

Minnesota Attorney General: Administrative Rules Proceedings

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file

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL

Office Memorandum

TO : George R. Pettersen, MD
Commissioner of Health
Attn: Richard Wexler
Assistant Attorney General

DATE: December 10,1981

FROM : Ted A. Martinez
Special Assistant Attorney General

PHONE: 296-0315

SUBJECT: 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.

The rules in the above-entitled matter have not been approved by this office for the following reason:

Minn. Stat. §145.835 Subd. 3 regarding Physicians; notice of acquisition of equipment provides in relevant part that "(t)he Commissioner of Health shall within 60 days of receipt of the notice determine whether or not the proposed acquisition or purchase is designed to circumvent the provisions of sections 145.832 to 145.845 (emphasis added)." However, 7MCAR §1.662 C.2 of the rule as adopted provides that "(w)ithin 20 days of receipt of the notice, the commissioner shall decide whether the information submitted prusuant to 7MCAR §1.662 C.1. is complete." 7 MCAR §1.662 C.2.b. goes on to state that "(t)he 60 day period in which the commissioner must decide whether the proposed acquisition is designed to circumvent the Act shall not commence to run until the commissioner determines that the notice is complete."

The statute requires a decision to be made within 60 days of receipt of the notice without mention of any review period as to completeness. It appears then, that the Agency cannot by rule establish when the notice will be deemed received but must proceed to act upon the notice within 60 days upon its actual receipt. Any other method would result in a decision as to circumvention to be made in a period greater than 60 days which is contrary to the language of the statute. Therefore this rule must be re-written to allow only for a 60 day determiniation period. Any period for review as to completeness must be accomplished within this time frame.

After consideration of the above comments and agency action, if any, these rules may be resubmitted for review. Upon resubmission, please include two copies of a new or supplemental Order Adopting, and the original and two copies of the new Rule as Adopted. Also, please include a memorandum specifying that the rules are being resubmitted so that we may obtain our initial file in this matter.

Please be advised that pursuant to Minn. Stat. § 15.0412 subd. 4g effective July 1, 1981, "(n)o rule shall be filed with the secretary of state or published in the state register unless the revisor of statutes has endorsed on the rule that it is approved as to form." Therefore, at the time when you resubmit the new rule to this office, you must submit two copies of the same to the revisor of statutes.

If you have any questions concerning the issues raised in this memorandum, please do not hesitate to call me.

TAM:keo

Enc.

cc: Duane Harves
Susan Robertson
Sheri Yudelman
Minnesota Association of Health Care Facilities
Ann Bateson

SF-00006-02

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL - Health

Office Memorandum

TO : Ted Martinez
Special Assistant
Attorney General

DATE: December 18, 1981

FROM : Richard A. Wexler
Assistant Attorney General

PHONE: 341-7272

SUBJECT: Certificate of Need Rules

By memorandum of December 10, 1981, you informed the Commissioner of Health that you were disapproving the above subject rules because of a determination that 7 MCAR § 1.662 C.2.b. was in conflict with Minn. Stat. § 145.835, subd. 3. The Commissioner has amended the rule in question in a manner consistent with your recommendation. The Commissioner therefore is hereby resubmitting the rules for your review and approval as to form and legality pursuant to Minn. Stat. § 15.0412, subd. 4e.

Because you already have the record of hearing, I am enclosing only the following items: four copies of the rules as adopted with 7 MCAR § 1.662 C.2.b. amended to correct the defect, two copies of the Commissioner of Health's Supplemental Findings, Conclusions, and Order of Adoption, and a copy of the Order of the Chief Hearing Examiner finding that the amendment to 7 MCAR § 1. 662 C.2.b. is not a substantial change. In addition, the rules have also been resubmitted to the Revisor of Statutes in order to obtain the Revisor's certificate of approval as to form.

We would appreciate it if you could expedite your review. Thank you for your attention to this matter.

RAW:sd

Enclosures

cc: Kent Peterson

Our File No. 257

RULE REVIEW CHECKLIST

DATE RULE RECEIVED 11-20-81
DATE FOR REVIEW 12-1-81
DATE DUE 12-10

Adopted w/a hearing X
Adopted w/o a hearing _____
Temporary rule _____

Approved _____ Disapproved 12/10/81 Returned to Agency _____

Resubmitted 12/18 Due _____
Approved 12/21 Disapproved _____ Returned to Agency 12/21

Date filed w/Secretary of State 12/21 Revisor approved ✓ 11/25/81
disapproved _____

____ Rule as Adopted

✓ Rule as Proposed see SR.

✓ Order Adopting 11.6.81 Date combined with F. of F.

✓ Notice of Intent to Solicit Outside Opinion 10.15.79.

✓ Order for rulemaking
6.9.81 Date of Hearing

N/A Certificate of Board's Authorizing Resolution

✓ Notice of rulemaking
✓ Sufficiency BUT see HE #7

✓ Affidavit of Mailing Notice or rulemaking
4.9.81 ✓ 5/6/81 At least 30 days prior to hearing/~~adoption~~

✓ Mailing list Certificate

✓ Publication in State Register
5.4.81 At least 30/~~20~~ days prior to hearing/~~adoption~~

✓ Hearing Examiner's Report

✓ Chief Hearing Examiner's Report(s)
8.12.81 Approving H.E.'s Report
✓ 11.18.81 Approving agency action

✓ Agency's Findings of Fact combined with Order Adopting

N/A LCRAR Report or agency Affidavit

N/A Certificate of Board's Resolution Adopting Rules

✓ Order Approving Incorporation by Reference

✓ Statement of Need and Reasonableness

N/A Petition for Adoption of a Rule

✓ Record (includes transcript or tape, exhibits, comments received by agency, requests for a hearing, and other relevant materials)

✓ Certificate of Compliance w/Rulemaking Procedures

✓ Affidavit of Mailing Notice of Submission to Attorney General

✓ Notice of Submission to the Attorney General

✓ Affidavits of Consultation with other agencies

Department of Health
Health Systems Division

Adopted Rules Implementing, Enforcing, and Administering the Minnesota Certificate of Need Act, Minn. Stat. SS 145.832-145.845, and Repealing State Planning Agency Certificate of Need Rules, 10 MCAR SS 1.201-1.210.

Rules as Adopted

7 MCAR S 1.661 General provision.

A. Purpose.

1. These rules, 7 MCAR SS 1.661 to 1.665, are intended to govern the implementation, enforcement and administration of the Minnesota Certificate of Need Act. The rules do not repeat provisions of the Act which are clear and complete without rules; therefore, the Act should be read with the rules. References to the Act are made in these rules in order to assist the public in cross-referencing the Act with the rules.

2. The commissioner has, within the limits of the Act, developed review procedures and criteria which involve a minimum period of time, require only essential information, and involve the least cost for the applicant, the health systems agency (HSA), and the department. These rules promote health planning cooperation by health care facilities and health systems agencies before the certificate of need review and encourage health system innovations and alternatives, as well as beneficial price competition.

B. Definitions. The definitions contained in Minn. Stat. S 145.833 apply to the terms as used in these rules. Some of the terms defined in Minn. Stat. S 145.833 are also defined in these rules in order to clarify certain sections or parts of the statutory language. Unless the context clearly requires otherwise, the following terms shall have the ~~meaning~~ meanings ascribed to them:

1. "Act" means the Minnesota Certificate of Need Act, Minn. Stat. SS 145.832 to 145.845.

2. "AIP" means annual implementation plan as defined in the Act, Minn. Stat. S 145.833, subd. 11.

3. "Application" means the submission by a person of the information required by 7 MCAR S 1.663 A. in requesting the issuance of a Certificate of Need.

4. "Capital expenditure" means any expenditure, regardless of type of financing mechanism, including gifts, donations and other philanthropic activities, utilized to purchase, acquire, renovate, remodel or substantially alter or modify real property, buildings, fixtures, equipment or a service. Whenever real property, buildings, fixtures or equipment are acquired by capitalized lease or any type of rental agreement, that capital expenditure for lease or rental agreement shall be the fair market value of the real property, buildings, fixtures or equipment at the date upon which the agreement is executed. Expenditures which, under generally accepted accounting principles, are properly chargeable as an expense of operation and maintenance are not capital expenditures. Capital expenditures include the total of all anticipated expenditures for a single undertaking with interdependent or interrelated components whether or not any individual expenditure exceeds the threshold of the Act.

5. "Category," as used in Minn. Stat. S 145.833, subd. 5(a)(2), means classification of beds within a health care facility according to licensure (such as, general hospital, psychiatric, alcoholic, nursing home, boarding care home and supervised living) or 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 ~~(such as skilled nursing care, intermediate nursing care and intermediate care for the mentally retarded and persons with related conditions)~~ as found in 42 United States Code, Section 1395x(e), hospital; Section 1395x(f), psychiatric hospital; Section 1395x(g), tuberculosis hospital; and Section 1395x(j), skilled nursing facility; and in Title XIX of the Social Security Act in 42 United States Code, Section 1396a (a) (28),

skilled nursing facility; Section 1396d(c), intermediate care facility; and Section 1396d(d), intermediate care facility for the mentally retarded.

6. "Commissioner" means the Commissioner of Health and includes any duly authorized representative of the commissioner.

7. "Construction or modification" means:

a. Any erection, building, alteration, renovation, reconstruction, conversion of any existing building, modernization, improvement, expansion, extension or other acquisition by or on behalf of a health care facility which:

(1) Requires a total capital expenditure in excess of $150,000; or

(2) Changes the bed capacity of a health care facility by more than ten beds or more than ten percent of the facility's total licensed bed capacity, whichever is less, over a two year period following the most recent bed capacity change, in a way which:

(a) Increases the total number of beds; or

(b) Changes the distribution of beds among various categories; or

(c) Relocates beds from one physical facility or site to another;

b. Any capital expenditure in excess of $150,000 by or on behalf of a health care facility, which is used to acquire diagnostic or therapeutic equipment. If the equipment is being updated rather than totally replaced, the capital expenditure ~~will~~ shall be ~~based upon~~ considered to be the cost of the equipment parts to be replaced, ~~or added~~ plus the cost of manufacturer's labor and installation, as well as any related financing costs ~~incurred~~ which are considered, according to generally accepted accounting principles, to be incurred;

c. Any expansion or extension of the scope or type of existing health service by a health care facility which requires a capital expenditure in excess of $50,000 during any consecutive 12 month period for that service. Change in scope or type of existing service means the difference between the

range and nature of the present service and the range and nature of the services contemplated under the proposal. An expansion or extension does not occur if ~~there~~ the result is solely increased efficiency of operations or increased square footage or spatial allocation. An expansion or extension shall occur if at least one of the following factors is ~~directly associated with~~ required by or a direct result of the proposed project:

(1) ~~An~~ A material increase in volume of services provided;

(2) The ability to perform treatments or procedures not previously performed;

(3) ~~An~~ A material increase in personnel associated with the capital expenditure;

(4) A material change in proportion of patient mix; or

(5) A material change in geographic source ~~or~~ of referrals to the facility~~.~~;

d. Any establishment of a new health care facility~~.~~;

e. Any reviewable predevelopment activity by or on behalf of a health care facility~~.~~; or

f. Any establishment by a health care facility of a new institutional health service, other than a home health service, which is to be offered in or through that facility and which was not offered on a regular basis in or through that facility prior to the twelve months before that service ~~which~~ will be offered under the terms of the proposal.

8. "Direct patient care service" means any health service designed to provide diagnosis, treatment, nursing, preventive care, rehabilitative care or habilitative care to any person.

9. "Exemption" means the decision by the commissioner to authorize an HMO or health care facility to proceed with a project reviewable under the Act, without request for a waiver or application for a certificate of need.

10. "Evidence" means any exhibit, oral or written testimony or other data or information submitted to an HSA prior to the close of the public hearing for the purpose of affecting

the determination of whether a certificate of need should be issued.

11. "Health maintenance organization" or "HMO" means any organization which operates or proposes to operate pursuant to Minn. Stat. SS 62D.01 to 62D.29.

12. "Hearing body" means:

a. The governing body of an HSA;

b. In the case of the Metropolitan Council, the Metropolitan Health Board; or

c. For HSAs other than the Metropolitan Council, a project review committee, the membership of which ~~conforms to~~ complies with the requirements of Minn. Stat. S 145.845, clauses (2), (3), (4) and (5) and 7 MCAR S 1.661 C.2.b.(2).

13. "HSA" means health systems agency as defined in the Act, Minn. Stat. S 145.833, subd. 7.

14. "HSP" means health systems plan as defined in the Act, Minn. Stat. S 145.833, subd. 10.

15. "Institutional health service" means any health service as defined in the Act, Minn. Stat. S 145.833, subd. 3, wherever and however that health service is provided.

16. "Long range development plan" means a health care facility's written description of its present and anticipated configuration of health services which is developed in consideration of the HSP for the health care facility's health service area.

17. "On behalf of" means in the ~~interests~~ principal interest of, at the behest of, or for the principal benefit of, a health care facility ~~or other entity~~.

18. "Patient" means any person receiving care in a health care facility and is synonymous with the term "resident."

~~18.~~ 19. "Predevelopment activity" means any activity by or on behalf of a health care facility or any person which involves architectural designs, plans, working drawings, specifications, feasibility studies, surveys, site acquisitions, contractual agreements, legal services, fund-raising and any other related pursuit and which occurs with intention to embark

upon a program of construction or modification.

a. "Reviewable predevelopment activity" means any predevelopment activity which occurs with intention to offer or develop a new institutional health service if:

(1) The predevelopment activity would require an expenditure in excess of $150,000; or

(2) The predevelopment activity involves any arrangement or committment for financing the new institutional health service.

b. "Non-reviewable predevelopment activity" means any predevelopment activity not included in ~~7 MCAR § 1.661 B. 18.~~ a.

~~19. "Patient" means any person receiving care in a health care facility and is synonymous with the term "resident."~~

20. "Project" means the proposed construction or modification. Project is used synonymously with proposal.

21. "Provider" means any person:

a. Whose primary occupation involves, or involved within the last 12 months previous to appointment to the HSA, provision of health services to individuals or the administration of health care facilities or other health service activities;

b. Who is, or was, within the 12 months previous to appointment to the HSA, employed by a health care facility as a health or mental health professional;

c. Who has a fiduciary interest in or position with a health care facility or other entity which has the provision of health services as its primary purpose;

d. Who has, or has had within the twelve months previous to appointment to the HSA, a material financial interest (more than one-fifth of the person's gross annual income) from any one or a combination of the following:

(1) Fees or other compensation for research into or instruction in the provision of health care;

(2) Producing or supplying drugs or other materials, articles or devices for individuals in the provision of, research into, or instruction in health care;

(3) Issuing any policy or contract of ~~individual or group~~ a health insurance company, a health service plan or a health maintenance organization;

(4) Any other material financial interest in rendering of a health service; or

e. Who is a spouse of an individual described in items a., b., c. or d. above.

22. "Recommendation of the HSA" means the report of the HSA to the commissioner which contains its recommendation as to what action should be taken with respect to judging ~~applications~~ if an application is complete or incomplete, if a project is subject to review, if a waiver should be granted or if a certificate of need should be issued. The recommendation includes submission to the ~~commission~~ commissioner of all information presented by the applicant and delineation of all ~~rationale~~ rationales developed by the HSA to support its recommendation.

23. "Region" means the geographic area designated by the Secretary of the United States Department of Health and Human Services upon recommendation of the Governor to be under the jurisdiction of an HSA for the purposes of health systems planning.

24. "Requester" means a licensed medical doctor or a group of licensed medical doctors, however legally organized.

25. "State Health Plan" means the document, developed by the ~~SPA~~ Department of Energy, Planning and Development pursuant to 42 United States Code, Section 300m-3 (c)(2)(A) and (B), which addresses statewide health needs and incorporates the HSPs of all Minnesota HSAs ~~pursuant to 42 U.S.C. 300k, Section 1524(c)(2)(A and B)~~.

~~26. "SPA" means the State Planning Agency established pursuant to Minn. Stat. SS 4.10 to 4.17.~~

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

1. Membership of HSA. HSAs may specify in their corporate bylaws provisions regarding eligibility for

membership, categories of members and similar items.

2. Membership ~~for~~ of the HSA governing body.

a. Each HSA shall select from its membership a governing body to conduct its business and to carry out its duties and functions. The Metropolitan Council shall use its health board to advise it~~, and may delegate any of its functions and duties to the health board and its staff~~. The establishment of a governing body shall not prohibit any delegation of HSA duties and functions to staff except as provided in these rules. Documentation of any such delegation shall be filed with the commissioner.

b. The membership of the governing body~~,~~ and the health board of the Metropolitan Council shall, in addition to complying with the requirements of Minn. Stat. S 145.845:

(1) Be chosen by election or other appropriate method approved by ~~SPA~~ the Department of Energy, Planning and Development and consistent with provisions of ~~42 U.S.C. 300k, et seq.~~ 42 United States Code, Section 3001-1 for a term of office not to exceed three years. No director may serve more than six consecutive years.

(2) Include only residents of, or individuals having their principal place of business in, the region in which the HSA has jurisdiction.

c. The membership of all HSA committees or subcommittees making recommendations to the governing board of an HSA or the Health Board of the Metropolitan Council on proposals for a certificate of need shall consist of a majority of consumers, and it shall include ~~representatives of the interests of~~ providers.

D. Conflicts of interest.

1. No HSA member or other person who assists the HSA in the review of a project may participate at any level of review, formally or informally, or in discussing or voting upon any project for a certificate of need if a conflict of interest exists. Persons having a conflict of interest, however, may participate in the proceedings in the same manner as any party

who is not a member of a hearing body~~,~~ or the Metropolitan Council.

2. A conflict of interest exists when a person:

a. Has a direct or indirect financial interest in the applicant;

b. Has a contract or has had within the preceding twelve months a contractual, creditor or consultative relationship with the applicant;

c. Is an employee, director, trustee, officer or has another fiduciary relationship with the applicant; or

d. Is a spouse of any person ~~listed in~~ falling under a., b., or c. above.

3. A person who is a member of a hearing body or the Metropolitan Council and who has a conflict of interest shall declare it in writing to the HSA before it starts its review of the application or when it becomes apparent to him that he has such a conflict.

4. Any person may question the HSA orally or in writing as to whether or not a conflict of interest exists in regard to any person involved in the review of a project on behalf of an HSA. The HSA shall determine in such case whether a conflict of interest exists. ~~Its findings shall be included in the recommendation of the HSA.~~

5. Any person who has a conflict of interest ~~as determined pursuant to 7 MCAR § 1.661 D.3. and 4.~~ shall be so identified in the recommendation of the HSA.

6. The minutes of the HSA hearing or meeting at which a project is being considered shall record a person having a conflict of interest as "absent" rather than "abstaining due to conflict of interest." Such a person shall not be counted in determining whether a quorum is present for consideration of the application being reviewed.

7. Nothing in this rule precludes any HSA from adopting bylaws or other procedures for determining conflicts of interest which are more stringent than these rules.

E. Ex parte communication.

1. "Ex parte communication" means a written or oral communication by any person as to the merits of an application which is not in a hearing record and with respect to which notice to all parties is not given. The term does not include any requests for status reports on any application, or any communication among HSAs, the ~~SPA~~ Department of Energy, Planning and Development and the commissioner or their staffs which relates solely to information found in a hearing record, the Act, these rules or any application or request for formal action under the Act.

2. Ex parte communication to or among the HSAs, the ~~SPA~~ Department of Energy, Planning and Development, the commissioner or their staffs and any other party, is prohibited, except when the communication relates to an allegation of material misrepresentation, inaccuracy or omission in information necessary to determine whether an action under the Act should be taken.

3. Ex parte communication received by the HSA, ~~SPA~~ Department of Energy, Planning and Development or commissioner shall not be considered in the review of the project and shall not be part of the record, except as provided under E.2.

F. Extension of review period.

1. The applicant, the HSA or the commissioner may request that the time periods for review as prescribed in the Act and these rules be extended.

2. The party requesting the extension shall notify the other two parties in writing specifying the length of the extension and the reasons therefor.

3. Within five working days of receipt of the request, the other two parties shall notify the requesting party in writing whether they agree to the extension. If all three parties agree to the extension, the new time period shall be in effect. If the parties do not agree to the extension, the time periods in effect prior to the making of the request shall remain in effect.

~~4. Time periods shall be deemed directory and not~~

~~mandatory.~~

G. Time computation.

1. ~~In computing~~ Computation of any period of time prescribed or allowed by these rules ~~or by any applicable statute, the day of the act or event from which the designated period of time begins to run shall not be included~~ shall be controlled by Minn. Stat. SS 645.15 and 645.151. ~~The last day of the period so computed shall be included, unless it is a Saturday, a Sunday or a legal holiday, in which event the period runs until the end of the next day which is not a Saturday, a Sunday, or a legal holiday. When the period of time prescribed or allowed is less than seven days, intermediate Saturdays, Sundays and legal holidays shall be excluded in the computation.~~

2. Whenever a person has the right or is required to do some act ~~or take some proceeding~~ within a prescribed period after the service of a document upon him, or whenever some service is required to be made in a prescribed period before a specified event, and the document is served by mail, the time period for exercising that right or performing that action shall begin to run, ~~under the terms described above,~~ upon receipt of the document and not upon it being mailed. However, an act or event which must be accomplished within a specific time period, shall be considered complete upon mailing of the document.

3. Time periods prescribed under these rules shall be deemed directory and not mandatory.

H. Evasions.

1. ~~A project is a single undertaking when its component parts have been jointly planned, when financing arrangements are made to cover the entire project or when component parts are so interdependent or interrelated that separate review would be inconsistent with the purpose of the Act~~ No health care facility may divide a single project into separate components in order to evade the cost limitations of Minn. Stat. S 145.833, subd. 5. Division of a single project shall be deemed to have occurred if either of the following conditions exists:

a. Components which have been jointly planned are

separated; or

b. Components which are so interdependent or interrelated that they could not feasibly be undertaken separately are separated.

2. The annual capital expenditure budget or long range development plan of the health care facility or health maintenance organization does not ~~neeessarily~~, in and of itself, constitute a single undertaking.

~~I. Interpretation of rules. Interpretation of these rules shall be governed by the provisions of Minn. Stat. ch. 645 except insofar as its provisions are in conflict with the definitions or other provisions of the Act or these rules which relate to construction or interpretation of these rules.~~

7 MCAR S 1.662 Determination of applicability and waivers.

A. Submission of notice of intent.

1. ~~Any person shall submit a notice of intent to the appropriate HSA when planning~~ If a person intends to embark upon a program of construction or modification*, as defined in Minn. Stat. S 145.833, subd. 5 and 7 MCAR S 1.661 B.7., prior to engaging in any predevelopment activities with respect to the program of construction or modification, that person shall submit a notice of intent to the appropriate HSA.

2. The notice of intent shall be submitted in writing to the HSA at least 60 days prior to the submission of an application. No HSA ~~shall~~ may accept or act upon an application until proper notice has been given.

3. Within ten days of receipt of a notice, the HSA shall forward a copy of such notice to the commissioner and to ~~SPA~~ the Department of Energy, Planning and Development. Upon receipt of a notice proposing construction or modification, the HSA shall notify the applicant of the schedule for submission of a certificate of need application as established pursuant to 7 MCAR S 1.663 A.

4. The notice of intent shall:

a. Identify the nature of:

(1) Architectural services;

(2) Professional consulting services; ~~or~~ and

(3) Fund-raising services;

b. Identify the name, address, contact person, and planned commencement date for activities listed above;

c. Describe the proposed construction or modification;

d. Estimate the capital expenditure associated with the construction or modification;

e. Specify the intended location or neighborhood of the project; and

f. Estimate the date of commencement of the construction or modification.

5. A notice of intent submitted by an applicant shall not preclude any other person from submitting a notice of intent for a similar undertaking.

6. A notice of intent shall be valid for a one year period within which time an application or an updated notice of intent may be submitted to the HSA.

7. If the applicant provides written verification that the necessity for an application could not have been reasonably anticipated 60 days prior to submission of an application for a certificate of need, the commissioner may reduce the time requirement for advanced submission of a notice of intent to less than sixty days.

B. Determination of applicability.

1. Written determination of applicability of the Act shall be made by the commissioner when an informational request for such determination is submitted from any person directly affected by the proposed construction or modification. Such request may be submitted at any time regardless of whether a notice of intent has been submitted. The foregoing shall not prohibit the commissioner from making his own determination, regardless of whether a notice of intent has been submitted, as to whether a proposed undertaking is subject to review under the Act as part of his general authority to enforce the provisions of the Act.

2. The HSA or the commissioner, when necessary to obtain

all relevant information in order to make a recommendation or to make the final determination respectively, may request additional clarifying information about the proposed undertaking. Any information requested shall relate to the provisions of Minn. Stat. S 145.833, subd. 5, and to 7 MCAR S 1.661 B.7. Failure to supply the information in a timely manner shall be sufficient grounds for determining that the proposed undertaking is subject to the Act.

3. Upon receipt of a request for determination of applicability, the HSA shall, within 30 days, submit a recommendation to the commissioner as to the applicability of the Act to the subject of the request. Within 30 days of receipt of the recommendation from the HSA, the commissioner shall review the matter and the HSA recommendation and shall notify the applicant in writing as to whether the Act is applicable to the subject of the request and the reasons for the decision.

C. Acquisition of equipment by physicians.

1. A requester proposing to purchase, lease, or otherwise acquire diagnostic or therapeutic equipment which requires a total capital expenditure in excess of $150,000 for one or more related items of diagnostic or therapeutic equipment shall submit a notice to the HSA and the commissioner of the proposed equipment acquisition. Such notice shall contain the following information:

a. The legal structure or organization of the requester;

b. A description of the equipment which is proposed to be acquired;

c. The proposed location of the equipment;

d. The estimated capital expenditure necessary to acquire the equipment as well as an estimate of those capital expenditures needed for installation and other related costs;

~~e.~~ e. The source of funds to be used to acquire the equipment;

f. The source and estimated volume of patients

utilizing the proposed equipment for the first three years of operation;

g. The party responsible for the operation of the proposed equipment;

h. The recipient of revenue generated by the proposed equipment;

i. The party responsible for any financial losses from the operation of the proposed equipment;

j. Delineation and description of the nature of any proposed existing formal or informal arrangement with a health care facility for use of equipment, including the proportions of total patients who will be either inpatients or outpatients of a health care facility during the time such equipment will be used on or for them; and

k. Whether the requester desires a public hearing.

2. Within 20 days of receipt of the notice, the commissioner shall decide whether the information submitted pursuant to 7 MCAR S 1.662 C.1. is complete.

a. If the commissioner decides that the information is not complete, he shall immediately notify the requester and specify in detail why the information is incomplete and what additional data must be submitted. A determination of incompleteness may occur under the following conditions:

(1) The items specified in 7 MCAR S 1.662 C.1. have not been fully answered or the answers need clarification; or

(2) The answers provided raise additional questions which must be answered in order to fully understand the situation.

b. The 60 day period in which the commissioner must decide whether the proposed acquisition is designed to circumvent the Act shall ~~not~~ commence to run ~~until the commissioner determines that the notice is complete~~ upon receipt of the notice, or, if the commissioner determines that the notice is incomplete pursuant to 7 MCAR S 1.662 C.2.a., upon receipt of the additional information required to complete the notice.

3. Within twenty days after the commissioner determines the notice is complete, the HSA shall forward comments to the commissioner regarding the proposed acquisition of the equipment and may request that a hearing be held.

4. If a hearing is requested by the requester or the HSA, a public hearing shall be held pursuant to the Administrative Procedure Act. The hearing results shall be considered to be fact-finding and advisory to the commissioner.

5. The following ~~factors~~ direct or circumstantial evidence shall be considered in determining whether a proposed acquisition is designed to circumvent the Act:

a. The existence of an explicit agreement to circumvent the Act;

~~a.~~ b. The projected proportion of patients who will use the equipment while also being inpatients or outpatients of a health care facility, if such inpatient use is not on a temporary basis, such as a result of a natural disaster, major accident or equipment failure;

~~b.~~ c. The existence of a relationship between the requester and a health care facility for purposes of making available the proposed equipment to the health care facility;

~~c.~~ d. The needs ~~for~~ of a health care facility to purchase such equipment if the proposed equipment were not acquired by the requester;

e. The past occurrence of a denial of a certificate of need for the same or similar equipment to a health care facility the patients of which would receive health services from the requester as a result of the proposed acquisition;

f. The financial ability of a health care facility to purchase or acquire the same or similar equipment, if patients of the health care facility would receive health services from the requester as a result of the proposed acquisition;

g. The past or present existence of an intention to acquire such equipment, as expressed in its long range development or other plan, on the part of a health care facility, the patients of which would receive health services

from the requester as a result of the proposed acquisition;

~~d.~~ h. The accrual to a health care facility of material benefit from the proposed acquisition ~~to a health care facility~~ and that, if the acquisition were made by the health care facility, the project would be reviewable under the Act; ~~or~~ and

~~e.~~ i. The existence of other information which shows that the acquisition of the equipment ~~will result in circumvention of~~ is designed to circumvent the Act.

