characteristics listed in this rule. The six characteristics are also taken from the Minnesota State Health Plan Development Policy and are used in all Minnesota HSPs and the State Health Plan.

Consideration of the State Health Plan in addition to the HSP and AIP is required by 7 MCAR § 1.663 E.1.a. Weight given to the State Health Plan is further described in 7 MCAR § 1.663 C.6.

B. Determination of completeness.

7 MCAR § 1.663 B.1. is needed to detail the application procedure requirements outlined in Minn. Stat. § 145.836, Subd. 1. The time

requirements in this rule are those required by the statute. They are included in this rule to assist the reader.

The rule clarifies the Act by requiring the HSA to identify the exact sections which it found to be incomplete and to explain why it concluded that the application was incomplete. Such identification and explanation is reasonable to assit the Commissioner in this decision on completeness and to notify the applicant how the application can be improved.

7 MCAR § 1.663 B.2. is needed and reasonable based on Minn. Stat. § 145.836, Subd. 1 which requires the commissioner to state the specific needs to be met for the application to be made complete. A determination that an application is incomplete does not necessarily mean that the application will not be reviewed during the review cycle in which it was initially submitted purusant to 7 MCAR § 1.663 A.1.

The rule specifies a procedure to allow the applicant to submit to the Commissioner the missing information within a short period of time (five working days) for a reconsideration of completeness. If the application is then found to be complete, it will not be deferred to the next review cycle. This provision is of obvious benefit to the applicant and grants a good deal of flexibility to the completeness determination, which could, as a narrow statutory interpretation, have been developed without a five day period for submission of missing information.

On the other hand, if the applicant cannot submit the additional information within five working days but does so within 60 days,

the application will be considered for completeness in the next cycle of reviews according to the schedule established in 7 MCAR § 1.663 A.1. If the applicant does not complete the application within 60 days, it is reasonable to assure that the applicant has decided for some reason to not immediately seek review of the proposed project. Sixty days is an intermediate period of time commonly used in the Act for decisions on progressing the application (i.e. length of time for HSA review). It is, therefore, reasonable that the commissioner no longer hold onto the incomplete application but return it to the applicant and require resubmission of an application when the applicant is ready to proceed.

7 MCAR § 1.663 B.3. is needed and reasonable to advise the applicant of the commissioner's interpretation of the meaning of a determination of completeness. The limited review for completeness should not be interpreted as a comment on the quality of the information but only that sufficient information has been supplied with respect to each part of the application so as to permit a meaningful review to begin. At a later time, a reviewing body may ask for additional clarifying information germane to its review responsibility. The determination of completeness is, however, an indication of the ability to start a review of each of the component parts of the application.

7 MCAR §§ 1.663 B.4. interprets Minn. Stat. § 145.837, Subd. 2 (6) to specify when the HSA review period begins. The HSA should not be expected to begin its 60 day review period until it has actually received notice from the commissioner that the application has been determined complete. It would be improper to expect the HSA to

assume that the commissioner has determined the application to be complete or incomplete without receiving the actual notice. If the HSA starts the review process prior to the commissioner's completeness determination, the HSA staff, HSA board members and interested public participants may not have information available which the commissioner may later find to be necessary for completeness. Additionally, because the notice from the commissioner might reasonably take two, three, or four days for handling and delivering, it would be improper to penalize the HSA in this regard.

C. HSA hearing process and procedures for determining recommendations on certificate of need applications.

This rule is needed to clarify and make specific the review procedures of Minn. Stat. § 145.837, Subd. 2. While the statute provides the framework for the review procedures, these rules provide the administrative details for accomplishing the review. These rules are also necessary to provide a consistent administration of the hearing process among all the HSAs in the state.

7 MCAR § 1.663 C.1. specifies that the first step shall be the scheduling of a date, time, and place for a public hearing. This is a reasonable procedure in order to establish the information necessary for notification of the public.

7 MCAR § 1.663 C.2. requires two types of notices of the public hearing. First, as required in Minn. Stat. § 145.837, Subd. 2 (2), notice shall be published in a legal newspaper. While the Act describes the time

limits for publication of the public hearing notice, it does not describe the contents of the notice. This rule describes the minimum contents to include a brief description of the project, date, time, and place of the hearing, and a description of how interested parties may obtain more information about the project prior to the hearing. This type of information is economically feasible for publication and provides interested parties with adequate opportunity to learn of any potential impact upon them. If interested parties wish to testify at the public hearing, they need this information about the project prior to such testimony.

The second required method of notice is the mailing of written notice of the public hearing to affected parties listed in the Act. This rule states that the notice shall go to all health care facilities located in the applicant's proposed service area. The Act states that the notice shall go to health care facilities located in the health service area and which provide institutional health services. As a clarification the rule specifies that the health service area described in the Act is most reasonably the facility's health service area and not the HSA health service area. In addition, since all health care facilities provide institutional health services, it is appropriate to include all health care facilities in this category. This scope of distribution would not unduly burden the HSA and is designed to provide appropriate notice to all persons who may have an interest in the project. Additionally, since the rate review agency in Minnesota is the Commissioner, separate notice to the rate review agency is not necessary.

This rule also requires additional written notification to HSAs which serve contiguous health regions. These contiguous HSAs have related health planning considerations. It is reasonable that they be given special notification and be requested to provide written comments prior to the public hearing or to appear at the public hearing to offer an opinion. It is also reasonable that these opinions be based upon facts and that these facts be cited at the public hearing.

7 MCAR § 1.663 C.3. further clarifies Minn. Stat. § 145.837, Subd. 2, by describing the proceedings of the hearing body which will conduct the public hearing. The procedure proposed in this rule is reasonable because it recognizes the importance of the public hearing and the need for careful delegation of responsibility by the HSA in conducting its review authority. Delegation is necessary in some HSAs to promote efficient use of board time and it is controlled by 7 MCAR §§ 1.661 B.12. and 1.661 C.2.c. In order to provide an opportunity for later examination of the public hearing proceedings by the Commissioner's staff, or by individuals who may appeal, there is clear reference to procedures for recording the proceedings in a tape recorder with either a verbatim transcript or written summary provided to the commissioner. The choice of either a verbatim transcript or written summary is provided in order to make an economical and flexible situation for HSAs.

The quorum requirements in 7 MCAR § 1.663 C.4. are needed and reasonable to assure that the recommendation from the hearing body and from the HSA has been reached after consideration of the evidence by a reasonable portion of the voting members and not only by a small

number of people in attendance. Robert's Rules of Order Revised, states that the quorum of a deliberative assembly with an enrolled membership shall, as the general rule, be a majority of all of the members.[6]

7 MCAR § 1.663 C.5. establishes an additional alternative procedure by allowing an HSA to conduct a public hearing before a project review committee. Such is an alternative may be appropriate because of the volume of project reviews, the large geographic area necessary for all HSA members to travel, time between regular meetings of the HSA, and other considerations which may be appropriate in different regions of the state. The full HSA governing body, however, shall after review of the evidence received at the public hearing, have the final authority to issue a recommendation to the commissioner. In the event that the full HSA wishes to receive evidence other than that presented to the hearing body it would be improper for the HSA to receive new evidence without complying with the full notice requirements of the Act.

7 MCAR § 1.663 C.6. clarifies the requirements of 145.837, Subd. 2 (3). This rule adds that clarification regarding admissibility of evidence and also clarifies the weight given to governmentally issued and sponsored planning documents.

The standard of evidence has been included because the HSA hearing is not a judicial hearing but is more closely analogous to a legislative type hearing. Maximum effort is made to encourage participation on

[6]Robert, Henry M., Robert's Rules of Order, New York, William Morrow and Company, Inc., 1971, p. 258

the local level by consumers, local officials and providers, as specified in Minn. Stat. § 145.832, Subd. 2.

The standards for making recommendations to the commissioner are not that of unquestioned compliance to specific criteria, but instead are interrelated health planning considerations which are different than judicial considerations. It is in this context that the rule recognizes as evidence governmentally issued or sponsored planning documents, studies and guidelines, such as the State Health Plan. To clarify the use of such documents, the rule notes that they are not to be considered as conclusive evidence yet nevertheless, are to be given substantial weight. This is justified because such documents are developed for the main purpose of aiding agencies make decisions, and thus they become useful tools in the review process. However, the rule allows room for persons to disagree with the conclusions or facts upon which the documents are based or even with the relevance of the documents themselves.