6. Within 60 days of determining the notice to be complete, the commissioner shall review the notice, any hearing record and hearing examiner recommendation and any information submitted by the requester, HSA and other persons, and make a decision as to whether the proposed acquisition is designed to circumvent the Act. The applicant and the HSA shall be informed in writing of the commissioner's ~~decisions~~ decision and underlying rationale.

7. If the commissioner decides that the proposed acquisition is designed to circumvent the Act, a certificate of need must be obtained according to the process described by the Act and these rules.

D. Waivers.

1. A proposed construction or modification involving an existing health care facility may be granted a waiver based upon the information forwarded by the HSA with its recommendation and the determination of the commissioner that the factors in 7 MCAR S 1.662 D.2. are substantially fulfilled and that any one of the following situations exists:

a. The proposed construction or modification falls within the situations described in Minn. Stat. S 145.835, subd. 4(a) or (b).* Additional examples or items that come ~~with~~ within subd. 4(b) are business related equipment, telephone systems, energy conservation measures, warehouse storage, activities space, ~~real estate~~ site acquisition and other projects of a like nature.

b. The proposed project is solely for acquisition of

diagnostic or therapeutic equipment which is to replace existing equipment only when the existing and replacement equipment have approximately the same capabilities.

c. The proposed project:

~~(1)~~ is subject to Minn. Stat. S 145.833, subd. 5 (a)(2) which governs changes in bed capacity of a health care facility; ~~**~~ and

~~(2)~~ is not reviewable under any other provisions of the Act or these rules~~, and~~

~~(3) If approved, would have no material impact on health planning consideration or on the provisions of health services within the facility's health service area.~~

d. The proposed project is solely to conduct reviewable predevelopment activity pursuant to 7 MCAR S 1.661 B. ~~18.~~ 19.a.

e. The proposed project is solely for acquisition of an existing health care facility and the change is not reviewable under the provisions of the Act other than 7 MCAR S 1.661 B.7.a.(1).

2. Waiver shall be granted for projects involving eligible situations if the following factors ~~shall be~~ are substantially fulfilled ~~as a prerequisite for granting of waivers~~:

a. The proposed project shall not result in an increase in patient charges of more than five percent over existing charges in either the average charge for all patients or the average charge for those patients who will benefit from the project; provided, for proposed waiver of changes in bed categories involving federal certification status of nursing homes, the proposed project shall not result in an increase in patient charges of more than 20 percent over existing charges in either the average charge for all patients or the average charge for those patients who will benefit from the project. The ~~five percent~~ percentages shall be calculated after including any projected inflation increases based upon~~, for hospitals,~~ the allowable increase limit established by the commissioner

pursuant to 7 MCAR S 1.504 ~~and, for other health facilities, a comparable inflation indicator established by a government agency~~.

b. The applicant has documented that the project:

(1) Is not unnecessarily duplicative of similar services in the facility's service area;

(2) Will ~~not~~ be ~~underutilized~~ adequately utilized compared with minimal utilization rates consistent with the efficient delivery of health care; and

(3) Will ~~not~~ otherwise result in an ~~ineffective or inefficient operations~~ effective and efficient operation.

c. The proposed project conforms to the facility's long range development plan, if any, and to the guidelines, criteria and goals for such services in the applicable HSP, AIP and the State Health Plan.

d. The applicant is not a health care facility against whom proceedings pursuant to Minn. Stat. S 144.55 or 144A.11 have been initiated. This factor shall not be considered if the proposed construction or modification is intended to correct, to the extent practicable, the causes of the violations.

3. The request for a waiver shall be submitted by the applicant to the HSA at the same time as submission of a notice of intent for a proposal would have been submitted ~~and~~. In situations in which the applicant has previously submitted a notice of intent alone, nothing shall preclude the applicant from submitting an amended or updated notice of intent concurrently with the waiver request. The waiver request shall include the following information:

a. Description of the project;

b. Estimated capital expenditures;

c. Annual operating budget of the current year;

d. Anticipated impact of the project on facility costs and patient charges; and

e. Information pertaining to the factors for a waiver specified in 7 MCAR S 1.662 D.2.b.

4. The HSA shall not proceed with a recommendation until

complete information is received. If any additional information is requested of an applicant, it shall be relevant to the eligibility standards specified in 7 MCAR S 1.662 D.1. and the factors specified in 7 MCAR SS 1.662 D.2.

5. Within 30 days of the receipt of a request accompanied by complete information, the HSA shall submit to the commissioner its recommendation for granting or denying the waiver. This recommendation shall be accompanied by supporting rationale based on the applicable item in 7 MCAR S 1.662 D.1. and the factors in 7 MCAR S 1.662 D.2. and all information submitted by the applicant.

6. Within 30 days of receipt of the recommendation of the HSA, the commissioner shall notify the applicant and the HSA of the decision.

7. Emergency waivers may be granted by the commissioner if the need for the project is a result of fire, tornado, flood, storm damage or other similar disasters.

a. The applicant shall submit a written request for an emergency waiver to the commissioner with a corresponding copy sent to the HSA. This request shall describe the project, estimated cost and type of disaster which occurred.

b. Within three working days, the HSA shall forward a recommendation and comments to the commissioner.

c. Within five working days of the receipt of the request from the applicant, the commissioner shall notify the applicant and HSA of the decision to grant or deny an emergency waiver.

d. An emergency waiver shall be granted if the need for the project is a result of fire, tornado, flood, storm damage or other similar disaster, and if both of the following conditions are found to exist:

(1) Adequate health care facilities are not available for the people who previously used the applicant facility; and

(2) The projected repair does not exceed the guidelines and goals for such services in the applicable health

systems plan or State Health Plan.

e. A request for an emergency waiver shall be limited in nature and scope to only those repairs necessitated by fire, tornado, flood, storm damage or similar disasters.

8. For purposes of Minn. Stat. S 145.842 and for the periodic reports in 7 MCAR S 1.664 E. of these rules, granting of a waiver of certificate of need review shall be considered to have the same effect as issuance of a certificate of need.

9. The applicant shall resubmit a request for a waiver if the construction or modification for which a waiver was initially granted is not commenced, as described in 7 MCAR S 1.664 C., within 18 months of the granting of waiver or within 90 days of the granting of an emergency waiver.

10. A project may not be separated into component parts if the granting of a waiver for one part would not subject the remaining parts to certificate of need review and if, when all parts are taken together, the project constitutes a single undertaking which is reviewable under the Act. If, however, the remaining component parts of a project would still be subject to review, a waiver may be requested for a specific component part of a project.

7 MCAR S 1.663 Review process, procedures, and criteria.

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

1. The commissioner shall establish a schedule specifying dates when applications may be submitted to the applicable HSA. The schedule may be revised periodically by the commissioner subject to a 60 day notice which shall be printed in the State Register and shall be provided to each HSA by written notice. The schedule shall provide that all applications may be submitted ~~not~~ as specified but in no case less frequently than every 30 days.

2. Fourteen copies of an application for certificate of need shall be submitted. The HSA, immediately upon receipt of the application, shall send a copy to both the commissioner and the ~~SPA~~ Department of Energy, Planning and Development.

3. The application shall be submitted on a form prepared by the commissioner and available through the HSA. Forms shall be printed for:

a. Hospitals;

b. Nursing homes and boarding care homes; and

c. Supervised living facilities certified or proposing to be certified as intermediate care facilities for the mentally retarded and persons with related conditions. This form shall allow substitution of acceptable alternative sets of pertinent information which have been prepared for the Department of Public Welfare to carry out its responsibility for determination of need, location and programming for the mentally retarded and for the purposes of program licensure and rate setting. In order to be acceptable substitutes, alternative sets of information shall be identifiable according to the topics specified in 7 MCAR S 1.663 A.4.; and

d. Other applicants.

4. The following information and other clarifying information shall be considered to be germane to the project and shall be in a prescribed form, as related to each type of application described in 7 MCAR S 1.663 A.3.

a. Description of the project.

(1) A description of any building or services to be constructed, modified or provided, including a comparison to existing building and services.

(2) A description of the present number and kinds of staff positions and those new staff positions to be created by the project, as well as the basis for anticipation of the successful recruitment of these new staff positions.

(3) A statement from the architect or other construction specialist describing the status of the project's conformance with applicable building codes and state licensure and federal certification requirements for physical plants.

(4) A description of the methods and projected costs of providing energy for operating the project, as well as methods of conserving energy.

(5) A statement of the anticipated dates for commencement and completion of the project.

b. Financial aspects of the project.

(1) Capital expenditures and financing.

(a) The estimated total capital expenditure for the project. There shall be a breakdown of the total capital expenditure based upon the following eight categories. The information provided with respect to each category shall include the major component expenditures within the category.

(i) Predevelopment activity;

(ii) Site acquisitions;

(iii) Land improvements;

(iv) New construction of buildings;

(v) Renovations of buildings;

(vi) Fixed equipment;

(vii) Movable equipment; and

(viii) Financing costs and any contingencies.

(b) A description of the effect of this project on the general solvency of the applicant, including the future effect on financial indicators, including ratio of debts to total assets, operating revenue to total assets, operating revenue to fixed assets, total revenue to fixed assets and interest to total expense plus interest.

(c) A description of the availability and method of financing, including the amount of all projected loans, refinancing of existing debt (if any), estimated interest rate and the projected debt service amount as a percentage of the cost per patient day, or, for hospitals, as a percentage of cost per adjusted admission, as defined in 7 MCAR S 1.472 U.

(2) Operating costs. An estimate of the total annual operating costs upon completion of the project for at least five years. The total annual operating costs shall include anticipated salary requirements of new staff. The estimated costs shall conform with the cost centers and other requirements of at least one of the following:

~~(i)~~ (a) The requirements for cost allocation

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under Title XVIII of the Social Security Act, 42 ~~U.S.C. § 1395,~~ ~~et seq.~~ United States Code, Section 1395x and 42 Code of Federal Regulations, Sections 405.401-405.406 and 405.453;

~~(ii)~~ (b) The requirements for cost allocation under Title XIX of the Social Security Act, 42 ~~U.S.C. §~~ United States Code, Section 1396a, ~~et seq.~~ and 42 Code of Federal Regulations, Sections 405.401-405.406 and 405.453;

~~(iii)~~ (c) The requirements for cost allocation under Minn. Stat. SS 144.695-144.703 (Minnesota Hospital Rate Review System); or

~~(iv)~~ (d) The cost allocation requirements utilized in generally accepted reports by applicants to any other agency or program of the State of Minnesota.

(3) Revenue.

(a) An estimate of the total annual revenue of the health care facility upon completion of the project for at least five years.

(b) A description of the anticipated effect of the project for the first five years of operation on the total patient charges per ~~outpatient~~ patient visit or service if applicable, and in the case of hospital projects, the total patient charges per adjusted admission as defined in 7 MCAR S 1.472 U. Average patient charges by service which are affected by the project shall be detailed.

(c) Where a health care facility does not already exist, a projection of the anticipated patient charges for the first five years of operation.

c. Geographic area to be served.

(1) A narrative description of and graphic identification of the health care facility's service area or areas, in terms of standard political boundaries.

(2) An identification of patient origin data, local surveys and other sources utilized in determining the service area of the project.

d. Requirements of the population served.

(1) Current and projected population for the ~~next~~

anticipated life of the project or 20 years, whichever is less, by applicable demographic categories, such as age, sex and occupational status, which will be served by the project and identification of sources of the information.

(2) Incidence and prevalence rates of diagnoses or conditions within the population related to the services proposed.

(3) The impact of the project upon the health needs of people who have traditionally experienced difficulties in obtaining equal access to health care.

(4) A description of the applicant's performance during the past five years related to access to health services including:

(a) Extent to which the facility met its obligations, if any, under federal regulations or state rules requiring provision of uncompensated care, community services or access to programs receiving federal financial assistance;

(b) The extent to which Medicare, Medicaid and medically indigent patients are served by the applicant; and

(c) The range of methods by which a person may have access to its services, such as, outpatient services, admission by house physicians or admission by physicians in the community.

e. Relationship to other health care facilities.

(1) Existing institutions within and contiguous to the proposed project that offer, or propose to offer, the same or similar service;

(2) The occupancy or utilization rates of the similar existing institutions during the past five years, only if such information is accessible to the applicant. Determination of incompleteness shall not be made solely because the applicant is unable to provide occupancy or utilization information for existing institutions due to inaccessibility of such information to the applicant;

(3) The anticipated effect that the project will have on existing facilities and services; and

(4) The relationship of the project to health professional training programs, biomedical and behavioral research projects and medical referral facilities.

f. A description of the applicant's participation, if any, in consumer choice health plans and ~~programs with which the applicant participates including~~ any other methods for offering health services based upon giving the purchaser choices in services and knowledge about the price and quality of such health services. The description shall include:

(1) Current and five-year projected number of consumers involved and

(2) ~~Methods of~~ Procedures by which public information regarding ~~cost~~ price and quality of health services will be made available to potential consumers and payors.

g. Anticipated need for the facility or service to be provided by the project and identification of the factors which create the need, including at least the following:

(1) Data, information and findings collected by the applicant which establish need for each service component of the project; and

(2) Relationship of the project to the facility's long range development plan.

h. Occupancy and utilization rates.

(1) Occupancy rates for the health care facility, based on both licensed beds and on beds which are set-up and staffed, for the following:

(a) Each of the past five years;

(b) Each of the preceding 12 months; and

(c) Each of the first five years after completion, including explanation of assumptions.

(2) Utilization rates for the health services related to the projected project for the following:

(a) Each of the past five years;

(b) Each of the preceding 12 months; and

(c) Each of the first five years after completion, including explanation of assumptions.

i. A copy of all survey reports during the last three years of operation from the Minnesota Department of Health~~, as well as voluntary survey groups, related to the quality of care provided by the health care facility during the past three years of operation~~ or from other quality assurance programs recognized in federal or state laws, such as the accreditation program of the Joint Commission on Accreditation of Hospitals.

j. Alternatives which were considered and found not to be acceptable as a substitute for the project and the reasons why they were determined to be unacceptable.

k. Relationship of project to the HSP, AIP and State Health Plan including established planning objectives pertaining to cost, availability, accessibility, need, quality and financial viability of health services.

B. Determination of completeness.

1. Within ten days of the receipt of an application the HSA shall review the application's contents and forward a recommendation to the commissioner and ~~SPA~~ the Department of Energy, Planning and Development as to whether it is complete. If the recommendation states that the application is incomplete, the HSA shall identify the sections which it found to be incomplete~~,~~ and explain why it concluded that they were incomplete. A determination of incompleteness may occur under the following conditions:

a. The items specified in 7 MCAR S 1.663 A.4. have not been fully addressed or the information needs clarification.

b. The information provided raises ~~additional~~ definite questions ~~which must be answered~~ directly relevant to the proposed project and which are critical and essential in order for the HSA and commissioner to perform their review under the Act and these rules.

2. Within ten days of receipt of the recommendation from the HSA, the commissioner, after reviewing the application in conjunction with the HSA recommendation and comments, shall notify the applicant, HSA and ~~SPA~~ Department of Energy, Planning and Development in writing as to whether the application is

complete. If the application is declared incomplete, the applicant shall be informed what additional information must be submitted.

a. If the applicant submits the required additional information to the HSA, SPA Department of Energy, Planning and Development and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA Department of Energy, Planning and Development within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the application may be found to be complete without being deferred to another cycle of reviews.

b. If the required information is submitted after five working days, but within 60 days of receipt of the commissioner's determination, the complete review will be made according to the schedule specified pursuant to 7 MCAR S 1.663 A.1. The result of this clause is that the application is considered for completeness in the next cycle of the commissioner's completeness determination process.

c. If an applicant has not fully responded to a request for additional information within 60 days of the request, the incomplete application shall be returned to the applicant.

3. A determination that an application is complete shall mean only that information has been given pertaining to each component part of the application as prescribed in 7 MCAR S 1.663 A.4. Determination that the application is complete shall carry no implication with respect to the quality of the information nor shall it preclude the HSA or the commissioner from requesting additional clarifying information during the review period.

4. The 60 day review period on the HSA level shall commence on the date that the HSA receives the notice from the commissioner that the application has been determined to be complete.

C. HSA hearing process and procedures for determining recommendations on certificate of need applications. No proposal may be reviewed nor may any recommendation on an application be made by an HSA in a manner which does not comply with the Act or these rules.

1. Upon determination by the commissioner that the application is complete, the HSA shall schedule the date, time and place of a public hearing at which a determination will be made as to whether to recommend issuance of a certificate of need.

2. Notice of the hearing shall be published in a legal newspaper as required in Minn. Stat. S 145.837, subd. 2(2). The notice shall contain a brief description of the project and the date, time and place of the hearing. A separate notification shall be mailed to all other affected persons, including at least the applicant, any contiguous HSA and all health care facilities located in the applicant's proposed service area. This separate notification shall contain information similar to that in the published notice, except that contiguous HSAs shall be requested to provide written comment prior to the public hearing or to appear at the public hearing to offer an opinion as to the need for the project and the factual basis for that opinion.

3. A hearing body shall conduct the public hearing. The chairman of the hearing body, or a member designated by the chairman, shall be the presiding officer and shall conduct the hearing and rule on all motions and on the admissibility of all evidence and testimony. The presiding officer shall designate a hearing secretary who shall tape record the proceedings and provide to the commissioner a verbatim transcript or a written summary of the hearing.

4. A majority of the members of the hearing body shall constitute a quorum. No hearing may be held ~~or~~, nor recommendation made ~~or~~ nor any other action be taken unless a quorum is present.

5. The hearing body, if other than the governing body of

the HSA, shall forward its recommendation, findings of fact, conclusions and all evidence to the governing body, which shall vote on the project as required in 7 MCAR S 1.663 C.7. The governing body shall not hear or receive evidence other than that forwarded by the committee unless it holds an additional hearing after first publishing a notice of hearing pursuant to the Act and 7 MCAR S 1.663 C.2.

6. All interested persons shall be given the opportunity to be heard, to be represented by counsel, to present any relevant oral or written evidence and to examine and cross-examine witnesses. The applicant and any person who testifies orally or otherwise submits evidence or testimony at the hearing shall be subject to questioning by any member of the hearing body. All relevant evidence shall be heard and considered, and the inadmissibility of such evidence in a court of law shall not be grounds for its exclusion. Evidence presented in the form of governmentally issued or sponsored planning documents, studies and guidelines, such as the State Health Plan and health systems plans, shall be ~~given substantial weight but shall not be considered conclusive~~ specifically considered. The hearing may be recessed to another day if the hearing body ~~find~~ finds that additional evidence or time is necessary. When the presiding officer determines that all available and relevant evidence has been heard, the hearing body shall then commence its deliberations.

7. The hearing body, if other than the governing body of the HSA, and the governing body, after receipt of a hearing body's recommendation and necessary deliberation, shall vote on the project as follows:

a. After a motion has been made with respect to the project, each member present and qualified to vote, including the chairman or presiding officer, shall vote, or abstain from voting, on the motion. The vote of each member, or the fact of his abstention, shall be recorded in the minutes of the hearing or meeting.

b. No member may vote on behalf of a member not

present.

c. A motion for approval of a project shall not pass unless a majority of the members voting, including abstentions, vote in favor of the motion. Failure to obtain a majority vote in favor of approval shall constitute the recommendation of denial.

d. An approval of the project with revisions may be recommended based upon findings of fact, conclusions and supporting evidence pursuant to 7 MCAR S 1.663 G.

(1) Within 30 days after the receipt of the HSA recommendation, the applicant shall notify the HSA and the commissioner by certified mail as to whether it accepts or rejects the revisions.

(2) If the applicant does not respond or rejects the revisions, the recommendation of the HSA to the commissioner shall remain as a recommendation for approval with revision including the findings of fact and conclusions which support revision of the application.

8. The recommendation of the HSA shall be forwarded to the commissioner and ~~SPA~~ the Department of Energy, Planning and Development in the format prescribed in 7 MCAR S 1.663 G.

9. If the applicant decides to withdraw from the review, it shall so inform the HSA and the commissioner in writing.

D. Consolidated review of life support transportation service projects. If a project subject to review under the Act is also subject to review under the process described in Minn. Stat. S 144.802 for the licensure of life support transportation services, a single consolidated review of the project may occur in conformance with Minn. Stat. SS 144.802 and 145.836 and the ~~recommended process described in attachment~~ commissioner will make available to anyone who requests it a recommended process for consolidated review. In order to facilitate consolidated review of such projects, the HSA shall, upon agreement of the applicant pursuant to Minn. Stat. S 145.837, subd. 3, extend its certificate of need review period from 60 to 90 days to coincide with the 90 day life support transportation service licensure

review period prescribed in Minn. Stat. S 144.802, subd. 3(d). Within that 90 day period, the HSA shall make both recommendations to the commissioner. If mutual agreement pursuant to Minn. Stat. S 145.837, subd. 3, cannot be reached, the HSA shall attempt to make both the licensure and certificate of need recommendations within the 60 day period. If the HSA finds that making both recommendations within the 60 day period is not possible, it shall make the certificate of need recommendation within the 60 day period and a separate licensure recommendation within 90 days, as ~~requested~~ required by Minn. Stat. S 144.802, subd. 3(d).

E. Review criteria. In reviewing a proposal, the HSA and the commissioner shall consider all evidence in the record and shall evaluate the evidence based upon the following factors, where applicable. In addition, these factors shall be specifically addressed in the findings of fact and conclusion required by 7 MCAR S 1.663 G.

1. Health plans and population needs.

a. The relationship of the project to, and the degree to which it is consistent with, the applicable HSP, AIP and State Health Plan.

b. The relationship of the project to, and the degree to which it is consistent with, the applicant's long range development plan.

c. The need for the project as determined by past, present and future utilization data with specific attention given to the following:

(1) Utilization rates of similar facilities within the facility's health service area for the most recent five years;

(2) Utilization rates of the existing facility or service for the most recent five years; and

(3) Five-year projected utilization rate for the proposed expanded facility or service.

d. The need for the project based upon the population requirements of the affected service area with specific

attention given to the following:

(1) The population required to support the project, examined by demographic categories such as age, sex and occupational status;

(2) Incidence and prevalence rates of diagnoses or conditions within the population related to the services proposed by the project;

(3) The contribution of the project in meeting the health needs of people who have traditionally experienced difficulties in obtaining equal access to health care, in particular low income persons, racial and ethnic minorities, women, handicapped persons and other groups identified as priorities in the HSP. If the project involves a reduction, elimination or relocation of a health service and the project is otherwise reviewable under the Act, consideration shall be given to the extent which the project will affect the ability of affected members of these above priority groups to obtain needed health care.

(4) The past performance of the applicant in meeting its obligations, if any, under the applicable federal regulations or state rules requiring provisions of uncompensated care, community service or access by minorities and handicapped persons to programs receiving federal financial assistance, including the existence of any substantiated civil rights access complaints against the applicant.

(5) The extent to which Medicare, Medicaid, and medically indigent patients are served by the applicant.

(6) The extent to which the applicant offers a range of methods by which a person may have access to its services, such as, outpatient services, admission by house physicians or admission by personal physicians in the community.

2. Alternative approaches and system-wide effects.

a. The availability and adequacy of other less costly or more effective health care facilities and services which may serve as alternatives or substitutes for the whole or any part of the project.

b. The relationship of the project to the existing health care system in the area, including the possible economies and improvements which may be derived from operation of joint, cooperative or shared health care resources. Specific consideration shall be given the following:

(1) The effect of the project on use, capacity, and supply of existing health care facilities and services.

(2) The possibility of increasing referrals to other health care providers to achieve higher utilization of existing resources.

(3) The degree to which the project facilitates the development of an integrated system of services among health care providers.

(4) The possibility of consolidating services with other health care providers.

(5) The existence of formal arrangements established between the applicant and other health care providers to provide similar or supporting services to that being proposed.

c. Preferred alternative uses of resources included in the application, including such resources as health care providers, management personnel and funds for both capital and operational needs, for the provision of other health services by the applicant, as identified by the applicable HSP, AIP and State Health Plan.

d. The effect of the project on the clinical needs of health professional training programs in the area, including access of such programs to the project.

e. The needs for and availability of services and facilities for osteopathic physicians and patients.

3. Price competition among similar services. Improvements or innovations in the financing and delivery of the proposed health services which foster price competition in a way that promotes quality assurance and cost effectiveness. Such consideration shall include:

a. The degree of participation by the applicant in consumer choice health plans ~~and programs~~, such as health

maintenance organizations and preferred medical provider programs, and other methods for offering health services based upon giving the purchaser choices in services and knowledge about the price and quality of such health services; and

b. The existence of ~~methods~~ procedures by which public information regarding ~~cost~~ price and quality of health services will be provided to potential consumers and payors.

4. Applicant and project attributes.

a. The availability of resources, including health manpower, management personnel, physical facilities and funds for capital and operating needs for the project.

b. The immediate and long-term financial feasibility of the project with specific analysis of the following:

(1) The comparison of the anticipated revenues with the anticipated expenses including an analysis of whether or not the estimated revenues and expenses appear accurate; and

(2) The impact of the project upon the immediate and long-term financial solvency of the facility.

c. The impact of the project on operational costs and patient charges with specific analysis of the following:

(1) The reasonableness of the proposed cost of the project compared to similar projects; and

(2) The reasonableness of proposed operating costs and impact on patient costs and charges compared with similar services in similar health care facilities.

d. The organizational and other relationship of the project to ancillary or support services including an analysis of the following:

(1) The availability of necessary ancillary or support services and arrangements made by the applicant for provision of those services;

(2) The development of multi-institutional arrangements for sharing support services.

e. The costs and methods of providing energy for the operation of the project including consideration of methods for conserving energy.

f. The quality of care as reflected in the most recent survey reports from the Minnesota Department of Health and other ~~generally accepted survey organizations~~ quality assurance programs recognized in federal or state laws, such as the accreditation program of the Joint Commission on Accreditation of Hospitals.

5. Special ~~considerations~~ needs and circumstances. ~~The review criteria specified above shall be considered in light of the special needs and circumstances of any applicant meeting at least one of the descriptions listed in this section as it relates to the project.~~

a. The special needs and circumstances of medical teaching, research facilities and referral facilities which provide a substantial portion of their services or resources, or both, to individuals outside of the health service area. Consideration shall also be given as to whether:

(1) The instruction, studies or consultation provided by the applicant is coordinated with other medical teaching, research facilities and referral facilities in the multi-health service area served by the applicant; and

(2) The project contributes to meeting the health service needs of the residents of the health service area.

b. The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need for which local conditions offer special advantages.

c. The special needs of hospitals to convert excess beds to long-term care or other alternative functions, but only where the termination of all acute care services is proposed and only if a need for the number of proposed long-term care beds can be shown to be consistent with the HSP.

F. Revisions.

1. A project may be revised by the applicant, the HSA or the commissioner at any time during the review process if:

a. The revision is acceptable to the HSA and the applicant; and

b. The revision is within the scope of the project as initially proposed.

2. For purposes of the Act and these rules, a revision shall be considered to be within the scope of the project as initially proposed if the revision is clearly and closely related to the proposed construction or modification and does not directly involve health services, physical plant, equipment or other services unrelated to the project as initially proposed.

G. Content of record. After making its recommendation, the HSA shall submit to the commissioner three copies of the complete record, absent the application which is part of the record and previously submitted to the commissioner. It shall include at least the items listed in this rule and when forwarded to the commissioner shall be in the following order:

1. A cover letter which includes:

a. Pertinent dates relating to the review including, but not limited to, dates of submission of application, determination of completeness, meetings of project review committee, holding of the public hearing and recommended action by the HSA;

b. Description of the project;

(1) If the project voted upon by the HSA is the same as proposed in the application, a summary only shall be provided; or

(2) If prior to the vote of the HSA, the project has been revised upon agreement of the HSA and applicant, a detailed description as revised shall be provided.

c. Estimated capital cost of the project; and

d. The recommendation of the HSA limited solely to a statement whether or not a certificate of need should be issued, denied or issued with revisions. Any revision shall be stated.