This rule additionally allows the hearing body to recess to another day if it finds that additional evidence or time is necessary. As prescribed in the Act, a formal extension must be sought if the 60 day review period cannot be met. If an extension of the 60 day review period is not agreed to by the applicant, the hearing body has no recourse but to commence its deliberations based upon the limited information available to it.

7 MCAR § 1.663 C.7. is needed to prescribe the methods of voting by the hearing body and by the HSA governing body. Since these are

public bodies with responsibilities which have widespread economic and social implications, it is critical that votes be fully open and recorded in the minutes of the hearing or meeting. Since the chairman or the presiding officer is a full member of the body, that person should be expected to vote under the same conditions as other members of the group. Because voting should be done after considering the evidence and discussion thereon, it would be unfair and unrepresentative to permit proxy votes.

The motion for approval of a project should not be considered to pass unless a majority of members eligible to vote support the motion (7 MCAR § 1.663 C.7.c.). This requirement is particularly important when the number of abstentions is large. 7 MCAR § 1.661 D.6. requires that members with a conflict of interest shall be counted as "absent"; such persons are not eligible to vote and should not therefore be included in the total denominator used to determine majority. However, other members present who are eligible to vote and voting "abstention" should be counted in the total eligible vote used in the denominator of the calculations of majority. This method is needed to assure favor vote from a larger number of persons and promotes the public interests indicated in the Act.

Existing SPA Rule 207 (e) has required approval of a majority of the governing body attending the hearing for a motion for approval of a proposal to be adopted. This rule is therefore a continuation of existing practices. Robert's Rules of Order[7] recognizes that rules may be adopted to vary from the common practice of majority being "more than

[7] Ibid., p. 202.

half of the votes casted, ignoring blanks." This rule continues the past practice of basically counting blanks in the total votes.

7 MCAR § 1.663 C.7.d. is needed to describe the procedures which the HSAs will follow in dealing with recommendations for approval with revisions. The standard time of 30 days for the applicant to notify the HSA is reasonable because it provides adequate time for the applicant to analyze the impact of the revision and make appropriate decision. A time period larger than 30 days would unduly prolong the review process. Certified mail is appropriate for the letter of acceptance or denial in order to specify the method of communications because of the greater reliability of it being delivered. Failure of an applicant to respond to a revision shall be considered a rejection of the revision and the HSA shall not be required to reconsider its recommendation.

Under the existing SPA 207 (i) if an applicant rejects revisions proposed by the HSA, the HSA recommendation is to be considered as a recommendation of denial of the project in its entirety. While this was a reasonable interpretation of the situation, the HSA authority in Minn. Stat. § 145.837, Subd. 2 (6) and the actual contents of the HSA report were written to justify the approval of the project <u>if</u> certain changes were made. Rather than outright denial, the option of revision was selected by the HSA. Thus, this new rule has opted to leave the recommendation unchanged rather than to interpret it as a denial. The Commissioner should make his determination based on the facts and conclusions contained in the record in accordance with the procedures prescribed in the Act and these rules.

7 MCAR § 1.663 C.8. is a connecting rule to describe the next step by the HSA in advance of the consideration by the Commissioner.

7 MCAR § 1.663 C.9. is needed to make clear that the applicant has the right to withdraw from the review. This rule requires that the applicant notify the HSA and the commissioner in writing of its decision to withdraw. This is a reasonable procedure in order to document the intentions of the applicant.

D. Consolidated review of Life Support Transportation Service projects.

The procedural requirements for review of life support transportation service projects under Minn. Stat. §§ 144.801 - 144.8091 frequently correlate with the requirements for review under the Certificate of Need Act. That is, whenever a health care facility develops a new institutional health service of this type or whenever a health care facility extends or expands an existing service with more than $50,000 in expenditure, both a Certificate of Need and life support transportation license change (or initial issuance) generally must be sought. Additionally, whenever a health care facility spends more than $150,000 on a "change in the type of service," a Certificate of Need and a licensure change must be sought. Therefore, in order to simplify the procedural and substantive actions by the applicant, possible opponents, the HSA and the Commissioner, 7 MCAR 1.663 D. proposes a consolidated review.

A consolidated review is not mandated by the rules. The crucial factor in obtaining a consolidated review is agreement by the applicant to extend the 60 day certificate of need review period provided by the

Act to 90 days. Ninety days is the period prescribed for review of life support transportation services projects. Minn. Stat. § 144.802, Subd. 3 (d). If the applicant does not agree to extend the 60 day certificate of need review period, two separate reviews shall be conducted although the rule does direct the HSA to try to complete both reviews within 60 days.

Should the applicant agree to extend the certificate of need review period to 90 days, a consolidated review shall be conducted. A suggested process for a consolidated review is outlined in attachment #1 to the rules. The attachment merely lists in two separate columns the procedures required by life support transportation services licensing law, and by the Act and these rules. In a third column, a way is suggested for meshing the two processes into one. It recognizes every requirement for both processes as specified in statute and rule. If the HSA may choose to combine review in some other manner, it may do so. It must only make sure that it complies with all requirements of Minn. Stat. §§ 144.801 to 144.8091, the Act, and these rules.

The reasonableness of encouraging a joint review is obvious on its face. Two separate reviews mean publication of two notices of hearing, conducting two separate hearings, drafting two separate reports, and duplication of other items which results in wasted time and resources. Because of the different time periods specified for HSA review in the life support transportation services law and the Act and because the former law does not grant rule-making authority to the Commissioner in this subject area, consolidated review cannot be mandated. It can be suggested and facilitated in these rules which is exactly what 7 MCAR § 1.663 D. attempts to do.

E. Review Criteria

This section of the rules is needed to clarify and reorganize the review criteria described in part in Minn. Stat. § 145.837, Subd. 1. The law states that rules shall be promulgated which shall include at least (emphasis added) the criteria listed in Minn. Stat. § 145.837, Subd. 1 (a) through (m). The proposed review criteria in these rules include the review considerations listed in the Act.

Some criteria for review are added in these rules in accordance with Minn. Stat. § 145.837, Subd. 2 (5). This clause of the statute requires the Commissioner to promulgate rules calling for findings of fact which address the criteria in Section 145.837, Subd. 1 and the criteria in the National Health Planning and Resources Development Act, 42 U.S.C. Section 300K. The federal criteria, 42 C.F.R. § 123.412, are consistent with the purposes of the Act and are not inconsistent with criteria in Minn. Stat. § 145.837, Subd. 1. They are therefore added to review criteria in this rule where appropriate. To promulgate rules calling for findings of fact which address criteria not in this section of the rules would be difficult for the reader to understand and apply. The subsections which have been, in part, developed to comply with this state-federal coordination requirement will be cited under appropriate subsections.

For convenience and clarity of the users of this rule, and, as well, to avoid misunderstandings and confusion, the language of the state law has been combined with the language of the rule to create a completely coordinated list of criteria. This approach is necessary due to the complexity of the state and federal laws. If a series of separate clarifying statements about the state law and references to

other criteria consistent with the state and federal laws were used, the comprehensibility of the Act and rules would suffer. This section will be used as the basic guide to Certificate of Need review criteria.

1. Health Plans and Population Needs.

Subsection a. of this rule is derived from Minn. Stat. § 145.837, Subd. 1 (a). This rule additionally recognizes that a relationship of the project to a health plan is not a yes or no situation but depends upon the degree to which it is consistent with the plan. This rule additionally adds the State Health Plan as a document for consideration. This is a reasonable inclusion because the State Health Plan is written to combine and clarify the Health Systems Plans and to implement a statewide, consolidated public policy.

The relationship between the State Health Plan and health systems plans (HSPs) has been the topic of a great deal of writing in the health planning field. In one of the basic texts about health planning, Reeves, Bergwall and Woodside[8] wrote that one of the key activities of the State Health Planning Agency (in Minnesota, the State Planning Agency) is preparation of the preliminary state health plan, which initially will consist of a compilation of the health systems plans developed by the HSAs within the state. Subsequently, and again based upon the areawide statements from each Region (contained in HSPs), the State Health Plan is adopted by action of another group, the Statewide Health Coordinating Council, which is staffed through the State Planning Agency and appointed by the Governor.

[8] Reeves, op.cit., p. 39.

In the American Hospital Association publication by Sievert[9] further acknowledgement is made that the State Health Plan is intended to relate to allocation of state-controlled resources for health care facilities and to coordinate, on a statewide basis, the areawide statements of long-range goals contained in the health systems plans (HSPs).

In the publication on state health plans by the Institute for Health Planning, a non-profit organization under contract to the federal government to assist planning agencies, considerable emphasis is placed upon the development of a State Health Plan based upon the HSPs in the state.[10] The federal law and regulations call for a continuing process of coordination between the HSPs and State Health Plan development. Basically, the State Health Plan is necessary to incorporate statewide considerations and to coordinate the content of the HSPs in order to accomplish rational state policy.

42 C.F.R. § 123.412 (a)(1) also requires consideration of the State Health Plan. This rule therefore accomplishes the necessary coordination with the federal Act.

The relationship to and the consistency with the applicant's long range development plan is the requirement for review in Subsection b, in accordance with Minn. Stat. § 145.837, Subd. 1 (b). As in the above subdivision, the degree to which the project is

[9]Sieverts, Steven, Health Planning Issues and Public Law 93-641, Chicago, American Hospital Association, 1977, p. 71.

[10]"The State Health Plan," Institute for Health Planning, Madison, Wisconsin, 1980, p. 2.

consistent with the plan is a reasonable addition to the criterion of relationship specific in statute. This allows for gradations of consistency instead of a yes or no relationship. In other words it is important to examine not only whether or not the project has some relationship to the plan but also the type of or degree of the relationship.

The need for health care facilities and services and the requirements of the population of the area (Subsection c and d) are perhaps among the most important criteria for examination. It is necessary that these criteria be expanded beyond the limited mention in Minn. Stat. § 145.837, Subd. 1 (c) because "need" and "requirements of the population" are very general terms.

7 MCAR § 1.663 E.1.c. lists information which directly bears upon the question of need for the project. An examination of past and existing utilization rates of similar facilities or services is necessary to determine where the prospective patients are currently receiving the services and whether there is sufficient population to adequately use the new facility or service. Five year projected utilization rates for a new facility or service also permit the HSA and the Commissioner to examine the potential costs and benefits of the facility or service.

Projects involving expansion of existing facilities or services have a past and existing utilization rate which can be used by the HSA and the Commissioner to evaluate potential costs and benefits. These rates can also be compared with past and existing utilization rates of similar facilities in the area to determine

where potential patients are currently receiving services. The five year projected utilization rate of the proposed expansion can also be examined to determine the potential costs and benefits of the expanded facility or service.

The requirements of the population of the area are addressed in 7 MCAR § 1.663 E.1.d. this subject needs to be examined with adequate specificity so that certain population groups, particularly those who have experienced traditional difficulty in obtaining equal access to health care, are considered in the review procedure. All certificate of need projects have a particular population for which they are designed and such population should be considered by the HSA and the Commissioner in terms of specific demographic categories to determine whether these population requirements are realistic. Such consideration would include whether it is to be expected that the population anticipated to support the project is accurate, and whether these population groups will be reasonably likely to utilize the project in question as compared to similar facilities in the area if any are available. For this reason 7 MCAR § 1.663 E.1.d.(1) is proposed.

Most projects include particular services for certain diagnoses or conditions within the population. This factor is addressed by 7 MCAR § 1.663 E.1.d.(2). These incidents and prevalence of such diagnoses or conditions should, therefore, be examined by the HSA and Commissioner. Examples of these include the incidence and prevalence of cancer, when a radiation therapy project is proposed or incidence and prevalence of pregnancy when an obstetrical service is proposed.

In order to assure adequate access for people who have traditionally experienced difficulty in obtaining equal access to health care, particularly those groups such as racial and ethnic minorities, it is reasonable to consider under 7 MCAR § 1.663 E.1.d.(3) the contribution of the project in the meeting the needs of these people. Shortages of health care are frequently a problem for the groups for which we are concerned in this subsection and therefore the projects which involve reduction, elimination, or relocation of a service should have special review to determine the impact on underserved groups.

Three other critical factors which are related to needs of the population of a particular service are listed in 7 MCAR §§ 1.663 E.1.d.(4), (5) and (6). These factors relate to performance by the applicant in specific areas where willingness to provide access can be judged. This is clearly related to what population will be served by a project. While it would not be necessary in all circumstances to have had 100% success in these areas, evaluation of such past performance may be critical to the HSA and Commissioner's review.

Inclusion of access considerations is appropriate because the concept of providing community health needs is valid only if the service will actually be made available to all members of the community. The presence of these access considerations in the rules shows that the Commissioner recognizes interrelationship between access and other project considerations in specific regard to the medically underserved.

In compliance with Minn. Stat. § 145.837, Subd. 2 (5), 7 MCAR §§ 1.663 E.1.d.(3),(4),(5) and (6) address certain significant provisions of the National Health Planning and Resources Development Act and regulations thereunder. 42 C.F.R. § 123.412 (a)(5) and (6) contain criteria relative to the needs for medically underserved persons.

2. Alternative Approaches and System-wide Effect.

7 MCAR § 1.663 E.2.a. is required by Minn. Stat. § 145.837, Subd. 1. (d).

7 MCAR § 1.663 E.2.b. is required by Minn. Stat. § 145.837, Subd. 1 (e). This rule, however, adds five specific considerations to be addressed regarding the project's relationship to the existing health care system. The first consideration is reasonable because of the interrelationship of health care facilities and the recognition that a change in one element of health care system may have a significant and perhaps negative impact on the use, capacity and supply of existing health care services.

The second consideration involves the possibility of increasing referrals to other health care facilities as an alternative. The public policy priority in this situation would be to achieve higher utilization of existing resources if that alternative is available.

A third criterion for evaluation of the relationship of the project to the existing health care system in the area is the degree to which the project facilitates the development of an integrated

system of services among health care providers. A properly integrated system eliminates unnecessary duplication by accomplishing economies of scale. Elimination of duplications are one of the specific purposes in the Act as listed in Minn. Stat. § 145.832, Subd. 1. Similarly consolidation of services with other health care providers and formal arrangements to share or support services of one another would also achieve the purposes of the Act and are accordingly covered in 7 MCAR § 1.663 E.2.b. (4) and (5) respectively.

7 MCAR § 1.663 E.2.c. is taken from the second portion of Minn. Stat. § 145.837, Subd. 1 (f). It is needed and reasonable by its inclusion in the above cited statute and aids in evaluating whether the project represents a good use of resources.

This rule clarifies the Act by referencing preferred alternatives uses. The mere consideration of alternative not preferrable in some respect would be a waste of time. Also, in order to give health care facilities more direction about alternatives to be considered, the specific alternatives identified in the HSP, AIP and State Health Plan are included in the rule.

7 MCAR § 1.663 E.2.d. relates to consideration of the clinical needs of health professional training programs. There are numerous system-wide effects from such training programs and the Act recognizes this and other issues in Minn. Stat. § 145.837, Subd. 1 (i). It is reasonable that these broad effects be examined during consideration of a certificate of need application. Additionally,

42 C.F.R. § 123.412 (a)(10) requires consideration of clinical needs of health professional training programs as a criteria for review.

The need for and availability of osteopathic physicians is a consideration required by 7 MCAR § 1.663 E.2.e. Osteopathic physicians and patients have need to have this specific review criteria in order to prevent the planning process from discriminating against osteopathic facilities. 42 C.F.R. § 123.412 (a)(21) requires consideration of osteopathic as a review criterion.

3. Competition among similar services.

7 MCAR § 1.663 E.3. requires the HSA and the Commissioner to consider competitive interrelationships in this system which relate to the combined effects of financing, delivery methods and availability of health services. Minn. Stat. § 145.832, Subd. 1, lists one of the purposes of the Act as assisting in providing the highest quality of health care at the lowest possible cost. Section 1.663 E.3. has been included to clarify this purpose statement and to further promote consumer choices for the most appropriate and acceptable health care provider. Improvements or innovations in financing and delivery are combined results of many of the review criteria in Minn. Stat. § 145.837.