2. Proof of publication of the notice of the public hearing;

3. A summary of evidence presented at the public hearing;

4. The recommendation of the HSA which shall contain the following parts:

a. Findings of fact which shall be based upon each applicable review criterion in 7 MCAR S 1.663 E.; provided, however, that for each project recommended for approval, written findings shall take into account the current accessibility of the facility as a whole and shall be based upon the criteria listed in 7 MCAR S 1.663 E.1.d.(1),(3),(4),(5) and (6);

b. Conclusions which shall be based on the findings of fact;

c. A recommendation which shall be based on conclusions; and

d. A record of the vote of each member of the HSA on all motions made with regard to the project.

5. Copies of all written evidence considered by the HSA as follows:

a. HSA staff reports and attachments;

b. Committee reports and attachments;

c. Any relevant correspondence between the HSA and the applicant;

d. All additional evidence submitted by the applicant, if not inserted into specific sections of the application; and

e. Any relevant evidence submitted by other affected persons including comments from contiguous HSAs.

H. Determination by commissioner.

1. The role of the commissioner in deciding whether or not a certificate of need should be issued is that of a final, independent decision maker. While the commissioner must base his review on the record presented by the HSA, his review is not merely in an appellate capacity and thus he is not required to adopt the HSA recommendation merely because it is supported by evidence in the record.

2. The commissioner shall review the application and the record presented by the HSA. The review shall include a determination as to whether the procedural requirements of the Act and these rules have been substantially met. The review by the commissioner may include other information not in the HSA record but only in order to assess the necessity of a remand to

the HSA for further consideration.

3. Within 30 days of receipt of the recommendation of the HSA, the commissioner shall make one of the following decisions based upon the record as considered in light of the review factors in 7 MCAR S 1.663 E.

a. Issue a certificate of need. If the commissioner's decision is consistent with the HSA recommendation, the commissioner may adopt the findings and conclusions of the HSA by reference.

b. Issue a ~~revised~~ certificate of need based upon a revised application.

(1) The commissioner may issue a decision ~~conditionally~~ approving ~~a project for~~ a certificate of need ~~provided that the HSA and applicant agree to specified revisions~~ based upon a revised application. Rationale shall be set forth for each revision proposed by the commissioner. ~~The decision shall also specify that the application shall be denied or remanded if the applicant or HSA reject the revisions.~~

(2) If the commissioner proposes a revision of the project, notice shall be mailed to the applicant and the HSA so informing them. Within 30 days after receipt, the applicant and the HSA shall inform the commissioner in writing as to whether or not they accept the revision.

(3) Upon the request of the HSA and the applicant, during the 30 days, the commissioner may amend his ~~final~~ decision by modifying the revisions as proposed ~~with the approval of the HSA and the applicant~~.

(4) The 30 day period in which reconsideration can be requested pursuant to Minn. Stat. S 145.838, subd. 2, or judicial review pursuant to Minn. Stat. SS 15.0424 and 145.838, subd. 3, shall commence to run after receipt by the commissioner of the written notice specifying whether or not the HSA and applicant accept the revisions ~~proposed by the commissioner~~, or if no notice is received, at the end of the 30 day period provided for in ~~section b~~ 7 MCAR S 1.663 H.3.b.(2).

(5) If the HSA and applicant accept the revision,

the commissioner shall issue a certificate of need and notify the HSA and SPA Department of Energy, Planning and Development.

(6) If the applicant or the HSA rejects the revision, the project shall be considered by the commissioner solely based upon the merits of the application and the record as proposed prior to the rejected revision, without prejudice due to rejection of the revision.

c. Deny a certificate of need. If a project is denied, the commissioner shall set forth in writing rationale for the action and notify the applicant, the HSA and the SPA Department of Energy, Planning and Development. If the commissioner's decision is consistent with the HSA recommendation, the commissioner may adopt the findings and conclusions of the HSA by reference.

d. Remand the application to the HSA.

(1) A remand may occur if, during the review of the HSA record, the commissioner finds that one or more of the following conditions exist and determines that a remand will materially aid in the decision-making process.

(a) Findings of fact were not supported by the record;

(b) Findings of fact were based on inaccurate information in the record;

(c) Significant issues relating to review criteria and other provisions of rules were not addressed by the HSA;

(d) Significant evidence within the record was not addressed by the HSA;

(e) Conclusions were not supported by findings of fact;

(f) Conclusions were based on inaccurate findings of fact;

(g) Significant conclusions were not drawn from findings of fact; ~~or~~

(h) The recommendation was not supported by the conclusions; or

(i) The existence of circumstances which arose under 7 MCAR SS 1.661 E.2. and 1.663 H.2.

(2) The commissioner shall provide the HSA and the applicant with written rationale for the remand action and instructions for further HSA review.

(3) Within 60 days of receipt of the remand, the HSA shall comply with the commissioner's instructions, hold another public hearing to review the project and forward a recommendation to the commissioner and the ~~SPA~~ Department of Energy, Planning and Development.

I. Determination by the commissioner: life support transportation service projects. For projects subject to review under the Act and also subject to review under the process described in Minn. Stat. S 144.802 for the licensure of life support transportation services, the commissioner shall make a certificate of need decision as provided in 7 MCAR S 1.663H.3. If the HSA submits a certificate of need recommendation and indicates that the life support transportation service licensure recommendation will be submitted separately, ~~and~~ the decision of the commissioner to issue a certificate of need in such a case shall not constitute a decision by the commissioner to issue a life support transportation service license.

7 MCAR S 1.664 Post determination actions.

A. Post determination appeals.

1. If the decision of the commissioner is consistent with the recommendation of the HSA, any person aggrieved by the decision may seek judicial review pursuant to Minn. Stat. S 145.838, subd. 3.

2. If the decision of the commissioner is contrary to the recommendation of the HSA, any person may, pursuant to Minn. Stat. S 145.838, subds. 2 and 3, either request the commissioner to reconsider his decision or seek judicial review.

a. A reconsideration request shall be submitted to the commissioner in writing within 30 days after receipt of the decision by either the HSA or the applicant. The request shall address the applicable condition specified in Minn. Stat. S

145.838, subd. 2(a) to (d). Within 30 days after receiving the reconsideration request, the commissioner shall determine whether to reconsider his decision.

b. If the commissioner determines his decision should be reconsidered, the matter shall be remanded to the HSA. The HSA shall conduct a new public hearing. The record of the second hearing shall include the record of ~~the~~ each previous hearing~~(s)~~ on the application. The HSA shall issue a new recommendation within 60 days of receipt of the remand from the commissioner.

c. If the commissioner determines that his decision should not be reconsidered, the HSA or the applicant may within 30 days request an administrative hearing pursuant to Minn. Stat. S 145.838, subd. 2.

3. Any aggrieved person may seek judicial review of the commissioner's decision rendered pursuant to Minn. Stat. S 145.838, subd. 1 or of the hearing examiner's decision rendered pursuant to Minn. Stat. S 145.838, subd. 2 by instituting an action pursuant to Minn. Stat. S 15.0424.

B. Amendment of certificate.

1. After a certificate of need has been issued and before completion of the project, an applicant may find it desirable or necessary to modify the approved project. The types of changes in or modifications to a project are described in 7 MCAR S 1.664 B.2., 3., and 4. When ~~more than one type of~~ a proposed change or modification ~~is proposed~~ falls into more than one of the types prescribed below ("immaterial," "minor," "significant"), the change shall be reviewed according to the ~~type of change~~ category which is most stringent. The effect of those changes on the issued certificate of need are as follows:

a. Changes and ~~modification~~ modifications which are immaterial in nature or result (see 7 MCAR S 1.664 B.2.) shall not require any additional certificate of need review.

b. Changes and modifications which are minor in nature or result (see 7 MCAR S 1.664 B.3.) shall not be made unless the commissioner, after review and recommendation by the HSA, issues

an amended certificate of need. The review conducted by the HSA and commissioner shall be limited to determining whether or not the changes or modifications are minor as defined in 7 MCAR S 1.664 B.3., that the changes or modifications fall within the scope of the project as initially approved for a certificate of need, and that the evidence supporting the certificate of need as initially issued supports the changes or modifications.

c. Changes and modifications which are significant in nature or results (see 7 MCAR S 1.664 B.4.) require the submission of a new application and require a full certificate of need review.

2. The following are immaterial changes:

a. Changes in spatial allocation or design;

b. Change in architectural plans to correct a facility's structural deficiencies or to comply with governmental rules or regulations;

c. An increase of less than 10% in the capital expenditure of the project, excluding inflation costs not projected at the time of application for a certificate of need; or

d. Other changes in project detail which will nevertheless result in the implementation of the project as approved.

3. The following are minor changes:

a. An increase of at least 10% but ~~not more~~ less than 20% of the capital expenditure of the project, excluding inflation costs not projected at the time of application for a certificate of need;

b. Deletions of portions of the originally approved project;

c. Change in financing mechanism which increases the cost of financing;

d. Change in the selection of health services equipment, if not technologically different from that approved in the certificate; or

e. Change in bed capacity of a facility in a manner

which increases the total number of beds, or distributes beds among various categories, by fewer than ten beds or ten percent of the licensed bed capacity, whichever is less.

4. The following are significant changes:

a. An increase equal to or in excess of 20% of the capital expenditure of the project, excluding inflation costs not projected at the time of application for a certificate of need;

b. Change in the type or scope of health service which was originally approved in the certificate;

c. Change in the selection of health services equipment, if technologically different from that approved in the certificate;

d. Change in the geographical location, if such change is relevant to the commissioner's reasons for approval of the certificate of need project; or

e. Change in bed capacity of a facility by more than ten beds or ten percent of the licensed bed capacity; or

f. Changes in the project which raise new material issues not previously considered by the HSA or commissioner related to:

(1) Guidelines, criteria or goals of comprehensive health planning in the applicable HSP, AIP or the State Health Plan;

(2) The quality of care as reflected in survey reports from the Department of Health and in other quality assurance programs recognized in federal and state laws;

(3) The proposed operating cost compared with similar services in similar health care facilities; or

(4) Unnecessary duplication of health care facilities and health services as reflected in governmentally issued or sponsored planning documents, studies or guidelines.

5. The applicant, prior to implementing any minor change in the project, shall submit a written request for an amended certificate to the HSA.

a. The request shall contain a narrative comparison of

the approved project and the proposed changes, a description of the cost implications and rationale for the proposed changes.

b. Within 30 days, the HSA shall review the request and forward all information submitted, a recommendation and rationale to the commissioner.

c. Within 30 days of receipt of the HSA recommendation, the commissioner shall review the applicant's request and the recommendation of the HSA and notify the applicant and the HSA in writing of the decision and reasons therefor.

6. The issuance of an amended certificate of need shall not result in the extension of the 18 month period which the applicant has to commence the project under the original certificate of need.

7. If a proposed amendment is not approved, the applicant shall either proceed under the certificate of need as initially issued or shall proceed through a full certificate of need review as a new applicant.

C. Expiration of certificate.

1. Notification of termination date. Pursuant to Minn. Stat. S 145.839, each certificate of need or waiver shall specify the termination date ~~pursuant to Minn. Stat. S 145.839~~.

2. Renewal of certificate or waiver.

a. If a project which had been granted a certificate of need or waiver has not commenced within 18 months, the applicant may submit information to the HSA and commissioner which updates the application and may request renewal of the certificate or waiver for a period up to 18 months.

b. Within 30 days of receipt of the request for renewal of the certificate of need or waiver, the HSA shall submit a recommendation to the commissioner as to whether the project or the reasons for approving the project have ~~changed~~ materially changed or been materially affected since the issuance of the certificate or waiver. If neither the project nor the reasons for approving the project have changed, renewal of the certificate ~~of~~ or waiver shall be recommended.

c. Within 30 days of receipt of the HSA recommendation regarding renewal, the commissioner shall determine whether renewal shall be granted based upon the HSA recommendation regarding renewal. Renewal may be granted for a period up to 18 months.

3. In the case of a construction project, the commissioner shall use all of the following criteria in determining whether the project has commenced:

a. Whether final working drawings and specifications have been approved by the Minnesota Department of Health;

b. Whether construction contracts have been let;

c. Whether a timely construction schedule has been developed stipulating dates for the beginning, various stages and completion of construction;

d. Whether all zoning and building permits have been secured;

e. Whether significant physical alteration of the site has been made and is continuing in accordance with the construction schedule; and

f. Whether other factors related to the above conditions exist.

4. In the case of a project solely involving the acquisition of equipment, the commissioner shall consider the following factors in determining whether the project has commenced:

a. Whether a final purchase order or lease arrangement for all component parts of the equipment has been executed; and

b. Whether the equipment has been delivered and installed or a firm delivery date has been set and a specific schedule has been established for commencing procedures.

5. In the case of offering of a service which does not require facility construction or equipment acquisition, the commissioner shall consider the following factors in determining whether the project has commenced:

a. Whether the new service has been introduced within the facility; and

b. Whether appropriate personnel, as set forth in the application, have been identified and an employment arrangement has been executed for commencing services on a specific schedule.

D. Transfer of certificate or waiver.

1. A certificate of need or waiver shall not be transferred independently of the project with which it is associated. A certificate of need or waiver and the associated project shall not be transferred without the prior approval of the commissioner. A transfer shall be approved by the commissioner if the information submitted pursuant to this section indicates that there will be no material changes in the project as originally approved in the certificate of need or waiver that has been issued.

2. An entity proposing to purchase or otherwise acquire the project and associated certificate of need or waiver shall apply for a transfer by submitting the following information to the HSA and the commissioner:

a. A statement that it agrees to be bound by all the terms and conditions of the certificate of need or waiver originally granted for the project;

b. The financial aspects portion of a certificate of need application or waiver request; and

c. A list of any changes or modifications it proposes to make in the project.

3. Within 30 days after receipt of this information, the HSA shall review the transfer request and shall submit its recommendation to the commissioner. Within 30 days after receipt of the recommendation, the commissioner shall inform the entity requesting the transfer, the HSA and the ~~SPA~~ Department of Energy, Planning and Development as to whether or not the transfer has been approved and the reasons for the decision.

E. Periodic report.

1. Within 60 days after completion of a project for which a certificate of need was issued or a waiver granted, the applicant shall submit actual capital expenditure information related to the project to the commissioner and the HSA. The

information submitted shall compare the estimated costs as outlined in the application with actual costs. A breakdown of costs, as specified in 7 MCAR S 1.663 A.4.b.(1)(a), shall be submitted.

2. If a discrepancy of more than 5% exists between estimated and actual costs in any of the reported line items or the total project cost, the applicant shall explain why the discrepancy occurred and indicate the additional impact on operating costs and patient charges resulting from the additional capital expenditures related to the project.

3. Completion of a project shall mean the earlier of the following:

a. The last payment for construction costs and other fees related to the project is made, not including debt service related to the project; or

b. The involved service is used for its intended purpose.

4. If the involved service is used for its intended purpose before the last related payment is made, an interim report shall be submitted utilizing actual and projected expenditures. In this case, the final report shall be submitted within 60 days after the last payment is made. Additional periodic reports may be required in connection with a revision to a project according to 7 MCAR S 1.663 F.

5. The requirements of this section shall apply to certificates of need and waivers issued or granted since August 1, 1979. If the project was completed prior to the effective date of these rules, the report shall be submitted within 60 days after the effective date of these rules.

~~F. Investigations. For the purposes of enforcement of the Act, the commissioner shall have access to all financial and other records of any entity subject to the Act.~~

7 MCAR S 1.665 Applications from health maintenance organizations.

A. An HMO shall be subject to certificate of need review, unless exempt under 7 MCAR S 1.665 C., if it proposes, or

undertakes on behalf of an inpatient health care facility, a project involving:

1. Any erection, building, alteration, reconstruction, modernization, improvement, extension, lease, equipment purchase or other acquisition related to inpatient institutional health services which requires, or would require if purchased, a total capital expenditure in excess of $150,000, and which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance;

2. The obligation of any capital expenditure related to a change in the bed capacity of a health care facility by more than ten beds or more than ten percent of the facility's total licensed bed capacity, whichever is less, over a two year period following the most recent bed capacity change, in a way which:

a. Increases or decreases the total number of beds;

b. Redistributes beds among various categories; or

c. Relocates beds from one physical facility or site to another.

3. The obligation of any capital expenditure which is associated with:

a. The addition of an institutional health service which was not offered within the previous twelve months; or

b. The termination of an institutional health service.

4. The addition of an institutional health service which was not offered during the twelve month period before the month in which the service would be offered, and which entails annual operating costs of at least $75,000; or

5. Acquisition of an existing health care facility if the institutional health services or bed capacity, according to 7 MCAR S 1.665 A.2., will be changed as a result of the acquisition.

B. The following entities may qualify for exemption from certificate of need review if the conditions of 7 MCAR S 1.665 C. are met.

1. An HMO;

2. A combination of HMOs;

3. A health care facility which primarily serves inpatients if it is:

a. Owned, or proposed to be owned, by an HMO ~~or HMOs~~; or

b. Governed by a controlling body which is composed of over fifty percent principal officers or board members of the HMO ~~or HMOs~~; or

4. A health care facility, or a portion of a health care facility, leased by an HMO ~~or HMOs~~ for a term of at least 15 years.

C. The conditions which must be met to qualify for exemption are:

1. The applicant shall be "qualified" under Title XIII of the Public Health Services Act, 42 ~~U.S.C.~~ S United States Code, Section 300e or the applicant shall satisfactorily document to the commissioner that the HMO ~~or HMOs have~~ has substantially fulfilled the requirements of Title XIII of the Public Health Services Act, 42 ~~U.S.C.~~ S United States Code, Section 300e.

2. At least 50,000 persons shall be enrolled in the pertinent HMO~~(s)~~ and shall have reasonable access to the proposed project; and

3. At least 75 percent of the potential patients shall be enrolled in the pertinent HMO~~(s)~~.

D. The following procedures shall be followed in applying for exemption of an HMO project from certificate of need review.

1. An application for exemption shall be submitted to the commissioner, HSA and SPA Department of Energy, Planning and Development. The application shall describe the project for which an exemption is sought and shall contain information demonstrating that the HMO meets the conditions for exemption specified in 7 MCAR S 1.665 C.

2. The HSA or the commissioner, in order to make a recommendation or to make the final determination, may request additional clarifying information about the project. Any information requested shall be pertinent to the provisions of 7 MCAR S 1.665 B. and C. Failure to supply the information in a

timely manner shall constitute sufficient grounds for determining that the entity is not eligible for exemption.

3. Within 30 days after the receipt of the request, the HSA shall forward its recommendation and all evidence to the commissioner. Within 30 days of the receipt of the HSA recommendation, the commissioner shall notify the HMO and the HSA of the decision to grant or deny the exemption and the reason therefor. The commissioner shall approve an application for exemption if the applicable requirements of 7 MCAR S 1.665 B. and C. have been met or will be met on the date the proposed activity will be undertaken.

E. The project granted exempt status may not be sold or leased, a controlling interest in a project may not be acquired ~~and~~ or a health care facility described in 7 MCAR S 1.665 B.3. and 4. may not be used in a manner other than proposed in the project, unless:

~~a.~~ 1. The commissioner issues a certificate of need approving the sale, lease, acquisition, or use; or

~~b.~~ 2. Upon request, the commissioner grants exempt status to such entity.

F. 7 MCAR SS 1.661 through 1.664 shall apply to the review of a certificate of need application submitted by an entity listed in 7 MCAR S 1.665 B. for a non-exempt project. Notwithstanding the general review criteria in 7 MCAR S 1.663 E., if an entity listed in 7 MCAR S 1.665 B. applies for a certificate of need, the commissioner shall approve the project if he finds that:

1. Approval of the project is required to meet the needs of the members of the HMO and of the reasonably anticipated new members of the HMO; and

2. The HMO is unable to provide, through services or facilities which can reasonably be expected to be available to the HMO, its health services in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO and which makes these services available through physicians and other health professionals associated with it.

In assessing the availability of these services from other providers, the HSA and commissioner shall consider only whether the services from these providers:

a. Would be available under a contract of at least five years duration;

b. Would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

c. Would cost no more to the HMO than if the services were provided by the HMO; and

d. Would be available in a manner which is administratively feasible to the HMO applicant.

G. Any party aggrieved by a decision of the commissioner pursuant to 7 MCAR S 1.665 D. may seek judicial review of the commissioner's decision by instituting action pursuant to Minn. Stat. S 15.0424.

[Repealer clause. State Planning Agency rules 10 MCAR SS ~~1.202~~ 1.201 to 1.210 (formerly SPA 201 to 210) are hereby ~~repeal~~ repealed.]

~~* The reader is advised to refer to the definition of "construction or modification" pursuant to 7 MCAR S 1.661 B.7.~~

~~* Minn. Stat. S 145.835, subd. 4. Waivers.~~
~~A proposed construction or modification may be granted a waiver from the requirements of section 145.834 by the commissioner of health if, based on the recommendation of the health systems agency, the commissioner determines that: (a) The proposed capital expenditure is less than three percent of the annual operating budget of the facility applying for a waiver, and the expenditure is required solely to meet mandatory federal or state requirements of the law; or (b) The construction or modification is not related to direct patient care services such as parking lots, sprinkler systems, heating or air conditioning equipment, fire doors, food services equipment, building maintenance, or other constructions or modifications of a like nature.~~

** Minn. Stat. S 145.833, subd. 5(a)(2).

Subd. 5 "Construction or modification" means:

(a) Any erection, building, alteration, reconstruction, modernization, improvement, extension, lease or other acquisition, or other purchase, lease or other acquisition of diagnostic or therapeutic equipment, by or on behalf of a health care facility which:

(2) Changes the bed capacity of a health care facility in a manner which increases the total number of beds, or distributes beds among various categories, or relocates beds from one physical facility or site to another, by more than ten beds or more than ten percent of the licensed bed capacity, whichever is less, over a two year period.

ATTACHMENT

RECOMMENDED PROCEDURE FOR HSA CONSOLIDATED REVIEW

OF

LIFE SUPPORT TRANSPORTATION SERVICE PROJECTS

Relevant Provisions of Certificate of Need Act and Rules

Minn. Stat. S 145.836 APPLICATION FOR CERTIFICATE OF NEED. Subdivision 1. Application procedure. Applications for certificate of need shall be submitted to the health systems agency serving the area in which the proposed construction or modification is to take place. Prior to acting on the application and within ten days of receipt, the health systems agency shall send a copy to the commissioner of health and to the state planning agency with a recommendation that the application be considered either complete or incomplete. The commissioner of health shall determine that the application is initially complete or incomplete within ten days of receipt of a recommendation from a health systems agency. If the application is incomplete, it is not to be considered to be submitted to the health systems agency or the commissioner and it shall be returned stating the specific needs to be met in order for the application to be considered complete.

7 MCAR S 1.663 B. Determination of completeness.

1. Within ten days of the receipt of an application the HSA shall review the application's contents and forward a recommendation to the commissioner and SPA as to whether it is complete. If the recommendation states that the application is incomplete, the HSA shall identify the sections which it found to be incomplete, and explain why it concluded that they were incomplete. A determination of incompleteness may occur under the following conditions:

a. The items specified in 7 MCAR S 1.663 A.4 have not been fully addressed or the information needs clarification.

b. The information provided raises additional questions which must be answered in order for the HSA and commissioner to perform their review under the Act and these

rules.

2. Within ten days of receipt of the recommendation from the HSA, the commissioner, after reviewing the application in conjunction with the HSA recommendation and comments, shall notify the applicant, HSA and SPA in writing as to whether the application is complete. If the application is declared incomplete, the applicant shall be informed what additional information must be submitted.

a. If the applicant submits the required additional information to the HSA, SPA and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the application may be found to be complete without being deferred to another cycle of reviews.

b. If the required information is submitted after five working days, but within 60 days of receipt of the commissioner's determination, the complete review will be made according to the schedule specified pursuant to 7 MCAR S 1.663 A.1. The result of this clause is that the application is considered for completeness in the next cycle of the commissioner's completeness determination process.

c. If an applicant has not fully responded to a request for additional information within 60 days of the request, the incomplete application shall be returned to the applicant.

3. A determination that an application is complete shall mean only that information has been given pertaining to each component part of the application as prescribed in 7 MCAR S 1.663 A.4. Determination that the application is complete shall carry no implication with respect to the quality of the information nor shall it preclude the HSA or the commissioner from requesting additional clarifying information during the review period.

4. The 60 day review period on the HSA level shall commence on the date that the HSA receives the notice from the commissioner that the application has been determined to be complete.

Minn. Stat. S 145.837, Subd. 2. Review procedures. In reviewing complete applications, the health systems agency shall:

(1) Hold a public hearing,

(2) Provide notice of the public hearing by publication in a legal newspaper of general circulation in the area for two successive weeks at least ten days before the date of such hearing and notify affected persons which shall include at least the applicant and other persons subject to review, contiguous health systems agencies, the health care facilities located in the health service area and which provide institutional health services, and the rate review agency,

(3) Allow any interested person the opportunity to be heard, to be represented by counsel, to present oral and written evidence, and to confront and cross-examine opposing witnesses at the public hearing,

(4) Provide a transcript of the hearing at the expense of any individual requesting it, if the transcript is requested at least three days prior to the hearing,

(5) Make written findings of fact and recommendations concerning the application. The commissioner of health shall promulgate by rule the required findings of fact which shall address the criteria specified in subdivision 1, and the provisions of the National Health Planning and Resources Development Act, 42 U.S.C., Section 300k, et seq. The findings of fact and recommendations shall be available to any individual requesting them, and

(6) Follow any further procedure not inconsistent with sections 145.832 to 145.845 or sections 15.0411 to 15.052, which it deems appropriate.

Within 60 days after the commissioner has determined the application to be complete, the health systems agency shall make its recommendation to the commissioner of health. The health

systems agency shall either recommend that the commissioner of health issue, deny or issue with revisions a certificate of need for the proposed construction or modification. The reasons for the recommendation shall be set forth in detail.

7 MCAR § 1.663 C. HSA hearing process and procedures for determining recommendations on certificate of need applications.

No proposal may be reviewed nor may any recommendation on an application be made by an HSA in a manner which does not comply with the Act or these rules.

1. Upon determination by the commissioner that the application is complete, the HSA shall schedule the date, time and place of a public hearing at which a determination will be made as to whether to recommend issuance of a certificate of need.

2. Notice of the hearing shall be published in a legal newspaper as required in Minn. Stat. § 145.837, subd. 2(2). The notice shall contain a brief description of the project and the date, time, and place of the hearing. A separate notification shall be mailed to all other affected persons, including at least the applicant, any contiguous HSA and all health care facilities located in the applicant's proposed service area. This separate notification shall contain information similar to that in the published notice, except that contiguous HSAs shall be requested to provide written comment prior to the public hearing or to appear at the public hearing to offer an opinion as to the need for the project and the factual basis for that opinion.

3. A hearing body shall conduct the public hearing. The chairman of the hearing body, or a member designated by the chairman, shall be the presiding officer and shall conduct the hearing and rule on all motions and on the admissibility of all evidence and testimony. The presiding officer shall designate a hearing secretary who shall tape record the proceedings and provide to the commissioner a verbatim transcript or a written summary of the hearing.

4. A majority of the members of the hearing body shall

constitute a quorum. No hearing may be held or recommendation made or other action taken unless a quorum is present.

5. The hearing body, if other than the governing body of the HSA, shall forward its recommendation, findings of fact, conclusions and all evidence to the governing body, which shall vote on the project as required in 7 MCAR S 1.663 C.7. The governing body shall not hear or receive evidence other than that forwarded by the committee unless it holds an additional hearing after first publishing a notice of hearing pursuant to the Act and 7 MCAR S 1.663 C.2.

6. All interested persons shall be given the opportunity to be heard, to be represented by counsel, to present any relevant oral or written evidence, and to examine and cross-examine witnesses. The applicant and any person who testifies orally or otherwise submits evidence or testimony at the hearing shall be subject to questioning by any member of the hearing body. All relevant evidence shall be heard and considered, and the inadmissibility of such evidence in a court of law shall not be grounds for its exclusion. The hearing may be recessed to another day if the hearing body finds that additional evidence or time is necessary. When the presiding officer determines that all available and relevant evidence has been heard, the hearing body shall then commence its deliberations.

7. The hearing body, if other than the governing body of the HSA, and the governing body, after receipt of a hearing body's recommendation and necessary deliberation, shall vote on the project as follows:

a. After a motion has been made with respect to the project, each member present and qualified to vote, including the chairman or presiding officer, shall vote, or abstain

(1) Within 30 days after receipt of the HSA recommendation, the applicant shall notify the HSA and the commissioner by certified mail as to whether it accepts or rejects the revisions.

(2) If the applicant does not respond or rejects the

revisions, the recommendation of the HSA to the commissioner shall remain as a recommendation for approval with revision including the findings of fact and conclusions which support revision of the application.