While there is sound logic in the development of this criterion regarding competition totally based upon interrelationships in

Minn. Stat. § 145.837, Subd. 1, the federal Act and 42 C.F.R. § 123.412 (a)(17) and (18) require consideration of competition which could be fostered by a certificate of need project reviewed.

4. Applicant and project attributes.

7 MCAR § 1.663 E.3. a. is taken from the first portion of Minn. Stat. § 145.837, Subd. 1 (f). Its need and reasonableness has been determined by the legislature by its inclusion in the above cited statute and is included here for comprehensiveness.

Much of the purpose and the impact of the Certificate of Need Act relate to the financial considerations of a proposed project. 7 MCAR § 1.663 E.4.b. (1) is based on the need to analyze both the immediate and long-term financial feasibility of the project related to Minn. Stat. § 145.837, Subd. 1 (g). This clause clarifies the type of data to be used in analyzing feasibility and makes the role of the HSA and Commissioner in reviewing this factor much more understandable. Similarly, 7 MCAR § 1.663 E.4.b. (2) allows review of the financial feasibility of a project as it relates to the project's affect on the solvency of the corporation responsible for the health care facility. If the financial soundness of a facility is impaired by a proposed construction/modification project, this would be a very important item for consideration by the HSA and Commissioner.

7 MCAR § 1.663 E.4.c. is necessary to clarify the specific type of analysis which the HSA and the Commissioner should undertake

to implement Minn. Stat. § 145.837, Subd. 1 (g) and (k). Section 1.663 E.4.e. (1) is needed to assure that the proposed cost of construction or modification is reasonable compared with the cost of similar projects. Such costs will generally become part of patient rates through debt service and depreciation. This clause is specifically mentioned as a review criteria in the case of construction projects in Minn. Stat. § 145.837, Subd. 1 (k).

Pursuant to Minn. Stat. § 145.837, Subd. 1 (g), 7 MCAR § 1.663 E.4.c. (2) requires the HSA and the Commissioner to compare operating costs of this facility with other similar health care facilities. For the purpose of cost containment, the differences in such operating costs should be analyzed and if there are significant increases in costs due to construction or modification, such increases should be a consideration of the HSA and the Commissioner.

7 MCAR § 1.663 E.4.d. relates to the criterion for review listed in Minn. Stat. § 145.837, Subd. 1, (h). The criterion is clarified by clauses (1) and (2) which relate to the availability of ancillary and support services and the nature of arrangements regarding sharing support services. If the applicant has uncertain availability of necessary ancillary and support services,this criterion should be considered. Similarly, arrangements made by the applicant for such support services should provide for sound financial costs control and other provisions which are within limits of contractual requirements.

7 MCAR § 1.663 E.4.d.(2) seeks to assure consideration of shared services which might be provided by multi-institutional arrangements. While shared services were mentioned as a criterion for review in 7 MCAR § 1.663 E.2.b., the importance of multi-institutional arrangements for ancillary and support services dictates that this item be additionally considered under this clause of the review criteria.

7 MCAR § 1.663 E.4.e. relating to costs and methods of energy provision is included as a criterion for review as a result of its listing in Minn. Stat. § 145.837, Subd. 1 (k). This criterion's need and reasonableness is therefore justified through the Act and is included here for comprehensiveness.

The criterion relating to the quality of care listed in 7 MCAR 1.663 E.4.f. is needed to accomplish the purposes of the Act as stated in Minn. Stat. § 145.832, Subd. 1 and it is in 42 C.F.R. § 123.412 (a)(20). The Act is intended to assist in promoting the highest quality of health care at the lowest possible cost. It is the position of the Department that quality of care is difficult to compare without using objective survey instruments which have been developed by generally accepted organizations, including the Department itself. The Joint Commission on Accreditation of Hospitals and the Professional Standards Review Organizations are two other examples of generally accepted survey organizations. The interpretation of quality of care is the most reasonable and objective means which is available for application to all health care facilities in the state.

7 MCAR § 1.663 E.5. prescribes special needs and circumstances which shall be considered when reviewing the project. Clause a. references the criterion from Minn. Stat. § 145.837, Subd. 1 (i) and clarifies the language of the Act by listing two minimum considerations for dealing with facilities in this category.

7 MCAR §§ 1.663 E.5.a.(1) directs attention to coordination of the instruction, studies and research among other facilities of a similar type in the area. In some situations, the teaching, research and referral activities can be maintained at an equally high level with less construction or modification by sharing or other coordination with other facilities.

Similarly, 7 MCAR § 1.663 E.5.a.(2) is needed to require consideration of the needs of the residents of the HSA area, not merely broad patient population from much larger geographic sources. Sometimes, special provisions are made to maintain high standards of primary health care (basic physician and other professional services) in an area of medical teaching and research.

7 MCAR §§ 1.663 E.5.b. and c. are taken directly from Minn. Stat. § 145.837, Subd. 1 (j) and (l). They are needed and reasonable for complete listing of the criteria, thereby promoting the understanding of readers.

F. Revisions.

7 MCAR § 1.663 F. is needed to clarify and amplify Minn. Stat. § 145.836, Subd. 3. The first section of this rule simply reorganizes

the language in the Act to more clearly show that there are two principal conditions necessary for a proposed revision to be approvable by the Commissioner. This is needed for completeness.

The second section of this rule defines when a revision shall be considered to be within the scope of a construction or modification as initially proposed. The language of this section is intended to help the HSA and the applicant judge acceptability of the revisions and to prevent coercion of the facility to make changes which are patently unrelated to the proposed project.

G. Content of Record.

7 MCAR § 1.663 G.1 to 5. provide the detail of the contents of the record which contains evidence has been prepared consistent with Minn. Stat. § 145.837. The record contains both procedural and substantive contents. Without very detailed listing of these contents, the Commissioner may have inadequate information upon which to base a decision.

The purpose of requiring the record to be submitted to the Commissioner in a specified manner is to aid the Department in its review and to save time. If each record is submitted in this manner, it will be easier to check to make sure it's complete. The material listed and the order of submission has been requested by the Commissioner over the years and has been complied with by most HSAs.

7 MCAR § 1.663 G.4. requires that the findings, conclusions, and a recommendation be supported by an understandable, logical flow from

one to the other. Such written findings and recommendations are required by Minn. Stat. § 145.837, Subd. 3 (5). This statute also requires the Commissioner to promulgate a rule linking the findings of fact and the criteria listed in 7 MCAR § 1.663 E.

Minn. Stat. § 145.837, Subd. 2 (5) requires rules related to certain written findings and recommendations, using state and federal criteria as the basis. State criteria and federal criteria from 42 C.F.R. § 123.412 (a) have been included in 7 MCAR § 1.663 E. Additionally, 42 C.F.R. 123.412 (b) calls for the HSA and Commissioner to address all applicable criteria, but specifically 42 C.F.R. § 123.413 requires the HSA and Commissioner to develop findings based upon considerations related to access. Those criteria are 7 MCAR §§ 1.663 E.1.d.(1),(3),(4),(5) and (6).

H. Determination by Commissioner.

7 MCAR § 1.663 H.1. is an introductory section to clarify the role of the Commissioner as a final, independent decision-maker. This section is needed to show the reader that the Commissioner's decision is independent and not merely appellate in nature. See Benedictive Sisters Benevolent Association v. Pettersen, 299 NW 2d 738 (Minnesota 1980).

7 MCAR § 1.663 H.2. describes the information to be reviewed by the Commissioner. Although the information to be reviewed will generally be only the application and the record presented by the HSA, the Commissioner may review additional information as necessary to consider a remand to the HSA for further consideration. This subsection does

not, however, authorize independent outside testimony to be considered by the Commissioner, but does allow consideration of information which the Department of Health obtains through its own investigations. For example, if the Department is aware of information which bears upon the application and which was not considered by the HSA, such as a newly issued research study or a change in the facts, the Department need not ignore it. Instead, the Department may consider it in the same manner as a request for reconsideration under Minn. Stat. § 145.838, Subd. 2. The information shall not be used in any way in making a decision as to whether a certificate of need should be issued. It shall only be used to determine if the application should be remanded. The question for the Commissioner is whether the information raise significant issues or considerations not previously covered by the HSA so as to justify a remand and further review.