8. The recommendation of the HSA shall be forwarded to the commissioner and SPA in the format prescribed in 7 MCAR S 1.663 G.

9. If the applicant decides to withdraw from the review, it shall so inform the HSA and the commissioner in writing.

Relevant Provisions of Life Support Transportation Service Law (Minn. Stat. SS 144.801-144.8091)

Minn. Stat. S 144.802 LICENSING

Subd. 3. (a) Each prospective licensee and each present licensee wishing to offer a new type or types of life support transportation service, to establish a new base of operation, or to expand a primary service area, shall make written application for a license to the commissioner on a form provided by the commissioner. The commissioner shall promptly send notice of the completed application to the health systems agency or agencies, the community health service agency or agencies, and each municipality and county in the area in which life support transportation service would be provided by the applicant. The commissioner shall publish the notice, at the applicant's expense, in the state register and in a newspaper in the municipality in which the service would be provided, or if no newspaper is published in the municipality or if the service would be provided in more than one municipality, in a newspaper published at the county-seat of the county or counties in which the service would be provided.

(b) Each municipality, county, community health service, and other person wishing to make recommendations concerning the disposition of the application shall make written recommendations to the health systems agency in its area within 30 days of the publication of notice of the application.

(c) The health systems agency or agencies shall:

(1) hold a public hearing in the municipality in which the services base of operation is or will be located;

(2) provide notice of the public hearing in the newspaper or newspapers in which notice was published under part (a) for two successive weeks at least ten days before the date of the hearing;

(3) allow any interested person the opportunity to be heard, to be represented by counsel, and to present oral and written evidence at the public hearing;

(4) provide a transcript of the hearing at the expense of any individual requesting it; and

(5) follow any further procedure not inconsistent with chapter 15, which it deems appropriate.

(d) The health systems agency or agencies shall review and comment upon the application and shall make written recommendations as to its disposition to the commissioner within 90 days of receiving notice of the application. In making the recommendations, the health systems agency or agencies shall consider and make written comments as to whether the proposed service, change in base of operations, or expansion in primary service area is needed, based on consideration of the following factors:

(1) the relationship of the proposed service, change in base of operations or expansion in primary service area to current health systems and annual implementation plans;

(2) the recommendations or comments of the governing bodies of the counties and municipalities in which the service would be provided;

(3) the duplication, if any, of life support transportation services that would result from granting the license;

(4) the estimated effect of the proposed service, change in base of operation of expansion in primary service area on the public health;

(5) whether any benefit accruing to the public health would outweigh the costs associated with the proposed service;

change in base of operations, or expansion in primary service area.

The health systems agency or agencies shall recommend that the commissioner either grant or deny a license or recommend that a modified license be granted. The reasons for the recommendation shall be set forth in detail. The health systems agency or agencies shall make the recommendations and reasons available to any individual requesting them.

Recommended Procedure for Consolidated HSA Review (Includes All the Requirements of Both Statutes and Assumes Certificate of Need Review Period Has Been Extended to 90 Days Pursuant to 7 MCAR § 1.663 D.

A. Submission of applications and determinations of completeness

The applicant shall submit a completed licensure application to the commissioner and should also submit a copy to the appropriate HSA. Simultaneously, the applicant should submit a completed certificate of need application to the appropriate HSA.

1. Within ten days of the receipt of the certificate of need application, the HSA shall review the application's contents and forward a recommendation to the commissioner and SPA as to whether it is complete. If the recommendation states that the application is incomplete, the HSA shall identify the sections which it found to be incomplete, and explain why it concluded that they were incomplete. A determination of incompleteness may occur under the following conditions:

a. The items specified in 7 MCAR § 1.663 A.4 have not been fully addressed or the information needs clarification.

b. The information provided raises additional questions which must be answered in order for the HSA and commissioner to perform their review under the Act and these rules.

2. Within ten days of receipt of the recommendation from the HSA, the commissioner, after reviewing the certificate of

need application in conjunction with the HSA recommendation and comments, shall notify the applicant, HSA, and SPA in writing as to whether both the licensure and the certificate of need applications are complete. If either application is declared incomplete, the applicant shall be informed what additional information must be submitted.

a. If the applicant submits the required additional certificate of need information to the HSA, SPA and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the certificate of need application may be found to be complete without being deferred to another cycle of reviews.

b. If the required certificate of need information is submitted after five working days, but within 60 days of receipt of the commissioner's determination, the complete review will be made according to the schedule specified pursuant to 7 MCAR § 1.663 A.1. The result of this clause is that the certificate of need application is considered for completeness in the next cycle of the commissioner's completeness determination process.

c. If an applicant has not fully responded to a request for additional certificate of need information within 60 days of the request, the incomplete certificate of need application shall be returned to the applicant.

d. The applicant should submit any additional information requested to complete the licensure application within the time frames specified in 2 a.-c. so as to assume a consolidated HSA hearing and consolidated determination by the commissioner.

3. If both applications are determined to be complete, the commissioner shall promptly send notice of the completed applications to the HSA(s), community health service agency or agencies, and each municipality and county in the area in which the life support transportation service would be provided by the

applicant. The commissioner shall publish this notice, at the applicant's expense, in the State Register, and in a legal newspaper of general circulation in the municipality in which the service would be provided. If no legal newspaper of general circulation is published in the municipality, or if the service would be provided in more than one municipality, the notice shall be published in a legal newspaper of general circulation published at the county seat of the county or counties in which the service would be provided.

4. A determination that a certificate of need application is complete shall mean only that information has been given pertaining to each component part of the application as prescribed in 7 MCAR S 1.663 A.4. Determination that the application is complete shall carry no implication with respect to the quality of the information nor shall it preclude the HSA or the commissioner from requesting additional clarifying information during the review period.

5. The 90 day review period on the HSA level shall commence on the date that the HSA receives the notice from the commissioner that the applications have been determined to be complete.

B. Any municipality, county, community health service agency, or other person wishing to make recommendations concerning the dispositions of the applications shall make recommendations to the HSA within 30 days of the publication of notice of the applications pursuant to A.3.

C. HSA hearing process and procedures for determining recommendations on consolidated review of certificate of need and life support transportation service licensure applications.

1. Upon determination by the commissioner that the applications are complete, the HSA shall schedule the date and time of a public hearing at which a determination will be made as to whether to recommend issuance of a certificate of need and licensure of a life support transportation service. The hearing shall be scheduled to be held in the municipality in which the service's base of operations is or will be located.

2. Notice of the hearing shall be published in the legal newspaper(s) in which notice of the applications was published pursuant to A.3. The notice shall contain a brief description of the project and the date, time and place of the hearing. A separate notification shall be mailed to all other affected persons, including at least the applicant, any contiguous HSA, and all health care facilities located in the applicant's proposed service area. This separate notification shall contain information similar to that in the published notice, except that contiguous HSAs shall be requested to provide written comment prior to the public hearing or to appear at the public hearing to offer an opinion as to the need for the project and the factual basis for that opinion.

3. A hearing body shall conduct the public hearing. The chairman of the hearing body, or a member designated by the chairman, shall be the presiding officer and shall conduct the hearing and rule on all motions and on the admissibility of all evidence and testimony. The presiding officer shall designate a hearing secretary who shall tape record the proceedings and provide to the commissioner a verbatim transcript or a written summary of the hearing. A majority of the members of the hearing body shall constitute a quorum. No hearing may be held or recommendation made or other action taken unless a quorum is present.

The hearing body, if other than the governing body of the HSA, shall forward its recommendation, findings of fact, conclusions and all evidence to the governing body, which shall vote on the project as required in 7 MCAR S 1.663 C.7. The governing body shall not hear or receive evidence other than that forwarded by the committee unless it holds an additional hearing after first publishing a notice of hearing pursuant to the Act and 7 MCAR S 1.663 C.2.

6. All interested persons shall be given the opportunity to be heard, to be represented by counsel, to present any relevant oral or written evidence, and to examine and cross-examine witnesses. The applicant and any person who

testifies orally or otherwise submits evidence or testimony at the hearing shall be subject to questioning by any member of the hearing body. All relevant evidence shall be heard and considered, and the inadmissibility of such evidence in a court of law shall not be grounds for its exclusion. The hearing may be recessed to another day if the hearing body finds that additional evidence or time is necessary. When the presiding officer determines that all available and relevant evidence has been heard, the hearing body shall then commence its deliberations.

7. The hearing body, if other than the governing body of the HSA, and the governing body, after receipt of a hearing body's recommendation and necessary deliberation, shall vote on the project as follows:

a. After a motion has been made with respect to the project, each member present and qualified to vote, including the chairman or presiding officer, shall vote, or abstain from voting, on the motion. The vote of each member, or the fact of his abstention, shall be recorded in the minutes of the hearing or meeting.

b. No member may vote on behalf of a member not present.

c. A motion for approval of a project shall not pass unless a majority of the members voting, including abstentions, vote in favor of the motion. Failure to obtain a majority vote in favor of approval shall constitute the recommendation of denial.

d. An approval of the certificate of need project with revisions may be recommended based upon findings of fact, conclusions and supporting evidence pursuant to 7 MCAR S 1.663 G.

(1) Within 30 days after receipt of the HSA recommendation, the applicant shall notify the HSA and the commissioner by certified mail as to whether it accepts or rejects the revisions.

(2) If the applicant does not respond or rejects the revisions, the recommendation of the HSA to the commissioner and

shall remain as a recommendation for approval with revision including the findings of fact and conclusions which support revision of the application.

8. The certificate of need recommendation of the HSA shall be forwarded to the commissioner and SPA in the format prescribed in 7 MCAR S 1.663 G.

9. The licensure recommendation of the HSA shall be to issue, deny or issue with modifications a life support transportation service license. The licensure recommendation shall contain the HSA's written and detailed comments as to whether the proposed service, change in base of operations, or expansion in primary service area is needed, based on consideration of the factors specified in Minn. Stat. S 144.804, subd. 3(d).

10. If the applicant decides to withdraw from the review, it shall so inform the HSA and the commissioner in writing.

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
1981
Secretary of State

APPROVED AS TO LEGALITY

Dec. 21 1981

WARREN SPANNAUS, ATTORNEY GENERAL

BY Ted A. Montano

SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
DEC 21 1981
Joan Anderson Growe
Secretary of State
3:01 p.m.

SF-00006-02

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL

Office Memorandum

TO : GEORGE R. PETTERSEN, M.D.
Commissioner, Dept. of Health
ATTENTION: Mr. Richard Wexler
Assistant Attorney General

DATE: 12/21/81

FROM : JUDITH V. WEHRWEIN
Legal Assistant
530 State Office Building

PHONE: 297-3471

SUBJECT: 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

Enclosed herewith are the rules you have submitted for approval. These rules have been approved by this office and filed with the Secretary of State. Please note that they have not been filed with the State Register. This must be done promptly by your agency.

Upon receipt and before transmittal to your agency, however, it is important that you recheck these rules as to:

1. Affixation of stamps of the Attorney General and Secretary of State to the last page of the rules;

2. Coverage by these stamps of all rules submitted; and

3. Inclusion of all pages to the rules in the approved set.

If you have any questions in this regard, please contact me.

Encs.

cc: Ms. Kathy Burek
Mr. Duane Harves

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

SUPPLEMENTAL FINDINGS, CONCLUSIONS, AND ORDER ADOPTING RULES

WHEREAS, on December 10, 1981, the Attorney General disapproved the above-captioned rules because he found 7 MCAR § 1.662 C.2.b. in conflict with Minn. Stat. § 145.835, subd. 3 (1980);

WHEREAS, the Commissioner has opted under Minn. Stat. § 15.0412, subd. 4e (Supp. 1981) to modify 7 MCAR § 1.662 C.2.b. to cure the illegality;

WHEREAS, upon consideration of the written comments of the Attorney General's office dated December 10, 1981, and based upon the entire record, files, and proceedings herein and applicable statutory standards and criteria, and confirming the need for and reasonableness of the above-captioned rules, the Commissioner makes and enters the following:

SUPPLEMENTAL FINDINGS OF FACT

1. The Attorney General, pursuant to Minn. Stat. § 15.0412, subd. 4.e. (Supp. 1981) disapproved 7 MCAR § 1.662 C.2.b. based upon his finding that it would, in effect, result in the Commissioner making a decision as to circumvention in a period greater than 60 days which would be contrary to the language of Minn. Stat. § 145.835, subd. 3 (1980). The Attorney General also stated that "the rules must be re-written to allow only for a 60-day determination period. Any period for review as to completeness must be accomplished within this time frame." Memorandum from Ted A. Martinez to George R. Pettersen, M.D. (December 10, 1981).

2. The rule, 7 MCAR § 1.662 C.2.b. has been amended to comply with the instructions of the Attorney General. It now reads:

> b. The 60 day period in which the commissioner must decide whether the proposed acquisition is designed to circumvent the Act shall ~~not~~ commence to run ~~until the commissioner determines that the notice is complete~~. upon receipt of the notice, or, if the Commissioner determines that the notice is incomplete pursuant to 7 MCAR § 1.662 C.2.a., upon receipt of the additional information required to complete the notice.

(Words deleted from rule as first adopted are indicated by ~~strikeout~~; new language is indicated by underline.)

3. The rule as re-written specifically states that the 60-day review period begins to run upon receipt of the notice. When this is read in connection with 7 MCAR § 1.662 c.2., it is clear that the Commissioner will include the 20 days in which to determine whether or not a notice is complete within the 60-day total review period.

4. The rule as amended also addresses the situation when the Commissioner determines that the notice is incomplete. The practical effect of such a determination is to find that no notice had been received and that the 60-day review period had not begun to run. Thus, the 60-day period does not continue to run while the requester is compiling the additional information necessary to complete the notice. However, upon receipt of the additional information, the 60-day review period begins to run if the supplemental data completes the notice. As with the original notice, the Commissioner has 20 days to determine whether the newly submitted information, when combined with the data in the originally submitted but incomplete notice, is sufficient to constitute a complete notice. This 20-day period shall be included within the total 60-day review period.

5. The Minnesota Medical Association objected to the 20-day period for determining completeness of the notice being in addition to the 60-day review period with respect to circumvention. Letter from William J. Keppel to Ted Martinez at pp. 3 and 4 (Dec. 4, 1981). However, the Minnesota Medical Association admitted that "if the required notice is incomplete the 60 day review period would not begin to run." Keppel letter at p. 4. Thus, the amended 7 MCAR § 1.662 C.2.b. is also consistent with the position of the Minnesota Medical Association.

Based upon the foregoing Supplemental Findings of Fact, the Commissioner makes the following:

SUPPLEMENTAL CONCLUSIONS

1. The amended rule, 7 MCAR § 1.662 C.2.b., complies with the instructions of the Attorney General for correcting the defect in the rule.

2. The amended rule is consistent with Minn. Stat. § 145.835, subd. 3 (1980).

3. Authority to adopt 7 MCAR § 1.662 C.2.b., as amended, is contained in Minn. Stat. § 145.834 (Supp. 1981) which directs the Commissioner to adopt rules "necessary to implement, enforce and administer" the Certificate of Need Act. Because a notice must contain certain information, it is necessary to specify exactly how determinations of completeness will be made, the time frames within which the decisions will be made, and the effect of the decisions on the 60-day review period with respect to circumvention. These provisions inform requesters as to how the Commissioner will administer Minn. Stat. § 145.835, subd. 3 (1980), are reasonable, and are supported by the record.

4. Amended 7 MCAR § 1.662 C.2.b. is not in any way substantially different from the rules as proposed and initially adopted within the meaning of Minn. Stat. § 15.0412, subd. 4.e. (Supp. 1981) and 9 MCAR § 2.111. The review period for completeness remains 20 days. The only difference is that it is folded into rather than in addition to the 60-day period for review as to circumvention. The amendment is simply an outgrowth of the comments received and made part of the record of the rulemaking processs.

SUPPLEMENTAL ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED:

1. That the amendment to 7 MCAR § 1.662 C.2.b. as contained in Finding 2 herein is adopted this 18 day of December, 1981, pursuant to the authority vested in me by the Minnesota Certificate of Need Act.

2. That these Findings, Conclusions, and Order are merely a supplement to and in addition to the Findings, Conclusions, and Order Adopting Rules executed on November 6, 1981, relating to the above-captioned rules and that the November 6 Findings, Conclusions, and Order Adopting Rules are to be read together with this Supplemental Findings, Conclusions, and Order Adopting Rules as if they were a single document.

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

for GEORGE R. PETTERSEN, M.D. DEPUTY COMMISSIONER
Commissioner of Health

HLTH-81-020-JL

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HEALTH

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

ORDER OF THE CHIEF HEARING EXAMINER

WHEREAS, a hearing was held on June 9, 1981, before Jon L. Lunde, a Hearing Examiner of the State Office of Administrative Hearings, on the above-entitled matter in compliance with Minn. Stat. § 15.0412, subd. 4; and

WHEREAS, the Report of Hearing Examiner made pursuant to Minn. Stat. § 15.052, subd. 3, was issued to the Department of Health; and

WHEREAS, the Department of Health adopted the rules and submitted them to the Chief Hearing Examiner who found by Order dated November 18, 1981, that the rules were not substantially different from those proposed at the public hearing and that the Department of Health had cured the defects in the rules as required; and

WHEREAS, the Department of Health submitted the rules to the Attorney General for review pursuant to Minn. Stat. § 15.0412, subd. 4(e) (Supp. 1981), which rules were disapproved on December 10, 1981, because of a defect found in 7 MCAR § 1.662 C.2.b; and

WHEREAS, the Department of Health has modified 7 MCAR § 1.662 C.2.b to correct the defect and is resubmitting the rules to the Chief Hearing Examiner for review pursuant to Minn. Stat. §§ 15.0412, subd. 4e and 15.052, subd. 4, and 9 MCAR § 2.111; and

WHEREAS, the Chief Hearing Examiner finds that the modified rule, 7 MCAR § 1.662 C.2.b, is not substantially different from that proposed at the public hearing;

NOW, THEREFORE, upon receipt of this Order, the Department of Health has the responsibility of submitting the complete hearing record and the rules as adopted by the Department of Health to the Attorney General and to publish in the State Register, all pursuant to Minn. Stat. § 15.0412, subd. 4e and 4f.

Dated: December 18, 1981

DUANE R. HARVES
Chief Hearing Examiner

By: George A. Beck
GEORGE A. BECK
Hearing Examiner

MINNESOTA ASSOCIATION OF HEALTH CARE FACILITIES

THE BETTER LIFE THROUGH TOTAL CARE

SUITE 429, 2850 METRO DRIVE
MINNEAPOLIS, MINNESOTA 55420

TELEPHONE: 612/854-2844

December 3, 1981

Mr. Ted Martinez
Office of the Attorney General
530 State Office Building
435 Park Street
St. Paul, MN 55155

Re: 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.

Dear Mr. Martinez:

Below you will find a summary of the concerns of our Association concerning the form and legality of the proposed rule.

The duties of the Attorney General are spelled out in 1 MCAR §1.206D. The rule states that a rule shall be disproved if:

1. The Agency has failed to comply with the applicable provisions of the Administrative Procedures Act or other requirements governing the promulgation of rules.

2. The rule exceeds the statutory authority conferred or the specifically required conditions of the authorizing statute have not been met.

3. The rule conflicts with the governing statute or other relevant law.

4. The rule has no reasonable relationship to statutory purposes.

5. The rule is unconstitutional or unreasonable.

Based on these criteria MAHCF recommends that the rule be found inappropriate as stated below.

Procedural Comments

1. First, Department failed to notify interested parties of submission of the rule as required by M.S. 15.0412(4)(c). This section says "The agency

shall give notice to all persons who requested to be informed that the hearing record has been submitted to the Attorney General. This notice shall be given on the same day the record is submitted." The record in the present matter was submitted to your office November 20. As of November 30, no written notice had been received by MAHCF. Telephone inquiries from this office to the Department on November 19 and 20 yielded only the information that the rules had returned from the chief hearing examiner's office and would be going to the attorney general "soon." Because of this procedural defect, the proposed rule should be withdrawn.

The second statutory provision with which the Commissioner has not complied is Minn. Stat. 1980 §15.0412, Subd. 7, which provides

> "If the adoption of a rule by an agency will require the expenditure of public moneys by local public bodies, the notice of the proposed rule as required by this section shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local public bodies in the state to implement the rule for the two years immediately following adoption of the rule if the estimated total cost exceeds $100,000 in either of the two years. For purposes of this section, local public bodies shall mean officers and governing bodies of the political subdivisions of the state and other officers and bodies of less than state wide jurisdiction which have the authority to levy taxes."

As indicated above, several of the provisions of this rule will require "expenditures of public moneys by local public bodies", and it would seem likely that the total of these expenditures will exceed $100,000 in the first year. The additional number of reviews imposed on the Metropolitan Council, for example, by the rule requiring review of all purchases of existing health care facilities, might very well exceed the $100,000 figure all by itself.

The third statutory requirement which the Commissioner has not satisfied is Minn. Stat. 1980 §15.065, which states

> "Notwithstanding any other law to the contrary, the departments of health, public welfare, economic security, corrections and the health related boards shall not put into effect any rule, regulation, or standard, which has a fiscal impact in excess of $100,000 annually without first providing the house appropriations and the senate finance committees with fiscal notes."

Given the broad scope of the proposed rule and the new activities the Commissioner will undertake, there can be no doubt that this $100,000 (state funds) figure will be exceeded. There is nothing in the record to indicate that the Commissioner has prepared or delivered the required fiscal note.

The fourth provision is a new requirement contained in Laws 1981, Chapter 360, Section 14 (effective July 1, 1981). That section provides

> "For the biennium ending June 30, 1983, the commissioner of public welfare, the commissioner of economic security, the commissioner of corrections, the commissioner of health and the various health-related boards shall not promulgate nor implement any rules which will increase state expenditures by more than $50,000 during the biennium without the review by, and approval of the governor after consultation with the legislative advisory committee."

Again, given the new activities to be undertaken, there can be no doubt that this $50,000 figure will be exceeded. This section requires that the Governor specifically approve these rules after consulting with the legislative advisory committee. Without this review and approval the Commissioner may not adopt these rules.

Substantive Comments

7 MCAR § 1.661(B)(4) Definition of Capital Expenditure. The Department proposes that the proper interpretation of the language in this section requires a certificate of need prior to the purchase or sale of any existing health care facility by another health care facility. Currently, no such certificate is needed. Requiring a certificate of need prior to purchase of a health care facility by another health care facility is unconstitutional and unreasonable for the following reasons:

1. Denial of a certificate of need in such a CON hearing upon purchase/sale constitutes a taking of private property without just compensation. The fifth and fourteenth amendments of the US Constitution guarantees that no person shall "be deprived of life, liberty, or property without due process of law; nor shall private property be taken for public use without just compensation." Likewise, this guarantee of due process is repeated in Art. I., Sec. 7 of the Minnesota Constitution.

At minimum, the due process clause requires that deprivation of property be preceeded by notice and an opportunity for hearing appropriate to the case. See Contos v. Herbst, 278 N.W. 2d 732 (1979) and Mullane v. Central Hanover Trust Co., 339 US 306, 70 S.Ct. 654, 94 L.Ed. 865 (1950.) In the instant case, opportunity to be heard at a certificate of need hearing would not be an appropriate hearing because economic value to the owner of the property is not a criteria used in the CON process (See M.S. 145.837); the entire CON process is based on estimated need by the public for the service in an effort to control costs without consideration of the value of the business as a going concern.

A long term care facility has value only as a long term care facility. As such, failure to issue a certificate pursuant to the rule is a deprivation of virtually the only reasonable use of the property. Such a taking was found unconstitutional in Czech v. City of Blaine, 253 N.W. 2d 272 (1977.) There, a city's failure to re-zone a piece of property which could only reasonably be used as a mobile home park, was held an unconstitutional taking of property. Similarly here, such action would be an unconstitutional taking of property.

In addition, this policy will cause serious financial harm to many long term care providers. An owner who becomes disabled or who wishes to retire will be unable to do so if a certificate is not granted unless that owner is willing to simply give up his or her entire financial investment. In enacting such a policy, the state runs the risk of causing facility owners serious financial harm, for which those owners may rightfully seek compensation. There is the additional concern that forcing an owner to continue operation against his or her wishes or when he or she is no longer able to carry out his or her duties could cause a decline in the quality of care at that facility.

If a certificate of need is denied for purchase of an existing facility, a series of unanswered questions arises concerning consequences of noncompliance with ICF or SNF regulations. One who buys without a certificate of need will automatically be out of compliance with federal certification requirements, and will be immediately ineligible for Title XIX funds. If this occurs, the provider will be compelled to discontinue serving medicaid patients for whom no reimbursement is available. It would then become necessary to transfer these medicaid patients to other certified nursing home beds. Due to the CON limitations on the number of available beds, this re-location will be difficult to achieve.

If no nursing home beds are available, these residents will necessarily be placed in acute care facilities where the cost of care may quintuple. The net result is that certificate of need, which is designed to cut costs, may actually increase costs by five times or more. Thus, the rule also has no reasonable relationship to its statutory purpose, and cannot be adopted.

3. It is not clear if the Commissioner plans to limit the proposed construction of the phrase "or other acquisition" in any way. It is unclear whether a certificate of need is required in the following situations, and it ought to be made clear whether the rule applies in these situations. If it does, the rule is clearly unreasonable:

A. Involuntary transfers caused by the death of a facility owner. As we understand the Commissioner's interpretation, the rule would require a certificate for heirs or devisees to continue to operate an inherited facility.

It appears that heirs or devisees in this situation would be out of compliance with Title XIX requirements beginning the day after death. This would trigger the cycle of non-reimbursement and transfer of residents outlined in 2. above. This does not seem to be good public policy.

B. Voluntary transfer by gift. It is not clear whether a certificate of need is necessary in the case of transfer of ownership by gift. If a certificate is necessary, this would severely hamper estate planning for those who use gifts as an estate planning tool.

C. Incorporation of a sole proprietorship or partnership. Since ownership of assets would have to be transferred from the individual(s) to the corporation, this is technically an acquisition by the corporation. The Commissioner's rule and its interpretation potentially would require a certificate of need to effectuate a mere change in form of business.

D. Bankruptcy proceedings. Since bankruptcy proceedings require transfer of assets to the trustee in bankruptcy and then to the creditors, a certificate of need would be necessary before a petition in a bankruptcy is filed. Subsequent denial of the certificate would take away the security of collateral held by secured creditors.

This policy will severly affect the ability of long term care facilities to obtain financing from the investment community. Lenders will be unlikely to make secured loans if they fear they will lose their security. If long term care facilities are unable to obtain necessary capital for their operations, this policy will have serious adverse consequences in the community.

E. Publicly traded stock. In the case of a publicly held corporation, it is unclear whether a certificate of need would be required before stock could be traded on any exchange or over the counter. It appears that any single sale of stock for more than $150,000 would definitely require a certificate of need. In other cases, it is not clear when a certificate will be required. For example, it is unclear whether the term "other acquisition" includes relicensing procedures.

Consider the following hypothetical: Suppose Corporation 1 (consisting of Shareholders A,B,C, and D) owns a facility which is managed by Corporation 2 under a lease agreement. Corporation 2 is owned by Shareholders E and F. Corporation 1 is valued at $1,000,000. Shareholder A owns 5% of the stock; B owns 5%; C owns 15%, and D owns 80%. Corporation 2 is worth $450,000. E owns 10% of the stock, and F owns 90%.

1. A sells her 5% interest which is worth $50,000. B, in an unrelated transaction, later sells her 5% interest, also worth $50,000. There has now been 10% change of ownership valued at $100,000. Will a certificate of need be required? While the $150,000 certificate of need threshold is not met, MHD licensing procedures mandate inspection and relicensing upon a 10% change in ownership (MHD Rule 44(r)). Here the value of the stock sold is under the $150,000 certificate of need threshold, but the MHD licensing rule ostensibly triggers a relicensing. It is unclear what action will be necessary in these circumstances. If a certificate of need is necessary, who must apply? A, B, the new owner(s), or the corporation? When must application be made? On A's sale, or B's? What if a series of much smaller sales by many stockholders takes place? (For example, if A, B, C, and D each sold $40,000 worth of stock in unrelated transactions.) Who will monitor these transactions and mark the point at which the cumulative trading exceeds 10% or $150,000? Potentially A corporation whose stock is actively traded will be technically out of compliance with SNF and ICF regulations without knowing this has occurred. If a corporation's stock is actively traded, it will be impossible to know when the thresholds have been exceeded. A corporation may technically be out of compliance and have no way to prevent that non-compliance.