The Commissioner's decision-making options are prescribed in 7 MCAR § 1.663 H.3. Besides the rather straightforward options to issue (Subsection 3.a.) or to deny (Subsection 3.c.), the Commissioner also has the option of issuing a revised certificate of need, or remanding the application to the HSA with instructions for further consideration.

7 MCAR §§ 1.663 H.3.b. describes the process by which the Commissioner can issue a certificate of need conditioned on revisions in the project. Revisions of a certificate of need were previously considered in 7 MCAR §§ 1.663 C.7.d. and f. which described the consideration for a revision by an HSA and the general standard for acceptability of a revision.

7 MCAR § 1.663 H.3.b.(1) describes what the Commissioner must do when he proposes a revision. The key element is the requirement to justify the action that is, to explain why a revision is deemed necessary based upon evidence in the record. Clauses (2) through (5) describe the process and procedures applicable where the Commissioner proposes a revision and the effect of a proposed revision on time limits for appeal. If the Commissioner proposed revisions not previously agreed upon, the HSA and applicant are given a period time to consider the acceptability of the revision. Thirty days provides ample opportunity to consider the Commissioner's action and to decide how to respond. It also recognizes that HSA's do not meet frequently enough to allow for a shorter time period. The Commissioner also has an opportunity to further modify the decision with the approval of the HSA and the applicant. This recognizes that counter proposals may be made which are acceptable to the Commissioner. The thirty day period for reconsideration or judicial review of the decision should not be forfeited by the thirty days in which the HSA and applicant consider acceptance of the revision. The rule specifies that this thirty day period begins to run after acceptance or rejection of the revisions which is the point at which the decision is final and ripe for appeal.

7 MCAR 1.663 H.3.d allows the Commissioner to remand the application to the HSA for further consideration as prescribed by Minn. Stat. § 145.838, Subd. 1 (c). Clause (1) lists the conditions under which the Commissioner may remand an application. Remand occurs when there is significantly inadequate information in the record to justify issuance of a certificiate, issuance of a revised certificate, or denial of the certificate of need. The conditions are both procedural

and substantive in nature and either may be grounds for remand of an application. Each of the conditions described presents a situation in which a gap in the chain of reasoning, in logic or in the HSA's deliberative processes calls into question the results.

Clause (2) is needed and reasonable to provide the applicant and the HSA with written rationale and instructions for further consideration of the application on remand. Since the HSA must conduct much the same type of review as was previously conducted, including staff preparation, public hearing, and a recommendation to the Commissioner, 60 days is needed for this process period. This is the same time period for a HSA review required in Minn. Stat. § 145.837, Subd. 2.

I. Determination by the Commissioner: life support transportation service projects.

7 MCAR § 1.663 I.1. is needed to describe the process used by and the options available to the Commissioner in making his decision when a life support transportation service project is subject to both the Act and Minn. Stat. § 144.802. The rule indicates that there are two separate decisions to be made, that the certificate of need decision will be made solely under the Act and these rules, and when the two processes have not been combined, that the certificate of need decision will have no bearing upon the licensure decision. In other words the rule is basically informative so as to avoid any confusion when a project is subject to both processes.

7 MCAR § 1.664 Post Determination Actions.

A. Reconsideration of Determination.

7 MCAR § 1.664 A. clarifies the various procedures available under Minn. Stat. § 145.838, Subds. 2 and 3 to an applicant who has been denied. This clarification is needed as has been demonstrated by the fact that the Department has been contacted by several persons who had been aggrieved by the Commissioner who asked whether their interpretation was correct. Each one had interpreted Minn. Stat. § 145.838, Subds. 2 and 3 as the Commissioner specifies in this rule, but because the Act is not totally clear on the matter, they wanted clarification.

There are two appeal routes provided for in Minn. Stat. § 145.838, Subds. 2 and 3. Which one is available depends upon whether or not the decision of the Commsissioner is consistent with the recommendation of the HSA. If the decision is consistent, then the only appeal available to an aggrieved person is district court under Minn. Stat. §§ 145.838, Subd. 3 and 15.0424 to 15.0426. On the other hand, if the Commissioner's decision is contrary to the recommendation of the HSA, then an aggrieved person may request the Commissioner to reconsider his decision under Minn. Stat. § 145.838, Subd. 2 or she/he may appeal directly to District Court under Minn. Stat. § 145.838, Subd. 3 and 15.0424 to 15.0426.

To remove confusion in the future, 7 MCAR § 1.664 A is proposed. It sets out the options which are available for an aggrieved person. Thus, sections 1.664 A. specifies that if the Commissioner's decision is consistent with the recommendation then the only appeal is to District Court.

Section 1.664 A.2. specifies the options of judicial appeal or requesting reconsideration of the Commissioner's decision is contrary to the recommendation of the HSA. It also spells out the reconsideration process. As required by Minn. Stat. § 145.838, Subd. 2, the request must be submitted within 30 days of receipt of the Commissioner's decision. The rule directs that the request shall address the reconsideration grounds specified in the statute. Such requirement is only logical. The rules also provides for a 30 day decision period by the Commissioner. The statute is silent on the point. Thirty days is consistent with the other decision making periods specified in the Act. There is nothing inherent in the reconsideration process to make 30 days unreasonable.

The reconsideration process also clarifies the reference to "new public hearing" in Minn. Stat. § 145.838, Subd. 2. because it does not specify who should hold the hearing. In order to clarify the nature of this "new public hearing," 7 MCAR § 1.664 A.2 explains that the HSA shall receive the case for fact finding is the Commissioner determines that good cause for reconsideration has been shown.

Within the Act, all public hearings involving the fact finding for issuance of a certificate of need are conducted by the HSA. Minn. Stat. § 145.832 specifies that the purpose of the Act is to promote comprehensive health

planning and to base the decisions on the maximum possible participation at the local level by consumers of health care, elected officials and directly concerned providers. The Department has determined that it would, therefore, be inconsistent with the rest of the Act for the Commissioner to conduct the "new public hearing" at the state level and that the proposed procedures are therefore reasonable.

7 MCAR §§ 1.664 A.3 describes that any aggrieved person, regardless of whether or not the Commissioner's decision is consistent with the recommendation, may appeal directly to District Court without first seeking reconsideration. It also notes that such appeal is also available from adverse decisions of a hearing examiner should the reconsideration process be pursued. This rule simply furnishes the list of appeal options.

B. Amendment of Certificate of Need

7 MCAR §§ 1.664 B.1. is needed to clarify the threshold where a project may be modified with or without further HSA and Commissioner action. Without inclusion of this section, any change in an approved project could be interpreted to require issuance of a new certificate of need.

It is the Department's opinion that immaterial or minor changes in a certificate of need should be accepted without a complete, new review and issuance of a new certificate of need. On the other hand, when there are modifications which are significant in nature so as to result in a project which is not within the scope of the project is initially approved for a certificate of need, it would be inconsistent with the purposes of the Act

if this revised project were not subject to the complete certificate of need review process.

To clarify whether the changes are immaterial, minor, or significant, 7 MCAR § 1.664 B.1 describes the concept of these changes and modifications.

Immaterial changes (not subject to any additional review) are described in 7 MCAR § 1.664 B.2. The factors listed as being immaterial are not by themselves of a nature or extent which would permit a denial of a certificate of need. For example, clauses a and b relate to physical plan changes where the type or scope of health service is not changed and the capital expenditure is not in excess of ten percent. In clause c, the increase of less than ten percent is specifically designed to not include the inflation costs which may have increased since the application of a certificate of need was originally submitted. Ten percent is a percentage figure which is used elsewhere in the Act to differentiate immaterial and material changes, including in Minn. Stat. § 145.833, Subd. 5, relating to changes in bed capacity. The figure of ten percent allows for considerable increase in certain items of the project but it assures that the basic purposes of avoiding unnecessary increases in costs is still fulfilled. 7 MCAR § 1.664 B.2.d. also notifies the applicant that other changes are immaterial when they are judged to result in the implementation of the project as approved and not be viewed as minor or significant. Details of a project may reasonably change without impacting the purposes or requirements of the Act.