2. Now assume C sells his stock to X. Is this a change of ownership? The $150,000 minimum is surpassed, but no event has occurred which will affect costs, because costs are still governed by the lease with Corporation 2. Is a certificate of need required?

3. Next, suppose E sells her stock and then F sells his stock. Arguably no certificate of need is required because no transaction has occurred "on behalf of" a facility. However, when C sold her stock a certificate of need was required of C, because C was an existing owner of a facility, even though C is not involved in management of the facility.

Finally, to require certificate of need in light of current budget constraints is contrary to the new direction in federal certificate of need policy. Although federal law clearly authorizes states to require certificates of need upon sale, recent federal policy documents discourage such action. A Bureau of Health Planning Program Policy document issued in September, 1981 advised that certificate of need should be reserved only for high-cost, high priority capital expenditure reviews. Sale of an existing facility clearly is not such an expenditure.

In light of this extensive discussion, it is clear that this interpretation of the law is a denial of due process, is contrary to the intent of the authorizing statute, and bears no relationship to the CON statute. It is therefore unreasonable and should not be adopted.

7 MCAR 1.661(B)(17) Definition of "on behalf of"

The Department's interpretation here, as discussed above, is that the words "on behalf of" as applied, will require a buyer who already owns a facility to obtain a certificate of need, but will not require a buyer who does not already own a facility to have a certificate. For the reasons stated above, this will result in creation of two classes of persons: those who already own facilities and those who do not. This distinction is not rationally related to furtherance of any stated objective of the Act, and is a denial of equal protection because it divides nursing home owners into two classes when there is no reasonable basis to do so.

The 14th amendment of the United States Constitution mandates that no state shall deny equal protection of the law to its citizens. Clearly, the law requires that classifications be based on real and substantial differences bearing a fair relationship to the legislation. Members of a class may not be singled out special members of a class from which others in the same class are exempt. City of Duluth v. Northland Greyhound Lines 52 N.W.2d 774 (1952). However, in this case there is no reasonable basis on which to distinguish those who currently own facilities from those who do not. If anything, the "reasonable basis" test would turn the requirement around and require those who currently own facilities not to apply for a certificate and those who don't currently own facilities to request one.

Assuming arguendo that the Commissioner chooses to adopt this proposed definition, he should be advised that the opportunity exists currently for facilities to circumvent the rule by forming a new corporation which will become the purchaser of the existing facility. As long as this option exists, enforcement of this section will be nothing more than a sham which punishes those not familiar with the technicalities of the law. Accordingly, MAHCF reiterates its recommendation that this provision be deleted.

7 MCAR § 1.661(B)(5) Definition of Category

The department proposes to require a certificate of need for any recertification of beds between ICF and SNF certified beds. This policy puts an unnecessary and cumbersome burden on providers. While it may be appropriate for certificate of need to regulate the number of licensed nursing home beds, requiring certificate of need for certification changes makes the system unresponsive to the needs of the people it serves. Consider this scenario: utilization review determines that a current ICF resident should be in an SNF facility. If the provider applies for and is denied the certificate of need necessary for reclassification from ICF to SNF as required by utilization review, it will be necessary to relocate the resident to another facility bearing the appropriate certification. This may result in transer trauma and its concomitant effects. Obviously, this is not in the best interest of the beneficiary of the program, the resident.

This policy would be unnecessarily duplicative, and would discourage providers from ever downgrading SNF beds to ICF beds. This is ultimately

cost-ineffective and therefore contrary to the dictates of the Act.

7 MCAR § 1.662 (D)(7) Granting of Emergency Waivers

The rule, which gives the Commissioner discretion in granting emergency waivers in the wake of a disaster, would adversely affect both facilities and their residents. MAHCF feels the Commissioner should be required to grant certificate of need in these situations. If the certificate to repair or rebuild is not granted, the facilities, which are legally responsible for their residents, could incur legal liability for the care or lack of care of the residents while the certificate of need application is pending or after a certificate has been refused.

The failure of an HSA to issue a certificate of need to allow rebuilding after such a disaster may also cause the damaged facility to continue operation while out of compliance with other required codes with which it must comply, including all applicable building, safety, fire, and health codes.

Failure to comply would result in loss of Title XIX certification and reimbursement for care of residents who are entitled to that care. The net result in such a situation will be increased costs, because Title XIX recipients will be transferred to other facilities. If insufficient certified long term care beds are available, they will be placed in acute beds which will cost as much as five times what care would cost in a long term care facility.

The Hearing Examiner indicated that a facility waiver was similar to re-issuance of a nonconforming use permit because neither must be granted. The significant difference is that a business that is a nonconforming use, although it may not be rebuilt in its old location, may be rebuilt in another location where it will meet all zoning requirements. Certificate of need is an essentially different kind of process which deals not with whether this facility meets the requirements to be built in this specific location, but whether it should be built at all. Although use of the Department's power to grant or deny a license or waiver after a disaster is appropriate to ensure the safety of facility residents, use of the power is not appropriate to review the need for a facility. In many cases, cost of the certificate of need process and care for patients in an acute care facility will exceed the cost of repair.

MAHCF therefore recommends that in 7 MCAR 1.662 (D)(7) the word "may" be changed to "shall."

7 MCAR 1.663 (A)(4)(i) Number of Copies of Survey Reports to Be Submitted

Currently it is not clear how many survey reports must be submitted with the certificate of need application when a single entity controls more than

onc facility. MAHCF has sought clarification on this issue, and urges the Commissioner to adopt the view that survey reports be submitted only for the applicant facility for two reasons. First, there are several entities in Minnesota which operate as many as 20 long term care facilities. It is a great burden and unnecessary expense to require the report from each facility to be submitted separately. Should an HSA wish to review surveys of any other facilities, they are available from the Department. Second, submission of the report for each facility will in no way further the cost containment objectives of certificate of need. Since no clarification has been provided, MAHCF urges that the rule not be approved until clarification is given on this issue.

Should you have any questions concerning our position on any of these issues, feel free to contact the undersigned or Rick Carter, Assistant Vice President, at the Association office. Should you wish to receive oral comments, we would be happy to provide them.

Sincerely,

Mary Martin
tw

Mary Martin
Staff Counsel

MM:tw

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*ADMITTED IN MONTANA

December 4, 1981

Mr. Ted Martinez
Office of the Attorney General
530 State Office Building
435 Park Street
St. Paul, Minnesota 55155

Re: 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

Dear Mr. Martinez:

We are counsel to the Minnesota Medical Association ("MMA"), and submit this letter to you in connection with your review of the above-referenced rules as to form and legality pursuant to Minn. Stat. §15.0412, Subd. 4e.

These rules govern the acquisition of equipment by physicians under the Minnesota Certificate of Need Act, Minn. Stat. §145.832 et seq. (hereinafter referred to as "Act"). MMA previously submitted Comments and Supplemental Comments (hereinafter collectively referred to as "Comments") to the Hearing Examiner in connection with this matter and copies thereof are attached hereto. For reasons fully discussed therein, proposed rule 7 MCAR §1.662 C must be disapproved by the Attorney General pursuant to 1 MCAR §1.206 because it exceeds statutory authority, conflicts with the governing statute and case law, has no reasonable relationship to statutory purposes, and otherwise is unreasonable.

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Minn. Stat. §145.835, Subd. 3, addresses the acquisition of equipment by physicians:

> A licensed medical doctor, a group of licensed medical doctors, or a professional corporation of licensed medical doctors organized pursuant to Minnesota Statutes, Chapter 319A, proposing to purchase, lease or otherwise acquire one or more items of diagnostic or therapeutic equipment which require a capital expenditure in excess of $150,000 shall, prior to purchasing or acquiring the equipment, notify the health systems agency and the commissioner of health of the proposed acquisition or purchase.
>
> The commissioner of health shall within 60 days of receipt of the notice determine whether or not the proposed acquisition or purchase is designed to circumvent the provisions of sections 145.832 to 145.845. A hearing shall be held if requested by the applicant or the health systems agency. The commissioner of health shall notify the applicant and the health systems agency in writing of its determination. If the commissioner of health determines that the proposed acquisition or purchase is not designed to circumvent the provisions of sections 145.832 to 145.845, no certificate of need shall be required of the applicant. If the commissioner of health determines that the proposed acquisition or purchase is designed to circumvent the provisions of sections 145.832 to 145.845, the applicant must obtain a certificate of need.

Any rule which is inconsistent with the foregoing statute is unlawful and must be disapproved. Guerrero v. Wagner, 310 Minn. 351, 246 N.W.2d 838 (1976). As explicated in MMA's previous comments, proposed §1.662 C is inconsistent with the above-quoted statute in the following areas: (1) the type of notice required, (2) the time period in which the Commissioner must determine whether a proposed acquisition is designed to circumvent the Act, and (3) the circumstances under which a physician purchase is subject to the Act.

Although Minn. Stat. §145.835, Subd. 3, is quite specific about the type of notice required and the time period in which the Commissioner must make his determination, the Agency insists that its conflicting proposed rules are proper. Rather than a simple notice by a physician or group of physicians of their intention to purchase certain diagnostic or therapeutic equipment, §1.662 C.1 would require that extensive and burdensome information be submitted with the notice. Compare Minn. Stat. §145.836 in which detailed informational requirements for certificate of need applications are set forth. The legislature could have provided for similar requirements in connection with physician acquisitions, but it clearly chose not to do so. The Agency's attempt to impose such requirements by rule is contrary to legislative intent and unlawful.

In its Post-Hearing Supplemental Comments (hereinafter referred to as "Post-Hearing Comments"), the Agency misstates MMA's position by suggesting that it would require nothing more than a notice stating: "We, the undersigned doctors, hereby notify that we are planning to acquire diagnostic or therapeutic equipment." Post-Hearing Comments at p. 17. However, MMA has never taken such a position and has no objection to including in a notice of proposed acquisition the type of equipment to be acquired, its cost, and its proposed location. However, proposed §1.662 C.1 requires burdensome information not contemplated by, or necessary to effect, the Act.

Physicians are aware of the Act's requirements, and must be presumed to conduct their practice in accordance therewith. If the Agency has reason to believe that a particular acquisition will violate the Act, a hearing can be demanded at which additional information may be sought. However, to suggest that the detailed information required by §1.662 C.1 is appropriate for each acquisition is ludicrous and contrary to statutory language and intent.

Under proposed §1.662 C.2 the Commissioner would be given a 20 day period to determine whether the notice was complete or whether additional information would be required. After the notice is deemed complete, the Agency then would have an additional 60 days to determine whether the proposed acquisition was designed to circumvent the Act. However, this provision also is inconsistent with the Act. The clear and unambiguous language of the Act requires the Commissioner to determine whether the proposed acquisition is designed to circumvent the Act within 60 days after receipt of notice thereof. Compare Minn. Stat. §145.866, Subd. 1, in which the Commissioner is

given 10 days to determine whether a certificate of need application is complete. Again, if the legislature had intended that a 20 day period be provided to determine whether a notice is complete it would have so stated, and the absence of such a provision supports MMA's contention that a simple notice requirement, not requiring extensive review, was contemplated by the legislature.

Obviously, if the required notice is incomplete the 60 day review period would not begin to run. However, when such a notice is complete as submitted the 60 day period begins to run upon receipt of the notice by the Commissioner. Any attempt to lengthen this period by giving the Commissioner an additional 20 days is in conflict with the statute and therefore patently unlawful.

Finally, proposed §1.662 C.5 must be disapproved because it misconstrues the standard under which physician acquisitions are to be judged. The Act requires a certificate of need only when a physician acquisition is "designed to circumvent" the Act. Minn. Stat. §145.835 Subd. 3. In its previous comments, MMA considered the meaning of "designed to circumvent" and demonstrated that such language requires planned and deliberate collusion with a health care facility to obtain equipment which the health care facility otherwise would be unable to obtain. In its Post-Hearing Comments, the Agency contends that it does not disagree with MMA's position. Post-Hearing Comments at pp. 19-20. Obviously, MMA would be pleased if this is so. However, proposed §1.662 C.5, as interpreted by the Agency's Statement of Need and Reasonableness, is quite inconsistent with MMA's position. This subsection enumerates factors to be considered by the Agency in determining whether an acquisition is designed to circumvent the Act.

Interestingly, in its Post-Hearing Comments, the Agency suggests that MMA somehow has misconstrued the impact of §1.662 C.5:

> Since there is agreement on how the statute should be read, the question becomes why [does MMA] find the factors so objectionable. The answer lies in [MMA's] misbelief that the factors permit the Commissioner to require physicians to obtain a Certificate of Need for equipment acquisition if he finds "any kind of incidental or potential benefit to a health care facility ...." Such is not the case.

Post-Hearing Comments at p. 20. However, the Agency's Statement of Need and Reasonableness is contradictory and demonstrates that the Agency, not MMA, is the confused party.

This is illustrated by the Agency's discussion of the second and third factors set forth in proposed §1.662 C.5:

> 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.

Statement of Need and Reasonableness at pp. 45-46 (emphasis added). Similarly, in its discussion of the fourth factor, the Agency contends:

> 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 comparable purchase by a physician's office.

Statement of Need and Reasonableness at p. 46 (emphasis added). As considered fully in MMA's previous comments, mere benefit to a health care facility is insufficient to bring the acquisition within the Act; nor does the Act contemplate equal treatment for physician acquisition.

The foregoing quotations evidence the Agency's failure to consider the legislative scheme embodied in the Act and its apparent position that proof of one or more of the factors set forth in §1.662 C.5 constitutes proof of a design to circumvent. With the exception of §1.662 C.5 a, added by the Agency in its Post-Hearing Comments, such a position is simply incorrect. The factors set forth in §1.662 C.5 b-f are nothing more than situations or sets of circumstances that arguably could motivate a design to circumvent. The Agency would then erect an irrebuttable presumption that a possible motive to engage in a strategy

designed to circumvent the Act establishes a design to circumvent the Act. Obviously, such proof is insufficient. MMA does not take issue with the position that motives may be probative of a design to circumvent, but surely without other evidence the Agency has failed to prove a design to circumvent the Act.

If the factors in §1.662 C.5 are mere evidence, then there is no reason to enumerate them in the rule because surely the Agency may look to any admissible, relevant, and probative evidence in making its determination. Rather, in light of comments in its Statement of Need and Reasonableness, the Agency seems to view the factors set forth in §1.662 C.5 as conclusive of a design to circumvent. This position is in obvious conflict with the Act, and therefore must be disapproved.

I have highlighted the primary arguments raised by MMA in its previous Comments, and responded to some of the positions taken by the Agency in its Post-Hearing Comments. Proposed rule 7 MCAR §1.662 C is nothing more than an attempt by the Agency to extend its jurisdiction over physicians and physician groups without statutory authority. Thus, it is unlawful and must be disapproved by the Attorney General pursuant to Minn. Stat. §15.042 Subd. 4e and 1 MCAR §1.206.

Thank you for your consideration.

Very truly yours,

William J. Keppel

WJK:jp
Enclosures
cc: George R. Pettersen, M.D.

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

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

COMMENTS OF THE MINNESOTA MEDICAL ASSOCIATION ON PROPOSED RULE 7 MCAR § 1.662 C

The Minnesota Medical Association (hereinafter referred to as "MMA") by and through its attorneys, Dorsey, Windhorst, Hannaford, Whitney and Halladay, has reviewed that part of the above referenced rules which concerns the acquisition of equipment by physicians (proposed rule 7 MCAR § 1.662 C). For the reasons set forth below, this provision is legally unacceptable because it is in conflict with and contrary to the Minnesota Certificate of Need Act, Minn. Stat. § 145.832 et seq. (hereinafter referred to as "Act").

Minn. Stat. § 145.835 Subd. 3 addresses the acquisition of equipment by physicians:

> A licensed medical doctor, a group of licensed medical doctors, or a professional corporation of licensed medical doctors organized pursuant to Minnesota Statutes, Chapter 319A, proposing to purchase, lease or otherwise acquire one or more items of diagnostic or therapeutic equipment which require a capital expenditure in excess of $150,000 shall, prior to purchasing or acquiring the equipment, notify the health systems agency and the commissioner of health of the proposed acquisition or purchase.
>
> The commissioner of health shall within 60 days of receipt of the notice determine whether or not the proposed acquisition or purchase is designed to circumvent the provisions of sections 145.832 to 145.845. A hearing shall be held if

> requested by the applicant or the health systems agency. The commissioner of health shall notify the applicant and the health systems agency in writing of its determination. If the commissioner of health determines that the proposed acquisition or purchase is not designed to circumvent the provisions of sections 145.832 to 145.845, no certificate of need shall be required of the applicant. If the commissioner of health determines that the proposed acquisition or purchase is designed to circumvent the provisions of sections 145.832 to 145.845, the applicant must obtain a certificate of need.

The proposed rules are in conflict with this statutory provision in the following areas: (1) the type of notice required, (2) the time period in which the Commissioner of Health must determine whether a proposed acquisition is designed to circumvent the Act and, most importantly, (3) the circumstances under which a physician purchase is subject to the Act.

Under § 145.835 Subd. 3, a physician proposing to purchase diagnostic or therapeutic equipment which requires a capital expenditure in excess of $150,000 must "notify the health systems agency and the commissioner of health of the proposed acquisition or purchase." Thereafter, "[t]he commissioner of health shall within 60 days of receipt of the notice determine whether or not the proposed acquisition or purchase is designed to circumvent the provisions of [the Act]". Thus, the Act requires nothing more than notice of the proposed acquisition and the Commissioner of Health must determine whether the acquisition is designed to circumvent the provisions of the Act within 60 days of receipt of the notice.

The proposed rules, however, take a quite different approach. Rather than requiring a simple notice of acquisition as contemplated by the Act, proposed rule 7 MCAR § 1.662 C.1 sets forth an extensive list of informa-

tion that must be included in such notice. Thereafter, under proposed § 1.662 C.2 the agency would be given 20 days to determine whether the notice was complete. If the notice is determined to be incomplete, then under proposed § 1.662 C.2.a additional data must be submitted. If and when the notice is deemed complete, the Agency then would be given an additional 60 days to determine whether the proposed acquisition was designed to circumvent the Act.

This language is patently in conflict with the Act, and must be rejected. The legislature did not give the Commissioner of Health authority to depart from the guidelines it established, including the requirement that the Commissioner decide whether the proposed acquisition was "designed to circumvent" within 60 days after receipt of the notice. Surely, this provision could have provided that a notice of acquisition contain other information and that the Commissioner be given a period of time in which to determine whether the notice is complete. Compare § 145.836 Subd. 1 in which the Commissioner is given 10 days to determine whether applications for a certificate of need are complete, and § 145.836 Subd. 2 in which detailed informational requirements for such applications are set forth. Moreover, the legislature specifically could have authorized the Agency to require additional information or to alter the time periods for making its determination. However, the legislature did not do so and in the face of clear directives such as those found in this provision, the Agency may not adopt contrary rules based upon what it wished the legislature had enacted. Although in § 145.834 the Agency is directed to "promulgated rules . . . necessary to implement, enforce and

administer [the Act]," it is elementary that such rules may not be inconsistent with the Act. Guerrero v. Wagner, 310 Minn. 351, 246 N.W.2d 838 (1976). Thus, MMA urges the Hearing Examiner to find that proposed § 1.662 C.1-3 is unauthorized.

Finally, and of greatest significance, the proposed rules are inconsistent with the Act because they would enlarge greatly the circumstances under which physician acquisitions require a certificate of need. Under the Act, a certificate of need is required only if "the proposed acquisition or purchase is designed to circumvent the provisions of [the Act]". Minn. Stat. § 145.835 Subd. 3 (emphasis added). This is strong, unambiguous language which clearly does not contemplate any kind of incidental or potential benefit to a health care facility. The word "designed" imports some planned purposeful activity, or some deliberate attempt. The word "circumvent" is synonymous with defeat or escape from and strongly suggests some devious strategy. Thus, a certificate of need is not required for physician purchases unless the Agency has demonstrated planned and deliberate collusion with a health care facility to obtain equipment which the health care facility otherwise would be unable to obtain.

Although the language of the Act clearly supports MMA's position, any doubts as to the intention of the legislature are resolved by the legislative history of this provision. Under the original certificate of need act, passed in 1971, "health care facilities" were defined to include hospitals, nursing homes and boarding care homes. In 1975, the legislature considered and debated several bills that would have broadened the definition of

health care facilities to include groups of physicians. However, these proposals were rejected, and the legislature enacted Minn. Stat. § 145.76 Subd. 2 which was not materially different from the current provision found in § 145.835 Subd. 3.[1/] Inasmuch as legislation that would have placed physicians within the Act was specifically considered and rejected, a clear policy can be discerned that physicians not be subject to the financial, administrative and legal burdens involved in the certificate of need process.

The intention of the legislature also can be ascertained from the statements of the Senators who introduced the 1975 Amendment. For example, Senator Kwalczyk stated:

> [T]he one thing I would like to point out particularly is that doctors' offices and clinics, the buildings are not included, just equipment over a

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1/ Minn. Stat. 145.76 Subd. 2 was repealed in 1979 when the present Act was passed. It provided as follows: "A licensed medical doctor, a group of licensed medical doctors, or a professional corporation of licensed medical doctors proposing to purchase or acquire one or more items of diagnostic or therapeutic equipment which require capital expenditure in excess of $100,000 for a single item or $200,000 for two or more items shall, prior to purchasing or acquiring the equipment, notify the area wide comprehensive health planning agency and the state board of health of the proposed acquisition or purchase. The state board of health shall, within 60 days of receipt of the notice, determine whether or not the proposed acquisition or purchase is designed to circumvent the provisions of sections 145.71 to 145.83. A hearing shall be held if requested by the applicant or the area wide comprehensive health planning agency. The board of health shall notify the applicant and the area wide comprehensive health planning agency in writing of its determination. If the state board of health determines that the proposed acquisition or purchase is not designed to circumvent the provisions of sections 145.71 to 145.83, no certificate of need shall be required of the applicant. If the state board of health determines that the proposed acquisition or purchase is designed to circumvent the provisions of sections 145.71 to 145.83, the applicant must obtain a certificate of need."

> hundred thousand for one piece and $200,000 on two or more pieces and there is not going to be a need for a Certificate of Need unless a hospital has been turned down and they are circumventing the Certificate of Need law.

Proceedings Had on May 17,1975, Regarding Senate File No. 177, at p.4 (emphasis added). Senator North gave a similar explanation:

> [T]he only provision relative to doctors or groups of doctors purchasing equipment and equipment only would be if it could be shown to the State Board of Health if a hospital was attempting to go around the Certificate of Need law by getting a group of doctors to purchase some equipment . . . .

Id. at p. 5 (emphasis added).

The following exchange between Senator Brown and Senator North clearly demonstrates the legislative intent:

> SENATOR BROWN: . . . it's my understanding, if a doctor or someone else wanted to put in a piece of equipment after it had been rejected on the Certificate of Need request for a hospital they could not do that, is that right? They'd have to get a Certificate of Need also?
>
> SENATOR NORTH: They wouldn't even have to get a Certificate of Need there unless it could be shown there was collusion between the doctor and hospital.
>
> . . .
>
> SENATOR BROWN: As I understand it this bill would not really affect their offices unless they were proven to be in collusion with the hospital and would try to get a Certificate of Need?
>
> THE PRESIDENT: Senator North?
>
> SENATOR NORTH: That's absolutely correct, sir.

Proceedings Had on May 19, 1975, Regarding Senate File No. 177 at p. 3-4 (emphasis added). Additional comments throughout these proceedings indicate that a Certificate of Need would not be required of a doctors' clinic "unless a hospital has been turned down" and there is a "deliberate attempt" to circumvent the Act. Proceedings Had on May 17, 1975, Regarding Senate File No. 177 at p. 4, 7.

Finally, MMA's position is supported by Metropolitan Council v. Minnesota State Board of Health, No. 414488 (Ramsey County Dist. Ct., Minn., Dec. 1, 1976). There a group of physicians (hereinafter referred to as "Clinic") was proposing to purchase a CAT Scanner for its office. Many area hospitals opposed the acquisition claiming that the CAT Scanners already in such facilities then would become under-utilized. The Metropolitan Council took the position that a physician acquisition was subject to the Act whenever it had the potential of frustrating the purposes of the Act. The Minnesota State Board of Health, however, supported the Clinic's position that unless the Metropolitian Council could prove some collusion or agency relationship between the Clinic and a health care facility, the proposed purchase could not be viewed as designed to circumvent the Act. Thus, the State Board of Health adopted a position consistent with the position now advanced by MMA.

In granting the Clinic's motion for summary judgment, the court interpreted the phrase "designed to circumvent" to require that "the proposed purchase of the CAT Scanner was planned and deliberately executed for the purpose of circumventing the legislative act." Id. at p. 4. The court also went on to observe that:

> The thrust of the legislation centers around "health care facilities", and although efforts were made to include such organizations as the "Clinic" or other groups of physicians, within the act, the legislature specifically decided otherwise. Hence, to require a certificate of need, petitioner would have to show that the Clinic was acting in behalf of a health care facility. The mere fact that equipment is being purchased by a group of doctors does not raise a presumption that the purchase is being rigged through a health care facility or perfected in some manner so as to fall outside the provisions of [the Act]. The burden is upon the petitioner

to show the collusion or circumvention, or whatever, which constitutes a violation of the statute. Here, petitioner proved nothing in that regard.

Despite the clear language of the Act, its legislative history, and the holding in Metropolitan Council, the proposed rules advance a position which conflicts with these authorities. Section 1.662.C.5 thereof sets forth five factors to be considered in determining whether an acquisition is designed to circumvent the Act:

> a. The projected proportion of patients who will use the equipment while also being inpatients or outpatients of a health care facility if such inpatient use is not on a temporary basis, such as a result of a natural disaster, major accident or equipment failure;
>
> b. The existence of a relationship between the requestor and a health care facility for purposes of making available the proposed equipment to the health care facility;
>
> c. The needs for a health care facility to purchase such equipment if the proposed equipment were not acquired by the requestor;
>
> d. The accrual of material benefit from the proposed acquisition to a health care facility and that, if the acquisition were made by the health care facility, the project would be reviewable under the Act; or
>
> e. The existence of other information which shows that the acquisition of the equipment will result in circumvention of the Act.

In proposing the foregoing factors, the Agency obviously has misconstrued the meaning of "designed to circumvent" as that phrase is used in the Act. This conclusion becomes even more evident after reading the Agency's comments in its Statement of Need and Reasonableness (hereinafter referred to as "Statement"). In its discussion of the first two factors, the Agency reasons:

> 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 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.

Statement at pp. 45-46 (emphasis added). Thus, the Agency is contending incorrectly that mere benefit to a health care facility is sufficient to bring an acquisition within the Act.

Similarly, in its discussion of the third factor, the agency contends:

> 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.

Statement at p. 46 (emphasis added). The underscored language clearly evidences the Agency's failure to consider the legislative scheme embodied in the Act. As the legislative history so clearly demonstrates, a physician acquisition is not to be given "equal treatment" with an acquisition by a health care facility merely because such facility would find it unnecessary to purchase equipment acquired by a physician. Obviously, this situation could exist without the required agreement or collusion to circumvent the Act.

The fourth factor enumerated in Section 1.662 C.5. is likewise unsound. It would subject physician acquisitions to the Act merely because a health care facility would benefit from the proposed acquisition.

Obviously, the Agency is seeking improperly to equate "benefit" with "designed to circumvent", an interpretation in conflict with the clear language of the Act.

The last factor in Section 1.662 C.5. instructs the Commissioner to consider "other information which shows that the acquisition of the equipment will result in circumvention of the Act." This illustrates the Agency's failure to recognize that the effect of circumvention is insufficient; rather, the Agency must establish a design to circumvent the Act.

A common fallacy is discernable in each of the factors quoted above. The Agency has taken situations or sets of circumstances that arguably could motivate a physician and a health care facility to engage in a strategy designed to circumvent the Act and has reasoned that the mere existence of such a potential motive is sufficient to bring the acquisition within the Act. Thus, under the scheme contemplated by the proposed rules there would be no need to prove the existence of an agreement designed to circumvent the Act. Surely, however, a possible motive to do a certain thing does not prove that the thing itself was done. Such an interpretation is contrary to the Act which requires a "design to circumvent", and the proposed rule based thereon is outside the Agency's delegated authority under the Act.

The authorities discussed herein compel the conclusion that physician purchases do not require a certificate of need unless there is planned and deliberate collusion with a health care facility to obtain equipment which the health care facility otherwise would be unable to obtain. Accordingly, MMA urges the Hearing Examiner to

find that proposed § 1.662 C.5. is inconsistent with the Act and therefore unauthorized.