7 MCAR § 1.664 B.3 describes the five situations where a change will be judged to be minor and therefore eligible for an amendment without full certificate of need review. As a general principle, these types of changes are situations which may have affected the HSA's and the Commissioner's findings, conclusions and recommendation or decision. While still considered to be minor, these situations may have become material within the context of the certificate of need review and therefore should be given at least minimal scrutiny by the HSA and the Commissioner before approval. To permit minor changes without further review by the HSA and the Commissioner would be inconsistent with the purposes of the Act and with the detailed application and the review conducted by the HSA and the Commissioner.

Increases in capital expenditures of at least ten percent but not more than twenty percent (section 1.664 B.3.c.) are judged to be minor in many projects because the projections submitted in the certificate of need were of a very preliminary nature. On the other hand, when there are increases in the range of ten to twenty percent, it is quite possible that an HSA may have cost control criteria which would have caused it to make a different recommendation if the accurate cost had originally been known. Additionally, the Commissioner may have found that such higher costs would have been unreasonable and contrary to the intentions in the Act.

If portions of the originally approved project are simply deleted (section 1.664 B.3.b.), these may or may not constitute a significant change and such determination would require in many circumstances a review by the

HSA and Commissioner. Components of the certificate of need application are frequently interdependent and interrelated in such a way that the deletion of one portion would materially affect other portion and perhaps would have influenced the HSA and the Commissioner to deny the project.

Similarly, changes in the financing mechanism (7 MCAR § 1.664 3.c.) and changes in the selection of health services equipment, if not technologically different from that approved in the certificate, (7 MCAR § 1.664 3.d.) may have influenced the HSA and the Commissioner to have denied the project. These changes are not sufficiently important by themselves to warrant a denial of certificate of need, and therefore an amendment review is needed to determine whether these changes are significant as a whole.

Finally, changes in the bed capacity of less than ten beds or ten percent (7 MCAR § 1.663 B.2.e.) is not generally reviewable. However, within the context of an approved certificate, this amount of change in bed capacity may not have been approved within the project if this information had been on the original application. The complete project with this change deserves evaluation. Therefore, a review by the HSA and the Commissioner is appropriate before this change is made.

7 MCAR 1.664 B.4 a. through f. list five types of significant changes and modifications which require submission of a new certificate of need application.

The level of twenty percent increase in capital expenditure (7 MCAR § 1.664 B.4.a.) is the maximum reasonable limit whereby the project could be changed without any new review by the HSA and the Commissioner. Since the cost of

the project is of paramount consideration in the threshold levels, the contents of the application, the review criteria, and the general purposes of the Act, increases in excess of this would damage the credibility of the Act. If a capital expenditure of greater than twenty percent is allowed without additional certificate of need review, the applicant would have an incentive to underestimate capital expenditures in the application and thereby to mislead the HSA and the Commissioner regarding the issuance of a certificate. However, even if the HSA and the Commissioner were not intentionally misled, an increase of more than twenty percent may dramatically affect the costs, and the overall justification for the capital expenditure may have been eliminated.

In 7 MCAR § 1.664 B.4.b. through e., changes in the type or scope of service, selection of technologically different health services equipment, changes in geographic location and changes in bed capacity are listed as being of major importance in reviewing a certificate of need application. These are either items which are thresholds by themselves for review or they they are items which are of particular importance in the application for a certificate of need.

7 MCAR § 1.664 B.4. f describes the condition whereby any changes which raise new issues not previously considered by the HSA or the Commissioner shall always require a new certificate of need review. The full public process therefore should be used in order to fully evaluate these items of new information and the opportunity for revision or denial of the project should be considered.

7 MCAR § 1.664 B.5 describes the process for applying for an amendment to a certificate of need. In order for this process to be effective, the amendment must be sought prior to any change in the project, and the amendment process must occur in a timely fashion. Additionally, the amount of information to be submitted by the applicant should be a minimum.

Since the amended certificate of need in force is the same as that which was originally issued, with only minor amendments, the eighteen month time period for commencement of the project should not be increased. It is the Department's position in 7 MCAR § 1.664 B.6. that the complete certificate of need process should be undertaken if the commencement of the project will be more than eighteen months past the original issuance. This is because the concept behind the minor changes is that they are merely an outgrowth of the project as originally proposed for a certificate of need and the result of detail planning. If the changes are so great as to delay commencement of the project, then a full review is warrented.

7 MCAR § 1.664 B.7 lists the options available to the applicant if the changes are not approved by the amendment process. This subdivision is necessary to notify the public of the options available.

C. Expiration of Certificate.

Minn. Stat. § 145.839 states that a certificate of need shall expire after eighteen months if the construction or modification has not begun. The Act further states that the certificate of need shall not be automatically renewed. To provide the public with information about the

expiration date, section 1.664 C.1. provides that the certificate of need or waiver shall specify the termination date.

Minn. Stat. § 145.839 does, on the other hand, does not prohibit the renewal of certificate of need or waivers after expiration of the certificate if there is an updated application and a redetermination of the recommendation by the HSA. 7 MCAR §§ 1.664 C.2. therefore prescribes a process for renewal of certificates and waivers, without a completely new application, completeness review, public hearing and other details of a full review.

Section 1.664 C.2.a. requires the applicant to submit the updated application. It is reasonable that there have been changes in 18 months which require identification and explanation.

As the next step, Section 1.664 C.2.b. is necessary in order to prescribe the time limitation for the HSA to "redetermine its recommendation," pursuant to Minn. Stat. § 145.839. The basic issue must be whether or not the project or reasons for approving the project have changed materially. To allow the HSA to consider other facts, not considered at the public hearing previously, would be inconsistent with the public notice and input requirements of the Act. Thirty days was selected as the period of review because that time period is used elsewhere in the Act for recommendations from the HSA without public hearing.

The new HSA recommendation shall then be submitted to the Commissioner analogous to the process for Commissioner determination in Minn. Stat. § 145.838, Subd. 1. The Act in all circumstances requires the Commissioner

to make the final decision and, consistent with other sections of the Act, it is reasonable that the Commissioner's decision be based upon the HSA recommendation regarding renewal. It should be reemphasized that neither the HSA recommendation nor the Commissioner's decision on renewal is directly related to the issue of "need" for the project; the issue is whether or not the project or reasons for approving the project have changed.

Six criteria shall be used to determine whether the project has commenced. The six criteria listed in 7 MCAR § 1.664 C.3. are those which, through the experience of the Commissioner, have been found to be appropriate in the past.

Final working drawings and specifications (7 MCAR § 1.664 C.3.a.) are available through the Department of Health for examination and approval. Minn. Stat. §§ 144.56 and 144A.08 and 7 MCAR § 1.112 B.[formerly MHD 112 (b)] require such submission to the Commissioner. There is expectation that construction contracts (7 MCAR § 1.664 C.3.b.) shall have been let. Timely construction schedule (7 MCAR § 1.664 C.3.c.) should have been developed. All zoning and building permits secured (7 MCAR § 1.664 C.3.d.). These above documents can be presented as proof that the applicant has gotten the external approvals and the project is going.

While physical alterations may vary according to the nature of the project in question, it is reasonable that some significant physical alterations should have been started in order for a project to have been considered commenced. (7 MCAR § 1.664 C.3.e.) The term "commence," according to

Webster's Third New International Dictionary, means "to initiate formally by performing the first act of." The allowance of 18 months for such commencement also indicates expectations that the project actually begin physical alteration.

7 MCAR § 1.664 C.3.f. permits use of other factors which may become relevant to a particular type of project. Since projects vary greatly in the type of construction, it is reasonable to remain open to other factors, related to the factors cited, to be considered in the future.

In dealing with acquisition of equipment, different considerations are needed to determine commencement. The two considerations in 7 MCAR § 1.664 C.4 have been developed based on the experience of the Commissioner.

Clause 4.a. relates to the written evidence which shows execution of some type of contract to acquire. The experience of the Commissioner has been that these documents are commonly available.

Similarly, the delivery date and specific schedule for establishing operations (Clause 4.b.) frequently available. This grants considerable flexibility to the facility to show "commencement" even when physicial alteration may not have occurred.

7 MCAR § 1.664 C.5. lists factors which the Commissioner shall consider in determining whether a new service has been commenced. The commencement of a new service is considered to be a modification and therefore subject to the Act.

Clause 5.a. is reasonable because they relate to initial introduction of the service -- with no equipment acquisition or construction it would not be reasonable to permit anything less than operations within 18 months. Initial introduction is frequently on a limited scale. Also, clause 5.b. relates to the selection of full, permanent staff and a schedule for commencing full services. This is reasonable because all personnel may not actually be on duty but, within 18 months after the Certificate of Need being granted, a specific schedule for all personnel is to be expected.

D. Transfer of Certificate

In the course of administering the Certificate of Need Act, the Commissioner has found that there are occasions where an applicant may wish to tranfer the ownership of a health care facility after an issuance of a certificate of need but before completion of a project. It is therefore necessary to include a section in the rules to describe the extent of such permissible transfers and the conditions under which they may be approved by the Commissioner.

7 MCAR § 1.664 D.1. establishes the general scope of such transfer and makes it clear that the certificate of need and all associated sections of the project are considered to be intact if any transfer occurs. If this statement were not clearly made, there may be situations where an applicant may tranfer certain numbers of approved expended bed capacity or equipment purchases, however the conditions for the operation and the conditions for assurance of financial solvency of continued operations may not be secured. Further, the project

to be transferred may no longer be needed; for example, population changes or changes in medical practices may have occurred since the certificate was approved. This rules is written to assure that there are no material changes in the project if there is to be an approved transfer. To have material changes in a project would mean that the certificate of need is being transferred to someone without authority pursuant to the Act.

This rule also provides the detailed information which should be included in a request for a transfer. Financial aspects of the certificate of need application are key to this proposed action and are ones which could be materially affected in the transfer situation.

Need to carefully review possibilities of increases in health care costs due to excessive construction or modification is one of the primary purposes of the Act as specified in Minn. Stat. § 145.832, Subd. 1. If a transfer of a certificate were sought due to, for example, a change of ownership, the new owner might significantly change the financial conditions or other key elements, without review by the HSA and Commissioner. This rule requires review of such situations.

Furthermore, the application for tranfer includes the statement binding the new operator to terms and conditions and a description of the changes and modifications. This is necessary to consider the original certificate, approved on the basis of certain information, to be valid after the transfer.

7 MCAR § 1.664 D.3. establishes the time limits and the procedures for the Commissioner to handle request for transfers. The procedures set forth are easily accomplished by the parties involved and have a standard 30 day time period for review of material by the HSA and the Commissioner. As pointed out previously, 30 days is used through the Act when a routine recommendation or decision is sought, without public hearing.

E. Periodic Report

Pursuant to Minn. Stat. § 145.84 health care facilities are required to submit a report to the Commissioner at the completion of construction and modification projects and to furnish financial information comparing actual costs with estimated costs. 7 MCAR § 1.664 E.1. grants 60 days for such report to be submitted to the Commissioner after completion of a project. Financial calculations on construction are maintained continuously throughout the construction period and this rule allows for a reasonable time for concluding computation of actual capital expenditures. While less than 60 days may be too little time, to allow more time would be unnecessary. Small changes or "settlements" from contractors would not be significant considering the use of these reports.

The rule furthermore specifies that the cost breakdown shall be that which was originally submitted in the application as listed in 7 MCAR § 1.663 A.4. Since the Act anticipates in section 145.84 a comparison between the cost estimate in the application and these costs in periodic reports, it naturally follows that the breakdown be on the same basis.

7 MCAR § 1.664 E.2. provides that the applicant shall explain discrepancies between the estimated and actual costs. Although the statute does not contain specific sanctions for penalizing an applicant who has significant discrepancies between estimated and actual costs, the existance of the periodic report itself suggests that the reason for and the impact of such discrepancies should be explained. Compilation of the discrepancies and the impacts over a period of time will be useful to evaluate the accuracy of estimated costs reports and the overall results of the construction and modification projects which have gone through the Certificate of Need process.

The definition of completion of a project is needed for easier understanding of this Section by the applicant. 7 MCAR § 1.664 E.3. recognizes two circumstances which basically constitute completion. First, it is reasonable that clause 3.a. relates to the payment of the last construction cost or other fee. Most contracts and other arrangements with contractors are considered complete at the final payment, other than warranties. Secondly, clause 3.b. is needed to deal with circumstances where the last payment has <u>not</u> been made but the involved service commences operation. Under this circumstance, the project is as a practical matter complete and construction costs can be projected quite accurately.

Furthermore, 7 MCAR § 1.664 E.4. is needed to require an interim report when occupancy or use of the project starts before final payment. The project is, in this case, complete, for purposes of practical use by the patients; however, since the final payment has not been made, the final report cannot yet be submitted. The purposes of periodic reports

could not be accomplished if the project were used, but due to small retained payments, the final payment was not made. "Periodic" report implies the possiblity of such interim report before completion. Finally, the project may be revised, based upon findings, and, through the process in these rules for revisions, the HSA and Commissioner may make an agreement with the applicant to obtain additional periodic reports.

7 MCAR § 1.664 E.5. requires periodic reports for projects which received certificates of need or waivers since the effective date of the Act. That date was August 1, 1979. The Act calls for periodic reports and the purposes of creation of a data base on capital expenditures is best served by the submission of periodic reports from these past projects which were issued under the Act. To require periodic reports from projects approved before August 1, 1979 would not be authorized, but to start only with newly completed projects would not produce a reliable, consistent data base for many months. Trends would also not be available for long periods.

F. Investigations.

7 MCAR § 1.664 F states that the Commissioner has authority to investigate all financial and other pertinent records of entities subject to the Certificate of Need Act. Such investigatory authority is based upon the general authority of the Commissioner of Health to promulgate rules and mechanisms to enforce the Act as specifically authorized in Minn. Stat. § 145.834. Access to financial and other records which relate to the threshold for Certificate of Need review is a minimally necessary authority in order for the Commissioner to enforce the Act.

7 MCAR § 1.665 Applications from health maintenance organizations

A. Review for HMOs.

Minn. Stat. § 145.844 specifies that health maintenance organizations shall be reviewed under the Certificate of Need Act to the extent that the Federal law or regulations requires the application of the Act to HMOs. Accordingly, the content of 7 MCAR § 1.665 is taken from the Federal law (42 U.S.C. 300k) and regulations (42 C.F.R. §§ 123).

In order to relate the application of HMO reviews to the language of the Minnesota Act, 7 MCAR § 1.665 A. lists the types of projects which would require review if proposed by a health maintenance organization. Pursuant to 42 CFR § 123.405, a state agency must review any activity undertaken by an HMO or combination of HMOs specified in 42 C.F.R. § 123.404. These activities are Sections A.1. through A.5. of this rule.

Under these Federal Regulations, there are two additional sets of circumstances which apply to this coverage. First, the undertaking may be by or on behalf of an inpatient health care facility as indicated in the 7 MCAR §§ 1.665 B.3 and 4. And secondly, under certain circumstances, the activities are exempt, as specified in 7 MCAR § 1.665 C.

The Department interprets Minn. Stat. § 145.844 as requiring the rules to be in compliance with federal regulations. There seems only to be authority to clarify terminology differences. Therefore, this rule relies almost entirely upon the federal regulation as justification and

the Statement of Need and Reasonableness is limited to showing that the rules do follow federal regulations.

The activities which the Federal Regulations specify as reviewable are listed in 7 MCAR § 1.665 A.1. through 5; however, terminology has been changed to made it consistent with that used throughout the Act and these rules. Section 1.665 A.1. is a summary in clarification of the provisions of 42 C.F.R. §§ 123.404 (a) (1) and (4). The Department believes that the operative language of this State Rule is adequate without the details which are listed in the Federal Rules. With the additional references to State Rules, there are no significant differences between the State and the Federal provisions referenced above.

Similarily, 7 MCAR §§ 1.665 A.2. and 3. are parallel to 42 C.F.R. §§ 123.404 (a) (2) and (3)(i). The language of the federal regulation are not complicated for these clauses.

On the other hand, 7 MCAR § 1.665 A.4., which is parallel to 42 C.F.R. § 123.404 (a)(3) (ii) and has features different that § 123.404 (a)(3) (i), although similar in language. The sum of $75,000 per year is the operating cost threshold of federal regulations when no capital expenditure is involved. The federal regulations disregard annual operating costs as a threshold when there is an obligation of any capital expenditure, as in § 1.665 A.3.