Finally, under Metropolitan Council, the burden of persuasion is on the Agency to prove that an acquisition is designed to circumvent the Act. MMA believes that any rules adopted should state that such burden is on the Agency.

Dated: June 9, 1981

Respectfully submitted,

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

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

SUPPLEMENTAL COMMENTS OF THE MINNESOTA MEDICAL ASSOCIATION ON PROPOSED RULES 7 MCAR §1.662 C AND 7 MCAR §1.661 B.17

The Minnesota Medical Association ("MMA") by and through its attorneys, Dorsey, Windhorst, Hannaford, Whitney and Halladay, previously submitted written Comments to the Hearing Examiner with respect to the above-referenced matter, and also made oral comments at a public hearing held on June 9, 1981. Herein, MMA wishes to supplement its written Comments.

1. Proposed §1.662 C Is Contrary to the Certificate of Need Act.

In its earlier Comments, MMA demonstrates that proposed rule 7 MCAR §'.662 C is unauthorized because it is contrary to the Minnesota Certificate of Need Act, Minn. Stat. §145.832 et seq. (the "Act"). In particular, proposed §1.662 C.5 is unlawful because it would subject physician acquisitions to the Act whenever there is potential benefit to a health care facility from such acquisition. This is contrary to Minn. Stat. §145.835, Subd. 3 which requires a certificate of need for physician acquisitions only when the acquisition is designed to circum-

vent the Act. Thus, proposed §1.662 C.5 is contrary to the clear language of the Act.

2. Proposed §1.662 C Is Contrary to Legislative Intent and Minnesota Case Law.

In addition, MMA's earlier Comments review the legislative history of the applicable provision in the Act and the decision in Metropolitan Council v. Minnesota State Board of Health, No. 414488 (Ramsey County Dist. Ct., Minn., Dec. 1, 1976). These authorities compel the conclusion that a certificate of need is required only when there is planned and deliberate collusion with a health care facility to obtain equipment which the health care facility otherwise would be unable to obtain. Mere benefit is not equivalent to a design to circumvent.

3. Proposed §1.662 C Is Contrary to the Legislative Scheme of the Act.

The informational and timing requirements of proposed §1.662 C, and the Agency's "control" of the application and decision making process, parallel those of the certificate of need process found in Minn. Stat. §§145.836 to 145.838, and are in direct contrast to the simple "notice" procedure of Minn. Stat. §145.835, Subd. 3, which governs acquisitions by physicians. A simple comparison of these distinctly different statutory procedures compels the conclusion that acquisitions by physicians are to be routinely approved within 60 days after notice (not after acceptance of notice) unless the Agency can show that the acquisition is designed to circumvent the Act.

On the other hand, the large chart regarding proposed §1.662 C which was displayed by the Agency at the June 9, 1981 rulemaking hearing demonstrated the Agency's

improper and unauthorized effort to expand the simple statutory notice procedure so that it would parallel the elaborate certificate of need procedure.

The Legislature could well have imposed more elaborate procedures on physicians, such as those now proposed by the Agency or such as those which the Legislature imposed on health care facilities, but it specifically declined to do so. The Agency's present attempt to expand its jurisdiction is contrary to this legislative scheme and must fail.

4. "Designed to Circumvent" Requires Planned and Deliberate Collusion to Avoid the Act, Not Mere Benefit.

The word "designed" requires some planned and purposeful activity, or some deliberate attempt. This position is consistent with countless judicial interpretations of that word. For example, in Le Pochat v. Pendleton, 187 Misc. 296, 63 N.Y.S.2d 313 (1946), the court declared that "[d]esign implies and indicates purpose or intention, combined with plan or implying a plan in the mind." 63 N.Y.S.2d at 315. Likewise, in State v. Gordon, 151 Kan. 932, 101 P.2d 888 (1940), the court reasoned that "the word 'design' may and usually does mean something more than the word 'intent' as ordinarily understood in connection with criminal offenses. It carries with it an idea of a plan, a scheme, a deliberate purpose." 101 P.2d at 891.

The word "circumvent" is synonymous with defeat or escape from and strongly suggests some devious strategy. This position also is well supported by case law. In Oregon v. Jennings, 119 U.S. 74 (1886), the United States Supreme Court reasoned that "[c]ircumvention seems

to be nearly, if not quite, synonymous with fraud." 119 U.S. at 89. Moreover, in Commonwealth v. Bessette, 345 Mass. 358, 187 N.E.2d 810 (1963), the court rejected an argument that "circumvention" has no clear definition:

> The word "circumvent" has been defined in Webster's New International Dictionary (2d ed.) as "to gain advantage over by arts, stratagem, or deception; deceive; cheat; delude; get around," and in Id. (3d ed.) as "to overcome or avoid the intent, effect, or force of: anticipate and escape, check, or defeat by ingenuity or stratagem." Circumvention is nearly if not quite synonymous with fraud.

187 N.E.2d at 811.

It is also instructive to consider cases in which courts have characterized situations as "designed to circumvent". In Penn Township v. Yecko Bros., 420 Pa. 386, 217 A.2d 171 (1966), cert. denied, 385 U.S. 826 (1966), land had been purchased and hastily converted to an automobile junk yard at the same time that local authorities were considering the adoption of a zoning ordinance forbidding such use. When the ordinance was enacted, the operators of the junk yard contended that a nonconforming use had been established that could continue despite the ordinance. In rejecting this contention, the court stated:

> Their action on July 27, 1962, in occupying and using the land was a calculated device resorted to in a belief that . . . the proposed zoning ordinance properly regulating land use and proscribing an automobile graveyard, being but two weeks from enactment and one month from effectiveness, had to be circumvented by quick action on their part. Their haste to occupy the property without any approval or permit, their bringing a used bus on the property as an office, their resourcefulness in painting a sign and placing a wrecked automobile on the premises, their consummation of but $109.50 of business all indicate the lack of good faith required by these cases. On the contrary, they illustrate a contrived series of maneuvers designed to circumvent a duly authorized ordinance so as to perpetuate a

> nonconforming use after the effective date of the ordinance.

217 A.2d at 174 (emphasis added).

Further guidance as to the meaning of "designed to circumvent" is found in Wood v. Sadler, 93 Idaho 552, 468 P.2d 45 (1970). There, parties to a loan agreement characterized certain payments of two percent per month as commissions for services rendered and to be rendered. In considering whether this transaction was usurious, the court stated:

> A "services" contract, of the sort involved in this action, readily lends itself to use as a shift to avoid the usury laws. As the Supreme Court of Washington has said,
>
> > "A money lender bent upon violating the rule of public policy contained in the statute against usury not infrequently resorts to the subterfuge of a contemporaneous contract for pay for services rendered or to be rendered by the lender, or for profits earned upon a transaction other than the making of the loan, to conceal the true nature of the transaction."
>
> We will not hesitate to pierce a device or form which is designed to circumvent the usury laws in order to reach the economic substance of a transaction.

468 P.2d at 45 (emphasis added)(footnotes omitted).

Finally, in United States v. Rogers, 624 F.2d 1303 (5th Cir. 1980), the defendants had been convicted of mail fraud in connection with a bid-rigging scheme in the the river construction industry. The government presented evidence of prebid allocation meetings over a period of years and collective agreements as to who would be awarded construction contracts. This evidence, the court stated, "indicated a long running scheme designed to circumvent competitive bidding procedures . . . ." 624 F.2d at 1307 (emphasis added).

These cases clearly and unambiguously support the position advanced by MMA in its earlier Comments. In each case the phrase "designed to circumvent" was applied to a set of circumstances evidencing a "calculated device", a "contrived series of maneuvers", a "lack of good faith", a "subterfuge ... to conceal", a "shift to avoid", and a "long running scheme", all of which were pursued with a specific intention to avoid and defeat applicable laws. In short, a planned and intentional collusion to defeat the law was required.

This is consistent with the Minnesota Medical Association's contention that physician acquisitions require a certificate of need only when the Agency has demonstrated planned and deliberate collusion with a health care facility to obtain equipment which the health care facility otherwise would be unable to obtain. However, proposed §1.662 C would require a certificate of need any time that a health care facility might potentially benefit from an acquisition of equipment by a physician. In fact, whether or not a health care facility, or its patients, would benefit by a physician acquisition is immaterial as long as the purchase was not collusive with the intention of circumventing the Act.

As explicated herein and in MMA's earlier Comments, the Agency's position as to proposed §1.662 C is simply wrong. Its position is inconsistent with the Certificate of Need Act, its legislative history, the statutory scheme, the only known Minnesota case law construing the applicable provision of the Act, and cases in other jurisdictions involving situations characterized as "designed to circumvent". The Agency has presented no

contrary law or credible argument, and its position is wholly without foundation. Thus, MMA urges the Hearing Examiner to find that proposed §1.662 C is inconsistent with, and unauthorized by, the Act and therefore outside the Agency's jurisdiction to promulgate.

5. "On Behalf of": 7 MCAR §1.661 B. 17.

Another area of concern for MMA is proposed §1.661 B.17. Thereunder, the statutory language "on behalf of" would be defined to mean "in the interests of, at the behest of, or for the benefit of, a health care facility or other entity" (emphasis added). When questioned as to the meaning of the underscored language, Kent Peterson of the Agency stated that it referred to physicians or groups of physicians.

The difficulty with this explanation is that nowhere in the Act is there any suggestion that the "on behalf of" language applies to physicians. On the contrary, for the reasons stated above and in MMA's original comments it is clear that the certificate of need requirements were not to apply to acquisitions by physicians or groups of physicians.

The phrase is used in the definition of "construction or modification" in Minn. Stat. § 145.833 Subd. 5(a):

> "Construction or modification" means: Any erection, building, alteration, reconstruction, modernization, improvement, extension, lease or other acquisition, or any purchase, lease or other acquisition of diagnostic or therapeutic equipment, by or on behalf of a health care facility which:
>
> (1) Requires, or would require if purchased, a total capital expenditure in excess of $150,000, and which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance; or

> (2) Changes the bed capacity of a health care facility in a manner which increases the total number of beds, or distributes beds among various categories, or relocates beds from one physical facility or site to another, by more than ten beds or more than ten percent of the licensed bed capacity, whichever is less, over a two year period . . . . (emphasis added).

Minn. Stat. §145.833, Subd. 5(c), which also uses the phrase "on behalf of", is similarly limited to health care facilities.

Obviously, these provisions refer only to acquisitions that are on behalf of a health care facility, and there is no statutory authorization for the Agency's application of such language to physicians. Again, the Agency is attempting improperly to extend its jurisdiction over physicians in the certificate of need area contrary to statutory language and legislative intent excluding them.

Moreover, the Agency's proposed definition of "on behalf of" is far too broad. Under this definition anything that is in the interests of or for the benefit of a health care facility would be within the definition. Incorporating this definition into Minn. Stat. § 145.833 Subd. 5(a), causes that section to read as follows:

> "Construction or modification" means: Any erection, building, alteration, reconstruction, modernization, improvement, extension, lease or other acquisition . . . [in the interests of, . . . or for the benefit of] a health care facility . . . ."

Taken literally the definition of "on behalf of" is so broad that completely unrelated construction or modification which quite incidentally and unintentionally serves the interest of a health care facility or benefits a health care facility would require a certificate of need. Thus, the Agency could argue that physician acquisitions that happen to benefit a health care facility require a

certificate of need, even though there is no collusion between a physician and a health care facility as discussed previously in these Comments. Such an interpretation, which could be permitted by the proposed regulation, is contrary to the Act for the reasons stated above, and evidences the inherent defect in proposed §1.661 B.17.

It is apparent that "on behalf of", as used in the Act, is referring to an agency relationship (in the traditional principal-agent sense) in which the health care facility acts by contract or agreement through another entity. This language should not be construed to apply to situations in which construction or modification is undertaken by an entity which is acting on its own behalf and in so doing incidentally and without plan or design also acts in the interest of or for the benefit of a health care facility.

Accordingly, MMA urges the Hearing Examiner to find that § 1.661 B.17 is unreasonable, ambiguous and inconsistent with the Act, and therefore unauthorized.

6. Conclusion.

Proposed Department of Health rule 7 MCAR §1.662 C is nothing more than an attempt by the Agency to circumvent Minnesota's Certificate of Need Act and to extend its jurisdiction without statutory authority over acquisitions of equipment by physicians and physician groups. In addition to the Agency's failure to prove need and reasonableness, the proposed rule is defective for the following reasons:

1. It is contrary to the language of the Minnesota Certificate of Need Act.

2. It is contrary to the clearly-stated intentions of the Minnesota Legislature which considered, and expressly rejected, inclusion of physicians and physician groups as subject to the general requirements of the Act.

3. It is contrary to the statutory scheme which expressly sets out elaborate procedures for the certificate of need process (such as those which the Agency seeks to impose on physicians by these proposed regulations) but only provides a simple notice procedure for acquisitions by physicians.

4. It is contrary to Minnesota case law interpreting the Certificate of Need Act and the burdens on the Agency thereunder.

5. It is contrary to interpretations of "designed," "circumvent" and "designed to circumvent" by courts in other jurisdictions which require planned and deliberate collusion.

Insofar as proposed 7 MCAR §1.661 B.17 also attempts to extend the Agency's jurisdiction over acquisitions of equipment by physicians and physician groups, the proposed rule must fail for the same reasons.

Dated: June 29, 1981

Respectfully submitted,

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RECEIVED
DEC 9 1981
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

December 9, 1981

Mr. Ted Martinez
Special Assistant Attorney General
530 State Office Building
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St. Paul, Minnesota 55155

Re: 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

Dear Mr. Martinez:

Pursuant to 1 MCAR § 1.206 C., the Minnesota Association of Health Care Facilities (herinafter "MAHCF") by letter of December 3, 1981, from Mary Martin, Staff Counsel, and the Minnesota Medical Association (hereinafter "MMA") by letter dated December 4, 1981, from William J. Keppel, counsel for the MMA, submitted comments challenging the legality of certain portions of the above subject rules. The Commissioner of Health hereby responds to those comments.

It should be noted at the outset that a notice of submission of the Certificate of Need Rules to the Attorney General's office was mailed to Craig Wildfang of MAHCF and to William Keppel, Carol Kaemmerer, and George C. Lohmer of MMA on November 20, 1981, which is the same day of submission. These are the only individuals from those organizations who had signed the hearing register and checked the block indicating they wanted to be informed of submission of the hearing record to the Attorney General. No other requests for notification were received by the Department after the hearing. Under 1 MCAR § 1.206 C., these individuals had until November 30, 1981, to file comments with the Attorney General's office. The Department was informed that representatives of the two associations had contacted you on November 30 and told you that they had either just gotten the notice or a copy of the rules that day and needed an extension for filing their remarks. They were given until December 4, 1981. Yet neither association filed comments until December 7, 1981.

The Department had complied with its obligation to mail a notice of submission to the Attorney General. The two associations did receive notice of the submission and were granted an extension of time yet neither met the deadline.

The controlling rule, 1 MCAR § 1.206 C., requires submission within the established time frames. The Department will not object to the original extension of time given by the Attorney General's office; however, it does object to the Attorney General's office considering the comments of MAHCF and MMA because they were both submitted after the extended deadline in violation of the controlling rule.

Response to Letter from MAHCF

MAHCF divided its comments into two parts, procedural and substantive. The Department will respond to each part separately.

Procedural Comments

1. MAHCF contends that the rules should be withdrawn because the Department did not comply with that part of Minn. Stat. § 15.0412, subd. 4e (Supp. 1981) which requires that the agency give notice to "all persons who request to be informed that the hearing record has been submitted to the attorney general." The hearing record was submitted on November 20, 1981. MAHCF asserts that as of November 30, 1981, no written notice had been received by MAHCF.

A review of the record will establish that MAHCF is wrong in its assertion that the Department has not complied with Minn. Stat. § 15.0412, subd. 4e (Supp. 1981). The record contains an affidavit of Linda Karowski which states that on the 20th day of November, 1981, she served a notice of submission to the Attorney General by depositing it in United States mail upon all persons who had requested to be so notified. MAHCF requested to be notified by checking the appropriate block on the hearing register. The person asking for receipt of a notice on behalf of MAHCF was Craig Wildfang at 270 Grain Exchange in Minneapolis. No other representative of MAHCF asked to be served with a notice. Mr. Wildfang was served on November 20, 1981. The facts clearly establish that MAHCF was served with a written notice in compliance with Minn. Stat. § 15.0412, subd. 4e (Supp. 1981).

MAHCF also received oral notice. It is significant that Minn. Stat. § 15.0412, subd. 4e (Supp. 1981) only requires notices and does not specify oral or written. MAHCF admits that it was told over the telephone on November 19 and 20, 1981, that the rules would "soon" be submitted to the Attorney General. In fact, soon thereafter, MAHCF was told in a telephone conversation with a representative of the Department that the rules had actually been submitted. Thus, Minn. Stat. § 15.0412, subd. 4e (Supp. 1981) was complied with by the Department because MAHCF had oral notice.

Finally, the fact that MAHCF submitted comments to the Attorney General is conclusive proof that it had actual notice. Assuming arguendo that the Department did not comply with the statute in question in some technical respect, which the Department vigorously denies, it is obvious that MAHCF was not prejudiced thereby. MAHCF heard of the Department's submission to the Attorney General and submitted comments. Thus, the purpose of Minn. Stat. § 15.0412, subd. 4e (Supp. 1981) was fulfilled. There is no justification for disapproving the Certificate of Need Rules.

2. MAHCF also contends that the Department failed to comply with three statutory provisions regarding the fiscal impact of rules. The statutes are Minn. Stat. § 15.0412, subd. 7 (1980), Minn. Stat. § 15.065 (1980), and Minn. Laws 1981, ch. 360, § 14, which took effect July 1, 1981. These laws require either notice to or approval of various governmental authorities if the fiscal impact of the rules will exceed certain limits.

These arguments have already been dealt with in the record by the Hearing Examiner and the Department and found to be without merit. The Attorney General is accordingly referred to the Report of the Hearing Examiner (hereinafter "Report"), Findings 7 and 8 at pp. 3 and 4 (which Report was adopted in large part by the Commissioner) as well as to the Findings, Conclusions, and Order Adopting Rules (hereinafter "Adoption Order") of the Commissioner, paragraph 3 at p. 2. Since MAHCF adds nothing new in its letter to the Attorney General with respect to these issues, there is no need to comment beyond what is in the Report and Adoption Orders.

Substantive Comments

MAHCF also raises a number of issues grouped under the heading "Substantive Comments," at pp. 3-9 of its letter. Almost all of these issues have been quite specifically addressed by the Department in previous submissions. See, for example, the Statement of Need and Reasonableness, the Post Hearing Supplemental Comments of Minnesota Commissioner of Health (hereinafter "Commissioner's Comments") and the Findings, Conclusions, and Order Adopting Rules (hereinafter "Adoption Order") of the Commissioner. The Department would like to indicate, however, precisely where in its past submissions such issues were most specifically addressed, and would like to further elaborate on just a few of the issues raised by the MAHCF letter. For clarity's sake, the issues will be discussed in this submission in the order in which they appear in MAHCF's letter.

7 MCAR § 1.661 B.4.

MAHCF claims (#1 at pp. 3-4) that an interpretation of this rule which would require certificate of need review of certain purchases of existing health care facilities by other health care facilities constitutes a denial of due process and a taking of private property without just compensation. The Department has amply addressed these issues previously in the rulemaking process (Commissioner's Comments at pp. 23-24), and the Hearing Examiner agreed with the Department (Report of the Hearing Examiner, hereinafter "Report," Finding 21 at p. 9). Further, as a review of the Act and the rules indicate, more than adequate procedural due process safeguards are provided to a facility owner who desires to sell his facility to another facility. Minn. Stat. § 145.837, subd. 2 (1980), in particular, as well as the rules themselves, provide all parties more than a fair modicum of due process. In addition, MAHCF is incorrect in stating that the economic value of the property may not be considered in a certificate of need review. In particular, 7 MCAR § 1.663 E.4. permits an explicit focus on the value of the enterprise in question. Clearly, then, the value of the property to the owner can be addressed under the procedures provided by the Act and the rules. Nor does

the relevant restriction on the alienation of the property offend principles of substantive due process. This restriction is an obviously rational way of addressing a legitimate concern of government - the astonishing rate of increase in health care costs. Such a restriction places some control on the ability of a health care facility to continue to acquire other health care facilities until it can "corner the market" and monopolistically begin to dictate prices to consumers - an evil ultimately sought to be avoided by the Act. Minn. Stat. § 145.832, subd. 1 (1980). Lastly, it should be emphasized that a possible denial of a certificate of need to permit the sale of a health care facility to another health care facility does not constitute a "taking" of the owner's property - it merely conditions the disposition of the property. In such an instance, the owner of the facility is free to sell it to another entity which is not a health care facility without certificate of need review, or to arrange for a sale to another health care facility which can apply for an appropriate certificate of need.

The issues MAHCF raises (#1 at p. 4) in this regard relating to the consequences of a sale without a required certificate of need, and relating to a remotely possible need to transfer residents are adequately addressed by the foregoing.

MAHCF raises a series of hypothetical cases in which it questions (#3 at pp. 4-6) the Commissioner's future interpretation of the phrase "or other acquisition." Minn. Stat. § 145.833, subd. 5(a) (1980); 7 MCAR § 1.661 B.4. This issue has been thoroughly addressed in the Commissioner's Comments at pp. 23-24, and the Department's approach has been endorsed by the Hearing Examiner in his Report, Finding 21 at p. 9. Moreover, the hypotheticals presented are generally speculative, and sufficient facts pertinent to their disposition are not presented by MAHCF. For example, in the bankruptcy hypothetical, whether or not the trustee were a health care facility would be crucial to a determination of the applicability of the Act. MAHCF shows by its restatement of the Department's interpretation of the relevant rule that it understands the rule to require "a certificate of need prior to the purchase or sale of any existing health care facility by another health care facility . . . ." (MAHCF letter at p. 3), yet it neglects to specify whether the trustee in bankruptcy would be a health care facility. (This is not to imply that a transfer to a health care facility trustee would necessarily come within the rule.) Plainly, information of this sort does not provide a sufficient basis for an administrative determination. Moreover, a slight variation in facts presented may dictate a different regulatory determination, and for the Department to announce its application of statute and rule to such a incomplete factual record may result in some serious misunderstandings in the regulated industry. The Department will apply the statute and rule to fully developed factual situations on a case-by-case basis. The statute and the rule as adopted give adequate notice of the Department's position for the vast majority of cases, and for truly unique and unusual circumstances, a case-by-case determination is the most reasonable method available, a method found authorized, necessary and reasonable by the Hearing Examiner in his Report, Finding 21 at p. 9.

7 MCAR § 1.661 B.17.

MAHCF argues with the Department's definition of "on behalf of," which would "require a buyer who already owns a facility to obtain a certificate of need, but will not require a buyer who does not already own a facility to have a certificate . . . ." (MAHCF letter at p. 7). MAHCF contends that the definition constitutes a denial of equal protection. The contention is without merit. The rational basis for distinguishing between the two classes of nursing home owners is discussed above in connection with the Department's analysis of MAHCF's substantive due process concerns. Additionally, this issue is definitively treated in the Department's Statement of Need and Reasonableness at pp. 26-27; the Commissioner's Comments at pp. 9-10, 23-24, and the Department's approach is approved by the Hearing Examiner in his Report, Findings 26-29 at pp. 11-13.

The Department wishes to comment upon MAHCF's claim that facilities may circumvent this provision by forming new and separate corporations to become purchasers of existing facilities (MAHCF letter at p. 7). The Department is of the opinion that non-arm's-length transactions of the nature described would not fall outside the Act, and would be subject to review under the definition of "on behalf of," and has been enforcing the Act under this interpretation. Such a treatment of parties with an identity of interest is not only reasonable, but it also vitiates the criticism of MAHCF that persons knowledgeable of technicalities will be able to "evade" the law.

7 MCAR § 1.661 B.5.

MAHCF also criticizes the policy reasons underlying the Department's application of the Act to certain changes in a facility's level of certification (MAHCF letter at pp. 8-9). (Because the Attorney General review relates to legality only, these policy arguments should be disregarded.) This issue has been comprehensively addressed by the Department previously in its Statement of Need and Reasonableness at pp. 18-19; the Commissioner's Comments at pp. 6-7, 24-25, and the Department's approach has been supported by the Hearing Examiner in his Report, Finding 22 at pp. 9-10. Additionally, the possible adverse effects of relocation of residents raised by MAHCF have been obviously specifically considered by the Legislature, which decided to exempt changes in bed capacity of ten beds or ten percent, whichever is less, over a two year period, thereby striking a balance between concerns about individual resident welfare in situations involving minimal changes in facility services and health care cost concerns in situtations involving a significant alteration in the nature of services provided by the facility.

7 MCAR § 1.662 D.7.

MAHCF recommends that the language of Minn. Stat. § 145.835, subd. 4 (1980), relating to emergency waivers, be interpreted in a way contrary to its plain meaning (MAHCF letter at p. 8). Specifically, MAHCF wants the verb "may" to be interpreted as "shall" in connection with the granting of waivers, thereby transmitting a permissible requirement into a mandatory one. Again, this issue has

been adequately addressed by the Department in its Statement of Need and Reasonableness at pp. 53-54 and approved by the Hearing Examiner in his Report, Finding 62 at p. 26.

7 MCAR § 1.663 A.4.

Lastly, MAHCF seeks clarification as to how many survey reports must be submitted with a certificate of need application in cases where the applicant controls facilities in addition to the one for which a certificate of need is sought (MAHCF letter at pp. 8-9). This issue has been addressed by the Department in its Statement of Need and Reasonableness at p. 70 and the Commissioner's Comments at p. 35. The Hearing Examiner recommended a clarification (Report, Finding 74 at p. 30), and the Commissioner of Health correspondingly clarified the meaning of the relevant language in his adoption of rules (Adoption Order at p. 11) in a manner consistent with MAHCF's desires. No further clarification is, therefore, necessary.

Response to Letter From MMA

The letter from MMA addressed only 7 MCAR § 1.662 C. , which implements Minn. Stat. § 145.835, subd. 3 (1980) relating to physicians' acquisition of diagnostic or therapeutic equipment. MMA challenges the authority of the Department to establish procedures for implementing and administering this provision of the Certificate of Need Act as well as the need for specifying the type of evidence which the Department will consider in determining whether a proposed acquisition is designed to circumvent the Act.

The objections of MMA are without merit. They are fully addressed in the Commissioner's Comments, paragraph 10 at p. 17, in the Report, Findings 48 to 50 at p. 20, and in the Adoption Order, paragraph 18 at p. 11. However, additional points must be raised with respect to MMA's letter.

MMA has throughout the proceeding asserted that Minn. Stat. § 145.835, subd. 3 "requires nothing more than notice of the proposed acquisition" (Comments of the Minnesota Medical Association of Proposed Rule 7 MCAR § 1.662 C. at p. 2), that the Department's rule is "in direct contrast to the simple 'notice' procedure of Minn. Stat. § 145.835, subd. 3" (Supplemental Comments of the Minnesota Medical Association on Proposed Rules 7 MCAR § 1.662 C. and 7 MCAR § 1.661 B.17 at p. 2), and that the statute is quite specific about the "simple notice by a physician" (MMA letter at p. 3). After repeatedly declaring that the Act only requires a "simple notice," MMA then complains when the Department spells out in black and white in the Commissioner's Comments at p. 17 the type of notice MMA claims is required. The Department repeats that the only notice permitted under MMA's interpretation is: "We, the undersigned doctors, hereby notify that we are planning to acquire diagnostic or therapeutic equipment." Such a notice accurately reflects MMA's prior position.

If some content is permitted by the statute, why not the content specified in 7 MCAR § 1.662 C.1.? It is a basic canon of statutory construction that the legislature does not intend a result that is absurd, impossible of execution, or unreasonable. Minn. Stat. § 645.17(1) (1980). MMA's position, even its now modified one, calls for a result which is absurd, impossible of execution, and unreasonable because it does not allow for the submission of a reasonable amount of information to enable the Commissioner to review the proposed acquisition and decide whether it is designed to circumvent the Certificate of Need Act. All that 7 MCAR § 1.662 C.1. asks for is information reasonably related to the purchase so that the Commissioner will have a meaningful factual basis from which to fulfill his statutory duty. Clearly such a concept is embodied in a logical interpretation of the word "notice" as that word is used in Minn. Stat. § 145.835, subd. 3 and falls within the grant of rulemaking authority of Minn. Stat. § 145.834 to promulgate rules "necessary to implement, enforce and administer" the Act.