Finally, Subdivision 5 of the State Rule is parallel to 42 C.F.R. § 123.404 (a) (5). This relates to a clearly understandable section

of the federal regulation and is consistent with the Act as well.

B. Entities which qualify for exemption from the state law.

42 CFR § 123.405 (b) lists four conditions under which an HMO or HMO related entity may be eligible for exemptions. 7 MCAR §§ 1.665 B.1. through 4. lists the four conditions of the federal law so that state readers will have clear reference to the type of applicants eligible for exemption. Clauses B.1. and B.2. are taken from 42 CFR § 123.405 (b)(1)(i). The language is not complicated and needs no further clarification.

Clause B.3. of this rule is taken from 42 FR 123.405 (b)(1)(ii). The language of the federal regulation is clarified in this rule by listing ownership (3.a.) and majority control of the governing body (3.b.) as ways by which an entity may show that it is controlled, either directly or indirectly, by an HMO or combination of HMOs. Ownership is direct control, Additionally, if over fifty percent governing body composition by HMO officers and board members assures the influence of HMO representative in all critical decisions related to the potentially exempt health care facility, this governing body control can be interpreted as indirect control.

Finally, Clause B.4. of this rule is parallel to the Federal Regulation, 42 CFR 123.405 (b)(1)(iii). The language of the federal regulation and this rule is clear without further clarification.

The Federal Regulation referenced above contains conditions which must be met to qualify for exemptions in each of the four situations of qualified entities. These are covered in §§ 1.665 C.

C. Conditions for exemptions.

7 MCAR § 1.665 C. lists the three conditions which otherwise are listed for each of the entities in the Federal Regulation 42 CFR §§ 123.405 (b) (1). The rule is needed to limit the application of this broad exemption authority to circumstances where the operations of HMOs are accurately projected to be consistent with the purposes of the Act without certificate of need review. It is also needed and reasonable because of its inclusion in the federal regulation. It is clarified here by application of the conditions of HMO operations in Minnesota.

7 MCAR § 1.665 C.1. uses the federal HMO Act (42 U.S.C. § 300 e) as the basic indicator of qualifications for exemption. However, the federal regulations [42 CFR § 123.401(8)] defines health maintenance organizations as both "federally-qualified" HMOs under Title XIII of the Public Health Service Act and other organizations which meet the federal alternative definition in 42 CFR § 123.401 (8). This alternative definition provides for comprehensive benefits, periodic payment without regard to frequency of service and arrangements with physicians to assure availability of services. This is substantial the requirements for an HMO in 42 U.S.C. § 300 e, and as a practical matter most HMOs which operate under Minn. Stat. § 62 D. also meet these basic standards. The language "substantially fulfilled" will allow HMOs and health care facilities, on behalf of HMOs, to show that their operation is that of an HMO. The Commissioner can

therefore grant exemption to entities other than the more stringently defined "qualified-HMO."

7 MCAR §§ 1.665 C.2. and 3. are based upon the limitimg factors in 42 CFR §§ 123.405 (b)(i)(A), (B) and (C) and similar limiting factors repeated in 42 CFR §§ 123.405 (b)(ii)(B), (C) and (D) and (iii)(A), (B) and (C). The language of this rule simplifies the conditions to two population related standards which must be applied to the potentially eligible entities specified in 7 MCAR § 1.665 B.

The 50,000 enrollee standard is written to also require reasonable access to the project by these 50,000 persons. Considering a reasonable hospital utilization pattern of 450 days per 1000 persons per year, this population would generate approximately 22,500 hospital days per year (average of 61 beds per day). While this would not be a practical number of projected days for an entire hospital, it may be practical for one unit or wing coordinated with other hospital services. Maximum effort would be made to encourage innovative plans which promote this marketplace approach.

The 75 percent potential use by HMO patients is important to prevent use of this exemption authority by those who would like to simplify evade review of a project for non-HMO patients. Since 7 MCAR § 1.665 D.3. requires this standard to be met either before exemption is granted or before the construction or modification is undertaken, there is a reasonable means for enforcement of this standard.

D. Procedures.

7 MCAR § 1.665 D. specifies procedures to be followed in order to apply for exemption of an HMO project. The procedures listed for time periods, for type of recommendations by an HSA, and for types of decisions by the Commissioner are consistent with the state standards elsewhere in the Act and these rules.

Application for exemption (7 MCAR § 1.665 D.1.) is submitted to the HSA, SPA and Commissioner as with other requests for action in the Act. The contents of the request is solely that information necessary to describe the project and demonstrate conformance with conditions in these rules. There is little need to know specifics of the nature of the project other than factors whic relate to the conditions in 7 MCAR § 1.665 C.

The reference to need for clarification and information (7 MCAR § 1.665 D.2.) is comparable to other procedures in the Act where certain minimum information is needed to make a recommendation or decision by an HSA or the Commissioner. Since the time period is of such a minimal amount, there needs to be clarity to the applicant that material must be provided in a timely fashion and in sufficient detail to make the decision pertinent to the limited items in these rules. For the most part, the conditions for exemptions are quite specific and the procedures proposed should not be of a difficult nature for easy compliance by eiher the applicant, the HSA or the Commissioner.

The 30 day time periods for HSA and Commissioner review of this request (7 MCAR § 1.665 D.3.) are used elsewhere in the Act and these rules when a recommendation or decision if made without public hearing. It is reasonable to use the same time period here.

This rule is needed to indicate the basis for the Commissioner's decision. The requirements of this rule must have already been met or will be met before the proposed activity will be undertaken. To grant an exemption or allow the activity to commence before the requirements are met would be inappropriate. The standards are minimum and the HMO or related health care facility can, without hardship, demonstrate compliance before obtaining the exemption.

E. Transfer of exemption.

7 MCAR § 1.665 E. is taken from 42 CFR § 123.405 (b)(3). The federal regulations specify that the state program must provise that a project granted exeption status be advised of this condition to its exemption. The requirement is a reasonable restriction. Without the restriction, an exempt entity could transfer its project to some not eligible and thereby, the new entity would have evaded review under the Act.

F. Criteria

In addition to the possibility of exemption of HMO projects, 42 CFR § 123.405 (d) specifies that non-exempt projects proposed by an HMO shall be automatically approved if they meet two criteria specified in 42 CFR

123.405 (d). 7 MCAR § 1.665 F.1. and 2. adopt those two criteria. In order to clarify the application of the second criteria listed in the Federal Regulation, it is necessary to have clauses a through d in 7 MCAR § 1.665 F.2.

Clause a clarifies the intent of the federal regulation which uses the term "long term basis." Five years duration is considered to be appropriate long term contract forthis Act. Five years is the length of time for information submitted in Minn. Stat. § 145.836, Subd. 2(d)(2) and (g).

In clause b, the term "conveniently" is a clarifying term to improve the understanding of accessibility in this context. Similarly, clause c presents a more objective standard for examination of cost effectiveness. The criteria uses the "cost" to the HMO. The "cost" may be otherwise confused with the aggregate costs which may be incurred for the general population.

Finally, clause d relates to the administrative feasibility of this clause for the HMO which should be considered as well. Such administrative feasibility is important to judge if the other potentially available services would be consistent with the basic method of operations of the HMO. Administrative feasibility can be described in detail on the basis of the past operating history of the HMO.

The final rule, 7 MCAR §§ 1.665 G. specifies that decisions in this rule shall be subject to judicial appeal. Since there are no provisions

for reconsideration and many other procedures are different as they relate to HMO, clarification of judicial appeal is needed.

REPEALER CLAUSE

The rules propose repeal of SPA rules 10 MCAR §§ 1.210 (formerly SPA 201 to 210). The SPA rules were adopted under the Old Act. When promulgated, SPA did not have the benefit of any operational experience to guide in identifying issues and questions on which guidance would be needed.

These proposed rules implement, enforce, and administer the Act which is an altered version of the Old Act in that some provisions have been changed and new items have need added. In addition, the years of operational experience under the Act have identified areas which need to be addressed in the rules. The changes in the Act and the new areas which needed to be covered in the rules made it necessary to draft an entirely new set of rules rather than to merely amend the SPA rules. (Comments under Section B, Statement of Need, supra, also demonstrate the need for and reasonableness of the repealer clause.)

Dated: May 14, 1981.

COMMISSIONER OF HEALTH

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