MMA also claims that the information required by 7 MCAR § 1.662 C.1. is "extensive and burdensome." MMA letter at p. 3. It is not explained, however, why the information requested is extensive and burdensome. If it really was, MMA should have been able to use as support of its contention the applications that doctors have submitted since 1975 when this requirement was first placed in the Certificate of Need Act. The information covered by the rule is essentially the same as what the Department has asked for since 1975. It can be adequately addressed in several pages as has been done in the past. Thus, as with MMA's other claims, this one must be rejected as it is without foundation or support.

Another MMA objection relates to 7 MCAR § 1.662 C.2. This rule gives the Commissioner 20 days in which to decide whether or not the notice is complete. The 60 day review period would begin to run only after the application has been ruled complete. MMA argues that this 20 day period is inconsistent with the Certificate of Need Act's 60 day review period. MMA letter at p. 3.

MMA does admit that the 60 day review period would not begin to run for incomplete applications; however, it begins to run immediately upon receipt of the notice if the notice is complete. MMA letter at p. 4. Exactly how the process is to work under MMA's view is difficult to determine. Just when is a determination of completeness made so that the Department would know upon receipt of the notice whether or not the 60 day period has started? MMA leaves that question unanswered. It is obvious that MMA admits that an application can be incomplete. By inference from that admission it must be concluded that MMA recognizes that the Department should be permitted to determine completeness. The only trouble with MMA's position is that it denies the Department the time to determine completeness. The internal inconsistency in MMA's position reveals that it is fallacious.

MMA tries to support its position by claiming that because Minn. Stat. § 145.835, subd. 3 is silent about the Commissioner having time to determine if a notice is complete that it must mean that the legislature did not intend to grant

the Commissioner the authority. To bolster the argument, MMA points to Minn. Stat. § 145.836, subd. 1, which specifically grants the Commissioner time to determine whether an application for a certificate of need is complete. Since the legislature addressed the issue in the one place, it would have addressed the issue in the other, MMA argues, if it had intended for the Commissioner to have time to determine completeness of physician notices.

Unfortunately, MMA does not reveal how it knows that legislative silence means that the legislature intended to deny the Commissioner a time period separate from the 60 day review period for determining notice completeness. The canons of statutory construction contained in Minn. Stat. ch. 645 do not address the issue of legislative silence. Obviously, it is mere conjecture on MMA's part as to how to interpret silence. Other meanings can be read into the silence on the subject. One alternative reading is that the legislature detailed the handling of certificate of need applications because that deals with the heart of the Certificate of Need Act whereas it dealt in broad strokes with physician notices of equipment acquisition because Minn. Stat. § 145.835, subd. 3, is an infrequently used process. Since 1975, only about 4 or 5 such notices have ever been submitted to the Department. Thus, it is just as reasonable to assume that the legislature decided to let the Department fill in the procedural details under its rulemaking authority in Minn. Stat. § 145.834 to adopt rules "necessary to implement, enforce and administer" the Certificate of Need Act. In any event, it is not possible to conclude that silence on the issue means that the 20 day period to determine notice completeness is contrary to the intent of the legislature. On the other hand, the 20 day period is a reasonable means of assisting the Department in implementing, enforcing, and administering the Act.

Finally, MMA urges disapproval of 7 MCAR § 1.662 C.5. The Department's position with respect to the types of evidence which can have bearing upon the subject of circumvention has been made clear in its previous submissions. The only point that MMA now raises that needs to be addressed is MMA's contention that the items in 7 MCAR § 1.662 C.5. do not need to be placed in rule. Because one purpose of rulemaking is to put the public on notice as to how an agency will interpret and administer a law, it is appropriate for the items enumerated in 7 MCAR § 1.662 C.5. to be placed, and left, in the rule.

We trust that the foregoing fully explains the Department's position with respect to the comments of MAHCF and MMA.

Very truly yours,

Dan McInerney
Assistant Director
Health Systems Division

DM:sd

cc: Mary Martin, MAHCF
William J. Keppel

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Department of Health
Health Systems Division

Adopted Rules Implementing, Enforcing, and Administering the Minnesota Certificate of Need Act, Minn. Stat. SS 145.832-145.845, and Repealing State Planning Agency Certificate of Need Rules, 10 MCAR SS 1.201-1.210.

Rules as Adopted

7 MCAR S 1.661 General provision.

A. Purpose.

1. These rules, 7 MCAR SS 1.661 to 1.665, are intended to govern the implementation, enforcement and administration of the Minnesota Certificate of Need Act. The rules do not repeat provisions of the Act which are clear and complete without rules; therefore, the Act should be read with the rules. References to the Act are made in these rules in order to assist the public in cross-referencing the Act with the rules.

2. The commissioner has, within the limits of the Act, developed review procedures and criteria which involve a minimum period of time, require only essential information, and involve the least cost for the applicant, the health systems agency (HSA), and the department. These rules promote health planning cooperation by health care facilities and health systems agencies before the certificate of need review and encourage health system innovations and alternatives, as well as beneficial price competition.

B. Definitions. The definitions contained in Minn. Stat. S 145.833 apply to the terms as used in these rules. Some of the terms defined in Minn. Stat. S 145.833 are also defined in these rules in order to clarify certain sections or parts of the statutory language. Unless the context clearly requires otherwise, the following terms shall have the ~~meaning~~ meanings ascribed to them: FofF 35

1. "Act" means the Minnesota Certificate of Need Act, Minn. Stat. SS 145.832 to 145.845.

2. "AIP" means annual implementation plan as defined in the Act, Minn. Stat. S 145.833, subd. 11.

3. "Application" means the submission by a person of the information required by 7 MCAR S 1.663 A. in requesting the issuance of a Certificate of Need.

4. "Capital expenditure" means any expenditure, regardless of type of financing mechanism, including gifts, donations and other philanthropic activities, utilized to purchase, acquire, renovate, remodel or substantially alter or modify real property, buildings, fixtures, equipment or a service. Whenever real property, buildings, fixtures or equipment are acquired by capitalized lease or any type of rental agreement, that capital expenditure for lease or rental agreement shall be the fair market value of the real property, buildings, fixtures or equipment at the date upon which the agreement is executed. Expenditures which, under generally accepted accounting principles, are properly chargeable as an expense of operation and maintenance are not capital expenditures. Capital expenditures include the total of all anticipated expenditures for a single undertaking with interdependent or interrelated components whether or not any individual expenditure exceeds the threshold of the Act.

5. "Category," as used in Minn. Stat. S 145.833, subd. 5(a)(2), means classification of beds within a health care facility according to licensure (such as, general hospital, psychiatric, alcoholic, nursing home, boarding care home and supervised living) or 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 ~~(such as skilled nursing care, intermediate nursing care and intermediate care for the mentally retarded and persons with related conditions)~~ as found in 42 United States Code, Section 1395x(e), hospital; Section 1395x(f), psychiatric hospital; Section 1395x(g), tuberculosis hospital; and Section 1395x(j), skilled nursing facility; and in Title XIX of the Social Security Act in 42 United States Code, Section 1396a (a) (28),

skilled nursing facility; Section 1396d(c), intermediate care facility; and Section 1396d(d), intermediate care facility for the mentally retarded. HE 22

6. "Commissioner" means the Commissioner of Health and includes any duly authorized representative of the commissioner.

7. "Construction or modification" means:

a. Any erection, building, alteration, renovation, reconstruction, conversion of any existing building, modernization, improvement, expansion, extension or other acquisition by or on behalf of a health care facility which:

(1) Requires a total capital expenditure in excess of $150,000; or

(2) Changes the bed capacity of a health care facility by more than ten beds or more than ten percent of the facility's total licensed bed capacity, whichever is less, over a two year period following the most recent bed capacity change, in a way which:

(a) Increases the total number of beds; or

(b) Changes the distribution of beds among various categories; or

(c) Relocates beds from one physical facility or site to another;

b. Any capital expenditure in excess of $150,000 by or on behalf of a health care facility, which is used to acquire diagnostic or therapeutic equipment. If the equipment is being updated rather than totally replaced, the capital expenditure ~~will~~ shall be ~~based upon~~ considered to be the cost of the equipment parts to be replaced, ~~or added~~ plus the cost of manufacturer's labor and installation, as well as any related financing costs ~~incurred~~ which are considered, according to generally accepted accounting principles, to be incurred; form chge

c. Any expansion or extension of the scope or type of existing health service by a health care facility which requires a capital expenditure in excess of $50,000 during any consecutive 12 month period for that service. Change in scope or type of existing service means the difference between the

range and nature of the present service and the range and nature of the services contemplated under the proposal. An expansion or extension does not occur if ~~there~~ the result is solely increased efficiency of operations or increased square footage or spatial allocation. An expansion or extension shall occur if at least one of the following factors is ~~directly associated with~~ required by or a direct result of the proposed project:

(1) ~~An~~ A material increase in volume of services provided;

(2) The ability to perform treatments or procedures not previously performed;

(3) ~~An~~ A material increase in personnel associated with the capital expenditure;

(4) A material change in proportion of patient mix; or

(5) A material change in geographic source ~~or~~ of referrals to the facility;

d. Any establishment of a new health care facility;

e. Any reviewable predevelopment activity by or on behalf of a health care facility; or

f. Any establishment by a health care facility of a new institutional health service, other than a home health service, which is to be offered in or through that facility and which was not offered on a regular basis in or through that facility prior to the twelve months before that service ~~which~~ will be offered under the terms of the proposal.

8. "Direct patient care service" means any health service designed to provide diagnosis, treatment, nursing, preventive care, rehabilitative care or habilitative care to any person.

9. "Exemption" means the decision by the commissioner to authorize an HMO or health care facility to proceed with a project reviewable under the Act, without request for a waiver or application for a certificate of need.

10. "Evidence" means any exhibit, oral or written testimony or other data or information submitted to an HSA prior to the close of the public hearing for the purpose of affecting

the determination of whether a certificate of need should be issued.

11. "Health maintenance organization" or "HMO" means any organization which operates or proposes to operate pursuant to Minn. Stat. SS 62D.01 to 62D.29.

12. "Hearing body" means:

a. The governing body of an HSA;

b. In the case of the Metropolitan Council, the Metropolitan Health Board; or

c. For HSAs other than the Metropolitan Council, a project review committee, the membership of which ~~conforms to~~ complies with the requirements of Minn. Stat. S 145.845, clauses (2), (3), (4) and (5) and 7 MCAR S 1.661 C.2.b.(2).

chge per FoF 4

13. "HSA" means health systems agency as defined in the Act, Minn. Stat. S 145.833, subd. 7.

14. "HSP" means health systems plan as defined in the Act, Minn. Stat. S 145.833, subd. 10.

15. "Institutional health service" means any health service as defined in the Act, Minn. Stat. S 145.833, subd. 3, wherever and however that health service is provided.

16. "Long range development plan" means a health care facility's written description of its present and anticipated configuration of health services which is developed in consideration of the HSP for the health care facility's health service area.

17. "On behalf of" means in the ~~interests~~ principal interest of, at the behest of, or for the principal benefit of, a health care facility ~~or other entity~~.

HE 26-29

18. "Patient" means any person receiving care in a health care facility and is synonymous with the term "resident."

FoF 35.

~~18.~~ 19. "Predevelopment activity" means any activity by or on behalf of a health care facility or any person which involves architectural designs, plans, working drawings, specifications, feasibility studies, surveys, site acquisitions, contractual agreements, legal services, fund-raising and any other related pursuit and which occurs with intention to embark

upon a program of construction or modification.

a. "Reviewable predevelopment activity" means any predevelopment activity which occurs with intention to offer or develop a new institutional health service if:

(1) The predevelopment activity would require an expenditure in excess of $150,000; or

(2) The predevelopment activity involves any arrangement or committment for financing the new institutional health service.

b. "Non-reviewable predevelopment activity" means any predevelopment activity not included in ~~7 MCAR § 1.661 B.18.~~ a. form chge

~~19. "Patient" means any person receiving care in a health care facility and is synonymous with the term "resident."~~

20. "Project" means the proposed construction or modification. Project is used synonymously with proposal.

21. "Provider" means any person:

a. Whose primary occupation involves, or involved within the last 12 months previous to appointment to the HSA, provision of health services to individuals or the administration of health care facilities or other health service activities;

b. Who is, or was, within the 12 months previous to appointment to the HSA, employed by a health care facility as a health or mental health professional; FoF 35

c. Who has a fiduciary interest in or position with a health care facility or other entity which has the provision of health services as its primary purpose;

d. Who has, or has had within the twelve months previous to appointment to the HSA, a material financial interest (more than one-fifth of the person's gross annual income) from any one or a combination of the following: FoF 35

(1) Fees or other compensation for research into or instruction in the provision of health care;

(2) Producing or supplying drugs or other materials, articles or devices for individuals in the provision of, research into, or instruction in health care;

(3) Issuing any policy or contract of ~~individual or group~~ a health insurance company, a health service plan or a health maintenance organization; FofF 35.

(4) Any other material financial interest in rendering of a health service; or

e. Who is a spouse of an individual described in items a., b., c. or d. above.

22. "Recommendation of the HSA" means the report of the HSA to the commissioner which contains its recommendation as to what action should be taken with respect to judging ~~applications~~ if an application is complete or incomplete, if a project is subject to review, if a waiver should be granted or if a certificate of need should be issued. The recommendation includes submission to the ~~commission~~ commissioner of all information presented by the applicant and delineation of all ~~rationale~~ rationales developed by the HSA to support its recommendation.

23. "Region" means the geographic area designated by the Secretary of the United States Department of Health and Human Services upon recommendation of the Governor to be under the jurisdiction of an HSA for the purposes of health systems planning.

24. "Requester" means a licensed medical doctor or a group of licensed medical doctors, however legally organized.

25. "State Health Plan" means the document, developed by the ~~SPA~~ Department of Energy, Planning and Development pursuant to 42 United States Code, Section 300m-3 (c)(2)(A) and (B), which addresses statewide health needs and incorporates the HSPs of all Minnesota HSAs ~~pursuant to 42 U.S.C. 300k, Section 1524(c)(2)(A and B)~~. change per FofF 5

~~26. "SPA" means the State Planning Agency established pursuant to Minn. Stat. SS 4.10 to 4.17.~~ form chge.

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

1. Membership of HSA. HSAs may specify in their corporate bylaws provisions regarding eligibility for

membership, categories of members and similar items.

2. Membership ~~for~~ of the HSA governing body.

a. Each HSA shall select from its membership a governing body to conduct its business and to carry out its duties and functions. The Metropolitan Council shall use its health board to advise it~~, and may delegate any of its functions and duties to the health board and its staff~~. The establishment of a governing body shall not prohibit any delegation of HSA duties and functions to staff except as provided in these rules. Documentation of any such delegation shall be filed with the commissioner.

b. The membership of the governing body~~,~~ and the health board of the Metropolitan Council shall, in addition to complying with the requirements of Minn. Stat. S 145.845:

(1) Be chosen by election or other appropriate method approved by ~~SPA~~ the Department of Energy, Planning and Development and consistent with provisions of ~~42 U.S.C. 300k, et seq.~~ 42 United States Code, Section 3001-1 for a term of office not to exceed three years. No director may serve more than six consecutive years.

(2) Include only residents of, or individuals having their principal place of business in, the region in which the HSA has jurisdiction.

c. The membership of all HSA committees or subcommittees making recommendations to the governing board of an HSA or the Health Board of the Metropolitan Council on proposals for a certificate of need shall consist of a majority of consumers, and it shall include ~~representatives of the interests of~~ providers.

D. Conflicts of interest.

1. No HSA member or other person who assists the HSA in the review of a project may participate at any level of review, formally or informally, or in discussing or voting upon any project for a certificate of need if a conflict of interest exists. Persons having a conflict of interest, however, may participate in the proceedings in the same manner as any party

who is not a member of a hearing body~~,~~ or the Metropolitan Council.

2. A conflict of interest exists when a person:

a. Has a direct or indirect financial interest in the applicant;

b. Has a contract or has had within the preceding twelve months a contractual, creditor or consultative relationship with the applicant;

c. Is an employee, director, trustee, officer or has another fiduciary relationship with the applicant; or

d. Is a spouse of any person ~~listed in~~ falling under a., b., or c. above. form chge.

3. A person who is a member of a hearing body or the Metropolitan Council and who has a conflict of interest shall declare it in writing to the HSA before it starts its review of the application or when it becomes apparent to him that he has such a conflict.

4. Any person may question the HSA orally or in writing as to whether or not a conflict of interest exists in regard to any person involved in the review of a project on behalf of an HSA. The HSA shall determine in such case whether a conflict of interest exists. ~~Its findings shall be included in the recommendation of the HSA.~~ form chge

5. Any person who has a conflict of interest ~~as determined pursuant to 7 MCAR § 1.661 D.3. and 4.~~ shall be so identified in the recommendation of the HSA. form chge

6. The minutes of the HSA hearing or meeting at which a project is being considered shall record a person having a conflict of interest as "absent" rather than "abstaining due to conflict of interest." Such a person shall not be counted in determining whether a quorum is present for consideration of the application being reviewed. See HE 33 + FofF 9

7. Nothing in this rule precludes any HSA from adopting bylaws or other procedures for determining conflicts of interest which are more stringent than these rules.

E. Ex parte communication.

1. "Ex parte communication" means a written or oral communication by any person as to the merits of an application which is not in a hearing record and with respect to which notice to all parties is not given. The term does not include any requests for status reports on any application, or any communication among HSAs, the SPA Department of Energy, Planning and Development and the commissioner or their staffs which relates solely to information found in a hearing record, the Act, these rules or any application or request for formal action under the Act. form chge

2. Ex parte communication to or among the HSAs, the SPA Department of Energy, Planning and Development, the commissioner or their staffs and any other party, is prohibited, except when the communication relates to an allegation of material misrepresentation, inaccuracy or omission in information necessary to determine whether an action under the Act should be taken. form chge

3. Ex parte communication received by the HSA, SPA Department of Energy, Planning and Development or commissioner shall not be considered in the review of the project and shall not be part of the record, except as provided under E.2. form change HE see 35 + FOF 10, 11

F. Extension of review period.

1. The applicant, the HSA or the commissioner may request that the time periods for review as prescribed in the Act and these rules be extended.

2. The party requesting the extension shall notify the other two parties in writing specifying the length of the extension and the reasons therefor.

3. Within five working days of receipt of the request, the other two parties shall notify the requesting party in writing whether they agree to the extension. If all three parties agree to the extension, the new time period shall be in effect. If the parties do not agree to the extension, the time periods in effect prior to the making of the request shall remain in effect.

~~4. Time periods shall be deemed directory and not~~ HE 37

~~mandatory.~~

G. Time computation.

1. ~~In computing~~ Computation of any period of time prescribed or allowed by these rules ~~or by any applicable statute, the day of the act or event from which the designated period of time begins to run shall not be included~~ shall be controlled by Minn. Stat. SS 645.15 and 645.151. ~~The last day of the period so computed shall be included, unless it is a Saturday, a Sunday or a legal holiday, in which event the period runs until the end of the next day which is not a Saturday, a Sunday, or a legal holiday. When the period of time prescribed or allowed is less than seven days, intermediate Saturdays, Sundays and legal holidays shall be excluded in the computation.~~

2. Whenever a person has the right or is required to do some act ~~or take some proceeding~~ within a prescribed period after the service of a document upon him, or whenever some service is required to be made in a prescribed period before a specified event, and the document is served by mail, the time period for exercising that right or performing that action shall begin to run, ~~under the terms described above,~~ upon receipt of the document and not upon it being mailed. However, an act or event which must be accomplished within a specific time period, shall be considered complete upon mailing of the document.

3. Time periods prescribed under these rules shall be deemed directory and not mandatory.

H. Evasions.

1. ~~A project is a single undertaking when its component parts have been jointly planned, when financing arrangements are made to cover the entire project or when component parts are so interdependent or interrelated that separate review would be inconsistent with the purpose of the Act~~ No health care facility may divide a single project into separate components in order to evade the cost limitations of Minn. Stat. S 145.833, subd. 5. Division of a single project shall be deemed to have occurred if either of the following conditions exists:

a. Components which have been jointly planned are

separated; or

b. Components which are so interdependent or interrelated that they could not feasibly be undertaken separately are separated.

2. The annual capital expenditure budget or long range development plan of the health care facility or health maintenance organization does not ~~necessarily~~, in and of itself, constitute a single undertaking.

~~I. Interpretation of rules. Interpretation of these rules shall be governed by the provisions of Minn. Stat. ch. 645 except insofar as its provisions are in conflict with the definitions or other provisions of the Act or these rules which relate to construction or interpretation of these rules.~~

7 MCAR S 1.662 Determination of applicability and waivers.

A. Submission of notice of intent.

1. ~~Any person shall submit a notice of intent to the appropriate HSA when planning~~ If a person intends to embark upon a program of construction or modification*, as defined in Minn. Stat. S 145.833, subd. 5 and 7 MCAR S 1.661 B.7., prior to engaging in any predevelopment activities with respect to the program of construction or modification, that person shall submit a notice of intent to the appropriate HSA.

2. The notice of intent shall be submitted in writing to the HSA at least 60 days prior to the submission of an application. No HSA ~~shall~~ may accept or act upon an application until proper notice has been given.

3. Within ten days of receipt of a notice, the HSA shall forward a copy of such notice to the commissioner and to ~~SPA~~ the Department of Energy, Planning and Development. Upon receipt of a notice proposing construction or modification, the HSA shall notify the applicant of the schedule for submission of a certificate of need application as established pursuant to 7 MCAR S 1.663 A.

4. The notice of intent shall:

a. Identify the nature of:

(1) Architectural services;

(2) Professional consulting services; ~~or~~ and

(3) Fund-raising services;

b. Identify the name, address, contact person, and planned commencement date for activities listed above;

c. Describe the proposed construction or modification;

d. Estimate the capital expenditure associated with the construction or modification;

e. Specify the intended location or neighborhood of the project; and

f. Estimate the date of commencement of the construction or modification.

5. A notice of intent submitted by an applicant shall not preclude any other person from submitting a notice of intent for a similar undertaking.

6. A notice of intent shall be valid for a one year period within which time an application or an updated notice of intent may be submitted to the HSA.

7. If the applicant provides written verification that the necessity for an application could not have been reasonably anticipated 60 days prior to submission of an application for a certificate of need, the commissioner may reduce the time requirement for advanced submission of a notice of intent to less than sixty days.

B. Determination of applicability.

1. Written determination of applicability of the Act shall be made by the commissioner when an informational request for such determination is submitted from any person directly affected by the proposed construction or modification. Such request may be submitted at any time regardless of whether a notice of intent has been submitted. The foregoing shall not prohibit the commissioner from making his own determination, regardless of whether a notice of intent has been submitted, as to whether a proposed undertaking is subject to review under the Act as part of his general authority to enforce the provisions of the Act.

2. The HSA or the commissioner, when necessary to obtain

all relevant information in order to make a recommendation or to make the final determination respectively, may request additional clarifying information about the proposed undertaking. Any information requested shall relate to the provisions of Minn. Stat. S 145.833, subd. 5, and to 7 MCAR S 1.661 B.7. Failure to supply the information in a timely manner shall be sufficient grounds for determining that the proposed undertaking is subject to the Act.

3. Upon receipt of a request for determination of applicability, the HSA shall, within 30 days, submit a recommendation to the commissioner as to the applicability of the Act to the subject of the request. Within 30 days of receipt of the recommendation from the HSA, the commissioner shall review the matter and the HSA recommendation and shall notify the applicant in writing as to whether the Act is applicable to the subject of the request and the reasons for the decision.

C. Acquisition of equipment by physicians. See HE 48-50 + FoF 18

1. A requester proposing to purchase, lease, or otherwise acquire diagnostic or therapeutic equipment which requires a total capital expenditure in excess of $150,000 for one or more related items of diagnostic or therapeutic equipment shall submit a notice to the HSA and the commissioner of the proposed equipment acquisition. Such notice shall contain the following information:

a. The legal structure or organization of the requester;

b. A description of the equipment which is proposed to be acquired;

c. The proposed location of the equipment;

d. The estimated capital expenditure necessary to acquire the equipment as well as an estimate of those capital expenditures needed for installation and other related costs;

~~e.~~ e. The source of funds to be used to acquire the equipment;

f. The source and estimated volume of patients

utilizing the proposed equipment for the first three years of operation;

g. The party responsible for the operation of the proposed equipment;

h. The recipient of revenue generated by the proposed equipment;

i. The party responsible for any financial losses from the operation of the proposed equipment;

j. Delineation and description of the nature of any proposed existing formal or informal arrangement with a health care facility for use of equipment, including the proportions of total patients who will be either inpatients or outpatients of a health care facility during the time such equipment will be used on or for them; and

k. Whether the requester desires a public hearing.

2. Within 20 days of receipt of the notice, the commissioner shall decide whether the information submitted pursuant to 7 MCAR S 1.662 C.1. is complete.

a. If the commissioner decides that the information is not complete, he shall immediately notify the requester and specify in detail why the information is incomplete and what additional data must be submitted. A determination of incompleteness may occur under the following conditions:

(1) The items specified in 7 MCAR S 1.662 C.1. have not been fully answered or the answers need clarification; or

(2) The answers provided raise additional questions which must be answered in order to fully understand the situation.

b. The 60 day period in which the commissioner must decide whether the proposed acquisition is designed to circumvent the Act shall not commence to run until the commissioner determines that the notice is complete.

3. Within twenty days after the commissioner determines the notice is complete, the HSA shall forward comments to the commissioner regarding the proposed acquisition of the equipment and may request that a hearing be held.

4. If a hearing is requested by the requester or the HSA, a public hearing shall be held pursuant to the Administrative Procedure Act. The hearing results shall be considered to be fact-finding and advisory to the commissioner.

5. The following ~~factors~~ direct or circumstantial evidence shall be considered in determining whether a proposed acquisition is designed to circumvent the Act:

a. The existence of an explicit agreement to circumvent the Act;

~~a.~~ b. The projected proportion of patients who will use the equipment while also being inpatients or outpatients of a health care facility, if such inpatient use is not on a temporary basis, such as a result of a natural disaster, major accident or equipment failure;

~~b.~~ c. The existence of a relationship between the requester and a health care facility for purposes of making available the proposed equipment to the health care facility;

HE SO + FOF 18

~~c.~~ d. The needs ~~for~~ of a health care facility to purchase such equipment if the proposed equipment were not acquired by the requester;

e. The past occurrence of a denial of a certificate of need for the same or similar equipment to a health care facility the patients of which would receive health services from the requester as a result of the proposed acquisition;

f. The financial ability of a health care facility to purchase or acquire the same or similar equipment, if patients of the health care facility would receive health services from the requester as a result of the proposed acquisition;

g. The past or present existence of an intention to acquire such equipment, as expressed in its long range development or other plan, on the part of a health care facility, the patients of which would receive health services from the requester as a result of the proposed acquisition;

~~d.~~ h. The accrual to a health care facility of material benefit from the proposed acquisition ~~to a health care facility~~ and that, if the acquisition were made by the health

care facility, the project would be reviewable under the Act; ~~or~~ and

~~c.~~ i. The existence of other information which shows that the acquisition of the equipment ~~will result in circumvention of~~ is designed to circumvent the Act.

6. Within 60 days of determining the notice to be complete, the commissioner shall review the notice, any hearing record and hearing examiner recommendation and any information submitted by the requester, HSA and other persons, and make a decision as to whether the proposed acquisition is designed to circumvent the Act. The applicant and the HSA shall be informed in writing of the commissioner's ~~decisions~~ decision and underlying rationale.

7. If the commissioner decides that the proposed acquisition is designed to circumvent the Act, a certificate of need must be obtained according to the process described by the Act and these rules.

D. Waivers.

1. A proposed construction or modification involving an existing health care facility may be granted a waiver based upon the information forwarded by the HSA with its recommendation and the determination of the commissioner that the factors in 7 MCAR S 1.662 D.2. are substantially fulfilled and that any one of the following situations exists:

a. The proposed construction or modification falls within the situations described in Minn. Stat. S 145.835, subd. 4(a) or (b).* Additional examples or items that come ~~with~~ within subd. 4(b) are business related equipment, telephone systems, energy conservation measures, warehouse storage, activities space, ~~real estate~~ site acquisition and other projects of a like nature.

b. The proposed project is solely for acquisition of diagnostic or therapeutic equipment which is to replace existing equipment only when the existing and replacement equipment have approximately the same capabilities.

c. The proposed project~~:~~

~~(1)~~ is subject to Minn. Stat. S 145.833, subd. 5 (a)(2) which governs changes in bed capacity of a health care facility; ** and

~~(2)~~ is not reviewable under any other provisions of the Act or these rules~~; and~~

~~(3) If approved, would have no material impact on health planning consideration or on the provisions of health services within the facility's health service area.~~

d. The proposed project is solely to conduct reviewable predevelopment activity pursuant to 7 MCAR S 1.661 B. ~~18.~~19.a.

e. The proposed project is solely for acquisition of an existing health care facility and the change is not reviewable under the provisions of the Act other than 7 MCAR S 1.661 B.7.a.(1).

2. Waiver shall be granted for projects involving eligible situations if the following factors ~~shall~~ be are substantially fulfilled ~~as a prerequisite for granting of waivers~~:

a. The proposed project shall not result in an increase in patient charges of more than five percent over existing charges in either the average charge for all patients or the average charge for those patients who will benefit from the project; provided, for proposed waiver of changes in bed categories involving federal certification status of nursing homes, the proposed project shall not result in an increase in patient charges of more than 20 percent over existing charges in either the average charge for all patients or the average charge for those patients who will benefit from the project. The ~~five~~ ~~percent~~ percentages shall be calculated after including any projected inflation increases based upon~~, for hospitals,~~ the allowable increase limit established by the commissioner pursuant to 7 MCAR S 1.504 ~~and, for other health facilities, a comparable inflation indicator established by a government agency~~.

b. The applicant has documented that the project:

(1) Is not unnecessarily duplicative of similar services in the facility's service area;

(2) Will ~~not~~ be ~~underutilized~~ adequately utilized compared with minimal utilization rates consistent with the efficient delivery of health care; and

(3) Will ~~not~~ otherwise result in an ~~ineffective or inefficient operations~~ effective and efficient operation.

c. The proposed project conforms to the facility's long range development plan, if any, and to the guidelines, criteria and goals for such services in the applicable HSP, AIP and the State Health Plan.

d. The applicant is not a health care facility against whom proceedings pursuant to Minn. Stat. S 144.55 or 144A.11 have been initiated. This factor shall not be considered if the proposed construction or modification is intended to correct, to the extent practicable, the causes of the violations.

3. The request for a waiver shall be submitted by the applicant to the HSA at the same time as submission of a notice of intent for a proposal would have been submitted ~~and~~. In situations in which the applicant has previously submitted a notice of intent alone, nothing shall preclude the applicant from submitting an amended or updated notice of intent concurrently with the waiver request. The waiver request shall include the following information:

a. Description of the project;

b. Estimated capital expenditures;

c. Annual operating budget of the current year;

d. Anticipated impact of the project on facility costs and patient charges; and

e. Information pertaining to the factors for a waiver specified in 7 MCAR S 1.662 D.2.b.

4. The HSA shall not proceed with a recommendation until complete information is received. If any additional information is requested of an applicant, it shall be relevant to the eligibility standards specified in 7 MCAR S 1.662 D.1. and the factors specified in 7 MCAR ~~S~~S 1.662 D.2.

5. Within 30 days of the receipt of a request accompanied by complete information, the HSA shall submit to the commissioner its recommendation for granting or denying the waiver. This recommendation shall be accompanied by supporting rationale based on the applicable item in 7 MCAR S 1.662 D.1. and the factors in 7 MCAR S 1.662 D.2. and all information submitted by the applicant.

6. Within 30 days of receipt of the recommendation of the HSA, the commissioner shall notify the applicant and the HSA of the decision.

7. Emergency waivers may be granted by the commissioner if the need for the project is a result of fire, tornado, flood, storm damage or other similar disasters.

a. The applicant shall submit a written request for an emergency waiver to the commissioner with a corresponding copy sent to the HSA. This request shall describe the project, estimated cost and type of disaster which occurred.

b. Within three working days, the HSA shall forward a recommendation and comments to the commissioner.

c. Within five working days of the receipt of the request from the applicant, the commissioner shall notify the applicant and HSA of the decision to grant or deny an emergency waiver.

d. An emergency waiver shall be granted if the need for the project is a result of fire, tornado, flood, storm damage or other similar disaster, and if both of the following conditions are found to exist:

(1) Adequate health care facilities are not available for the people who previously used the applicant facility; and

(2) The projected repair does not exceed the guidelines and goals for such services in the applicable health systems plan or State Health Plan.

e. A request for an emergency waiver shall be limited in nature and scope to only those repairs necessitated by fire, tornado, flood, storm damage or similar disasters.

8. For purposes of Minn. Stat. S 145.842 and for the periodic reports in 7 MCAR S 1.664 E. of these rules, granting of a waiver of certificate of need review shall be considered to have the same effect as issuance of a certificate of need.

9. The applicant shall resubmit a request for a waiver if the construction or modification for which a waiver was initially granted is not commenced, as described in 7 MCAR S 1.664 C., within 18 months of the granting of waiver or within 90 days of the granting of an emergency waiver.

10. A project may not be separated into component parts if the granting of a waiver for one part would not subject the remaining parts to certificate of need review and if, when all parts are taken together, the project constitutes a single undertaking which is reviewable under the Act. If, however, the remaining component parts of a project would still be subject to review, a waiver may be requested for a specific component part of a project. F&F 35.

7 MCAR S 1.663 Review process, procedures, and criteria.

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

1. The commissioner shall establish a schedule specifying dates when applications may be submitted to the applicable HSA. The schedule may be revised periodically by the commissioner subject to a 60 day notice which shall be printed in the State Register and shall be provided to each HSA by written notice. The schedule shall provide that all applications may be submitted ~~not~~ as specified but in no case less frequently than every 30 days. HE 64

2. Fourteen copies of an application for certificate of need shall be submitted. The HSA, immediately upon receipt of the application, shall send a copy to both the commissioner and the ~~SPA~~ Department of Energy, Planning and Development. form

3. The application shall be submitted on a form prepared by the commissioner and available through the HSA. Forms shall be printed for:

a. Hospitals;

F&F 35

b. Nursing homes and boarding care homes; ~~and~~

c. Supervised living facilities certified or proposing to be certified as intermediate care facilities for the mentally retarded and persons with related conditions. This form shall allow substitution of acceptable alternative sets of pertinent information which have been prepared for the Department of Public Welfare to carry out its responsibility for determination of need, location and programming for the mentally retarded and for the purposes of program licensure and rate setting. In order to be acceptable substitutes, alternative sets of information shall be identifiable according to the topics specified in 7 MCAR S 1.663 A.4.; and

d. Other applicants.

4. The following information and other clarifying information shall be considered to be germane to the project and shall be in a prescribed form, as related to each type of application described in 7 MCAR S 1.663 A.3.

a. Description of the project.

(1) A description of any building or services to be constructed, modified or provided, including a comparison to existing building and services.

(2) A description of the present number and kinds of staff positions and those new staff positions to be created by the project, as well as the basis for anticipation of the successful recruitment of these new staff positions.

(3) A statement from the architect or other construction specialist describing the status of the project's conformance with applicable building codes and state licensure and federal certification requirements for physical plants.

(4) A description of the methods and projected costs of providing energy for operating the project, as well as methods of conserving energy.

(5) A statement of the anticipated dates for commencement and completion of the project.

b. Financial aspects of the project.

(1) Capital expenditures and financing.

(a) The estimated total capital expenditure for the project. There shall be a breakdown of the total capital expenditure based upon the following eight categories. The information provided with respect to each category shall include the major component expenditures within the category.

(i) Predevelopment activity;

(ii) Site acquisitions;

(iii) Land improvements;

(iv) New construction of buildings;

(v) Renovations of buildings;

(vi) Fixed equipment;

(vii) Movable equipment; and

(viii) Financing costs and any contingencies.

(b) A description of the effect of this project on the general solvency of the applicant, including the future effect on financial indicators, including ratio of debts to total assets, operating revenue to total assets, operating revenue to fixed assets, total revenue to fixed assets and interest to total expense plus interest.

(c) A description of the availability and method of financing, including the amount of all projected loans, refinancing of existing debt (if any), estimated interest rate and the projected debt service amount as a percentage of the cost per patient day, or, for hospitals, as a percentage of cost per adjusted admission, as defined in 7 MCAR S 1.472 U.

(2) Operating costs. An estimate of the total annual operating costs upon completion of the project for at least five years. The total annual operating costs shall include anticipated salary requirements of new staff. The estimated costs shall conform with the cost centers and other requirements of at least one of the following:

~~(i)~~ (a) The requirements for cost allocation under Title XVIII of the Social Security Act, 42 ~~U.S.C. S 1395,~~ ~~et seq.~~ United States Code, Section 1395x and 42 Code of Federal Regulations, Sections 405.401-405.406 and 405.453;

~~(ii)~~ (b) The requirements for cost allocation

under Title XIX of the Social Security Act, 42 ~~U.S.C.~~ S United States Code, Section 1396a, ~~et seq.~~ and 42 Code of Federal Regulations, Sections 405.401-405.406 and 405.453;

~~(iii)~~ (c) The requirements for cost allocation under Minn. Stat. SS 144.695-144.703 (Minnesota Hospital Rate Review System); or

~~(iv)~~ (d) The cost allocation requirements utilized in generally accepted reports by applicants to any other agency or program of the State of Minnesota.

(3) Revenue.

(a) An estimate of the total annual revenue of the health care facility upon completion of the project for at least five years.

(b) A description of the anticipated effect of the project for the first five years of operation on the total patient charges per ~~outpatient~~ patient visit or service if applicable, and in the case of hospital projects, the total patient charges per adjusted admission as defined in 7 MCAR S 1.472 U. Average patient charges by service which are affected by the project shall be detailed.

(c) Where a health care facility does not already exist, a projection of the anticipated patient charges for the first five years of operation.

c. Geographic area to be served.

(1) A narrative description of and graphic identification of the health care facility's service area or areas, in terms of standard political boundaries.

(2) An identification of patient origin data, local surveys and other sources utilized in determining the service area of the project.

d. Requirements of the population served.

(1) Current and projected population for the ~~next~~ anticipated life of the project or 20 years, whichever is less, by applicable demographic categories, such as age, sex and occupational status, which will be served by the project and identification of sources of the information.

(2) Incidence and prevalence rates of diagnoses or conditions within the population related to the services proposed.

(3) The impact of the project upon the health needs of people who have traditionally experienced difficulties in obtaining equal access to health care.

(4) A description of the applicant's performance during the past five years related to access to health services including:

(a) Extent to which the facility met its obligations, if any, under federal regulations or state rules requiring provision of uncompensated care, community services or access to programs receiving federal financial assistance;

(b) The extent to which Medicare, Medicaid and medically indigent patients are served by the applicant; and

(c) The range of methods by which a person may have access to its services, such as, outpatient services, admission by house physicians or admission by physicians in the community.

e. Relationship to other health care facilities.

(1) Existing institutions within and contiguous to the proposed project that offer, or propose to offer, the same or similar service;

(2) The occupancy or utilization rates of the similar existing institutions during the past five years, only if such information is accessible to the applicant.

Determination of incompleteness shall not be made solely because the applicant is unable to provide occupancy or utilization information for existing institutions due to inaccessibility of such information to the applicant;

amended per HE 70

(3) The anticipated effect that the project will have on existing facilities and services; and

(4) The relationship of the project to health professional training programs, biomedical and behavioral research projects and medical referral facilities.

f. A description of the applicant's participation, if HE 71

any, in consumer choice health plans and ~~programs with which the applicant participates including~~ any other methods for offering health services based upon giving the purchaser choices in services and knowledge about the price and quality of such health services. The description shall include:

(1) Current and five-year projected number of consumers involved and

(2) ~~Methods of~~ Procedures by which public information regarding ~~cost~~ price and quality of health services will be made available to potential consumers and payors.

HE 71

g. Anticipated need for the facility or service to be provided by the project and identification of the factors which create the need, including at least the following:

(1) Data, information and findings collected by the applicant which establish need for each service component of the project; and

(2) Relationship of the project to the facility's long range development plan.

h. Occupancy and utilization rates.

(1) Occupancy rates for the health care facility, based on both licensed beds and on beds which are set-up and staffed, for the following:

(a) Each of the past five years;

(b) Each of the preceding 12 months; and

(c) Each of the first five years after completion, including explanation of assumptions.

(2) Utilization rates for the health services related to the projected project for the following:

(a) Each of the past five years;

(b) Each of the preceding 12 months; and

(c) Each of the first five years after completion, including explanation of assumptions.

i. A copy of all survey reports during the last three years of operation from the Minnesota Department of Health~~, as well as voluntary survey groups, related to the quality of care provided by the health care facility during the past three years~~

HE 72, 73 + F of F 35

~~of operation~~ or from other quality assurance programs recognized in federal or state laws, such as the accreditation program of the Joint Commission on Accreditation of Hospitals. HE 72, 73 FoF 35.

j. Alternatives which were considered and found not to be acceptable as a substitute for the project and the reasons why they were determined to be unacceptable.

k. Relationship of project to the HSP, AIP and State Health Plan including established planning objectives pertaining to cost, availability, accessibility, need, quality and financial viability of health services.

B. Determination of completeness.

1. Within ten days of the receipt of an application the HSA shall review the application's contents and forward a recommendation to the commissioner and ~~SPA~~ the Department of Energy, Planning and Development as to whether it is complete. form If the recommendation states that the application is incomplete, the HSA shall identify the sections which it found to be incomplete~~,~~ and explain why it concluded that they were incomplete. A determination of incompleteness may occur under the following conditions:

a. The items specified in 7 MCAR S 1.663 A.4. have not been fully addressed or the information needs clarification.

b. The information provided raises ~~additional~~ definite questions ~~which must be answered~~ directly relevant to the proposed project and which are critical and essential in order for the HSA and commissioner to perform their review under the Act and these rules. per HE 71

2. Within ten days of receipt of the recommendation from the HSA, the commissioner, after reviewing the application in conjunction with the HSA recommendation and comments, shall notify the applicant, HSA and ~~SPA~~ Department of Energy, Planning and Development in writing as to whether the application is complete. form If the application is declared incomplete, the applicant shall be informed what additional information must be submitted.

a. If the applicant submits the required additional

information to the HSA, SPA Department of Energy, Planning and Development and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA Department of Energy, Planning and Development within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the application may be found to be complete without being deferred to another cycle of reviews.

b. If the required information is submitted after five working days, but within 60 days of receipt of the commissioner's determination, the complete review will be made according to the schedule specified pursuant to 7 MCAR S 1.663 A.1. The result of this clause is that the application is considered for completeness in the next cycle of the commissioner's completeness determination process.

c. If an applicant has not fully responded to a request for additional information within 60 days of the request, the incomplete application shall be returned to the applicant.

3. A determination that an application is complete shall mean only that information has been given pertaining to each component part of the application as prescribed in 7 MCAR S 1.663 A.4. Determination that the application is complete shall carry no implication with respect to the quality of the information nor shall it preclude the HSA or the commissioner from requesting additional clarifying information during the review period.

4. The 60 day review period on the HSA level shall commence on the date that the HSA receives the notice from the commissioner that the application has been determined to be complete.

C. HSA hearing process and procedures for determining recommendations on certificate of need applications. No proposal may be reviewed nor may any recommendation on an application be made by an HSA in a manner which does not comply

with the Act or these rules.

1. Upon determination by the commissioner that the application is complete, the HSA shall schedule the date, time and place of a public hearing at which a determination will be made as to whether to recommend issuance of a certificate of need.

2. Notice of the hearing shall be published in a legal newspaper as required in Minn. Stat. S 145.837, subd. 2(2). The notice shall contain a brief description of the project and the date, time and place of the hearing. A separate notification shall be mailed to all other affected persons, including at least the applicant, any contiguous HSA and all health care facilities located in the applicant's proposed service area. This separate notification shall contain information similar to that in the published notice, except that contiguous HSAs shall be requested to provide written comment prior to the public hearing or to appear at the public hearing to offer an opinion as to the need for the project and the factual basis for that opinion.

3. A hearing body shall conduct the public hearing. The chairman of the hearing body, or a member designated by the chairman, shall be the presiding officer and shall conduct the hearing and rule on all motions and on the admissibility of all evidence and testimony. The presiding officer shall designate a hearing secretary who shall tape record the proceedings and provide to the commissioner a verbatim transcript or a written summary of the hearing.

4. A majority of the members of the hearing body shall constitute a quorum. No hearing may be held ~~or~~, form nor recommendation made ~~or~~ nor any other action be taken unless a quorum is present.

5. The hearing body, if other than the governing body of the HSA, shall forward its recommendation, findings of fact, conclusions and all evidence to the governing body, which shall vote on the project as required in 7 MCAR S 1.663 C.7. The governing body shall not hear or receive evidence other than

that forwarded by the committee unless it holds an additional hearing after first publishing a notice of hearing pursuant to the Act and 7 MCAR S 1.663 C.2.

6. All interested persons shall be given the opportunity to be heard, to be represented by counsel, to present any relevant oral or written evidence and to examine and cross-examine witnesses. The applicant and any person who testifies orally or otherwise submits evidence or testimony at the hearing shall be subject to questioning by any member of the hearing body. All relevant evidence shall be heard and considered, and the inadmissibility of such evidence in a court of law shall not be grounds for its exclusion. Evidence presented in the form of governmentally issued or sponsored planning documents, studies and guidelines, such as the State Health Plan and health systems plans, shall be ~~given substantial weight but shall not be considered conclusive~~ specifically considered. The hearing may be recessed to another day if the hearing body ~~find~~ finds that additional evidence or time is necessary. When the presiding officer determines that all available and relevant evidence has been heard, the hearing body shall then commence its deliberations. HE 79

7. The hearing body, if other than the governing body of the HSA, and the governing body, after receipt of a hearing body's recommendation and necessary deliberation, shall vote on the project as follows:

a. After a motion has been made with respect to the project, each member present and qualified to vote, including the chairman or presiding officer, shall vote, or abstain from voting, on the motion. The vote of each member, or the fact of his abstention, shall be recorded in the minutes of the hearing or meeting.

b. No member may vote on behalf of a member not present.

c. A motion for approval of a project shall not pass unless a majority of the members voting, including abstentions, vote in favor of the motion. Failure to obtain a majority vote

in favor of approval shall constitute the recommendation of denial.

d. An approval of the project with revisions may be recommended based upon findings of fact, conclusions and supporting evidence pursuant to 7 MCAR S 1.663 G.

(1) Within 30 days after the receipt of the HSA recommendation, the applicant shall notify the HSA and the commissioner by certified mail as to whether it accepts or rejects the revisions.

(2) If the applicant does not respond or rejects the revisions, the recommendation of the HSA to the commissioner shall remain as a recommendation for approval with revision including the findings of fact and conclusions which support revision of the application.

8. The recommendation of the HSA shall be forwarded to the commissioner and ~~SPA~~ the Department of Energy, Planning and Development in the format prescribed in 7 MCAR S 1.663 G.

9. If the applicant decides to withdraw from the review, it shall so inform the HSA and the commissioner in writing.

D. Consolidated review of life support transportation service projects. If a project subject to review under the Act is also subject to review under the process described in Minn. Stat. S 144.802 for the licensure of life support transportation services, a single consolidated review of the project may occur in conformance with Minn. Stat. SS 144.802 and 145.836 and the ~~recommended process described in attachment~~ commissioner will make available to anyone who requests it a recommended process for consolidated review. In order to facilitate consolidated review of such projects, the HSA shall, upon agreement of the applicant pursuant to Minn. Stat. S 145.837, subd. 3, extend its certificate of need review period from 60 to 90 days to coincide with the 90 day life support transportation service licensure review period prescribed in Minn. Stat. S 144.802, subd. 3(d). Within that 90 day period, the HSA shall make both recommendations to the commissioner. If mutual agreement pursuant to Minn. Stat. S 145.837, subd. 3, cannot be reached,

the HSA shall attempt to make both the licensure and certificate of need recommendations within the 60 day period. If the HSA finds that making both recommendations within the 60 day period is not possible, it shall make the certificate of need recommendation within the 60 day period and a separate licensure recommendation within 90 days, as ~~requested~~ form required by Minn. Stat. S 144.802, subd. 3(d).

E. Review criteria. In reviewing a proposal, the HSA and the commissioner shall consider all evidence in the record and shall evaluate the evidence based upon the following factors, where applicable. In addition, these factors shall be specifically addressed in the findings of fact and conclusion required by 7 MCAR S 1.663 G.

1. Health plans and population needs.

a. The relationship of the project to, and the degree to which it is consistent with, the applicable HSP, AIP and State Health Plan.

b. The relationship of the project to, and the degree to which it is consistent with, the applicant's long range development plan.

c. The need for the project as determined by past, present and future utilization data with specific attention given to the following:

(1) Utilization rates of similar facilities within the facility's health service area for the most recent five years;

(2) Utilization rates of the existing facility or service for the most recent five years; and

(3) Five-year projected utilization rate for the proposed expanded facility or service.

d. The need for the project based upon the population requirements of the affected service area with specific attention given to the following:

(1) The population required to support the project, examined by demographic categories such as age, sex and occupational status;

(2) Incidence and prevalence rates of diagnoses or conditions within the population related to the services proposed by the project;

(3) The contribution of the project in meeting the health needs of people who have traditionally experienced difficulties in obtaining equal access to health care, in particular low income persons, racial and ethnic minorities, women, handicapped persons and other groups identified as priorities in the HSP. If the project involves a reduction, elimination or relocation of a health service and the project is otherwise reviewable under the Act, consideration shall be given to the extent which the project will affect the ability of affected members of these above priority groups to obtain needed health care. HE 80

(4) The past performance of the applicant in meeting its obligations, if any, under the applicable federal regulations or state rules requiring provisions of uncompensated care, community service or access by minorities and handicapped persons to programs receiving federal financial assistance, including the existence of any substantiated civil rights access complaints against the applicant.

(5) The extent to which Medicare, Medicaid, and medically indigent patients are served by the applicant.

(6) The extent to which the applicant offers a range of methods by which a person may have access to its services, such as, outpatient services, admission by house physicians or admission by personal physicians in the community.

2. Alternative approaches and system-wide effects.

a. The availability and adequacy of other less costly or more effective health care facilities and services which may serve as alternatives or substitutes for the whole or any part of the project.

b. The relationship of the project to the existing health care system in the area, including the possible economies and improvements which may be derived from operation of joint, cooperative or shared health care resources. Specific

consideration shall be given the following:

(1) The effect of the project on use, capacity, and supply of existing health care facilities and services.

(2) The possibility of increasing referrals to other health care providers to achieve higher utilization of existing resources.

(3) The degree to which the project facilitates the development of an integrated system of services among health care providers.

(4) The possibility of consolidating services with other health care providers.

(5) The existence of formal arrangements established between the applicant and other health care providers to provide similar or supporting services to that being proposed.

c. Preferred alternative uses of resources included in the application, including such resources as health care providers, management personnel and funds for both capital and operational needs, for the provision of other health services by the applicant, as identified by the applicable HSP, AIP and State Health Plan.

d. The effect of the project on the clinical needs of health professional training programs in the area, including access of such programs to the project.

e. The needs for and availability of services and facilities for osteopathic physicians and patients.

3. Price competition among similar services. Improvements or innovations in the financing and delivery of the proposed health services which foster price competition in a way that promotes quality assurance and cost effectiveness. Such consideration shall include:

a. The degree of participation by the applicant in consumer choice health plans ~~and programs~~, such as health maintenance organizations and preferred medical provider programs, and other methods for offering health services based upon giving the purchaser choices in services and knowledge about the price and quality of such health services; and

HE 82

b. The existence of ~~methods~~ procedures by which public information regarding ~~cost~~ price and quality of health services will be provided to potential consumers and payors. HE 82

4. Applicant and project attributes.

a. The availability of resources, including health manpower, management personnel, physical facilities and funds for capital and operating needs for the project.

b. The immediate and long-term financial feasibility of the project with specific analysis of the following:

(1) The comparison of the anticipated revenues with the anticipated expenses including an analysis of whether or not the estimated revenues and expenses appear accurate; and

(2) The impact of the project upon the immediate and long-term financial solvency of the facility.

c. The impact of the project on operational costs and patient charges with specific analysis of the following:

(1) The reasonableness of the proposed cost of the project compared to similar projects; and

(2) The reasonableness of proposed operating costs and impact on patient costs and charges compared with similar services in similar health care facilities.

d. The organizational and other relationship of the project to ancillary or support services including an analysis of the following:

(1) The availability of necessary ancillary or support services and arrangements made by the applicant for provision of those services;

(2) The development of multi-institutional arrangements for sharing support services.

e. The costs and methods of providing energy for the operation of the project including consideration of methods for conserving energy.

f. The quality of care as reflected in the most recent survey reports from the Minnesota Department of Health and other ~~generally accepted survey organizations~~ quality assurance programs recognized in federal or state laws, such as the HE 83 + FoF 35

accreditation program of the Joint Commission on Accreditation of Hospitals. FofF 35

5. Special ~~considerations~~ needs and circumstances. ~~The review criteria specified above shall be considered in light of the special needs and circumstances of any applicant meeting at least one of the descriptions listed in this section as it relates to the project.~~ see HE 84 + FofF.

a. The special needs and circumstances of medical teaching, research facilities and referral facilities which provide a substantial portion of their services or resources, or both, to individuals outside of the health service area. Consideration shall also be given as to whether:

(1) The instruction, studies or consultation provided by the applicant is coordinated with other medical teaching, research facilities and referral facilities in the multi-health service area served by the applicant; and

(2) The project contributes to meeting the health service needs of the residents of the health service area.

b. The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need for which local conditions offer special advantages.

c. The special needs of hospitals to convert excess beds to long-term care or other alternative functions, but only where the termination of all acute care services is proposed and only if a need for the number of proposed long-term care beds can be shown to be consistent with the HSP.

F. Revisions.

1. A project may be revised by the applicant, the HSA or the commissioner at any time during the review process if:

a. The revision is acceptable to the HSA and the applicant; and

b. The revision is within the scope of the project as initially proposed.

2. For purposes of the Act and these rules, a revision shall be considered to be within the scope of the project as

initially proposed if the revision is clearly and closely related to the proposed construction or modification and does not directly involve health services, physical plant, equipment or other services unrelated to the project as initially proposed.

G. Content of record. After making its recommendation, the HSA shall submit to the commissioner three copies of the complete record, absent the application which is part of the record and previously submitted to the commissioner. It shall include at least the items listed in this rule and when forwarded to the commissioner shall be in the following order:

1. A cover letter which includes:

a. Pertinent dates relating to the review including, but not limited to, dates of submission of application, determination of completeness, meetings of project review committee, holding of the public hearing and recommended action by the HSA;

b. Description of the project;

(1) If the project voted upon by the HSA is the same as proposed in the application, a summary only shall be provided; or

(2) If prior to the vote of the HSA, the project has been revised upon agreement of the HSA and applicant, a detailed description as revised shall be provided.

c. Estimated capital cost of the project; and

d. The recommendation of the HSA limited solely to a statement whether or not a certificate of need should be issued, denied or issued with revisions. Any revision shall be stated.

2. Proof of publication of the notice of the public hearing;

3. A summary of evidence presented at the public hearing;

4. The recommendation of the HSA which shall contain the following parts:

a. Findings of fact which shall be based upon each applicable review criterion in 7 MCAR S 1.663 E.; provided, however, that for each project recommended for approval, written findings shall take into account the current accessibility of

the facility as a whole and shall be based upon the criteria listed in 7 MCAR S 1.663 E.1.d.(1),(3),(4),(5) and (6);

b. Conclusions which shall be based on the findings of fact;

c. A recommendation which shall be based on conclusions; and

d. A record of the vote of each member of the HSA on all motions made with regard to the project.

5. Copies of all written evidence considered by the HSA as follows:

a. HSA staff reports and attachments;

b. Committee reports and attachments;

c. Any relevant correspondence between the HSA and the applicant;

d. All additional evidence submitted by the applicant, if not inserted into specific sections of the application; and

e. Any relevant evidence submitted by other affected persons including comments from contiguous HSAs.

H. Determination by commissioner.

1. The role of the commissioner in deciding whether or not a certificate of need should be issued is that of a final, independent decision maker. While the commissioner must base his review on the record presented by the HSA, his review is not merely in an appellate capacity and thus he is not required to adopt the HSA recommendation merely because it is supported by evidence in the record.

2. The commissioner shall review the application and the record presented by the HSA. The review shall include a determination as to whether the procedural requirements of the Act and these rules have been substantially met. The review by the commissioner may include other information not in the HSA record but only in order to assess the necessity of a remand to the HSA for further consideration.

3. Within 30 days of receipt of the recommendation of the HSA, the commissioner shall make one of the following decisions based upon the record as considered in light of the review

factors in 7 MCAR S 1.663 E.

a. Issue a certificate of need. If the commissioner's decision is consistent with the HSA recommendation, the commissioner may adopt the findings and conclusions of the HSA by reference.

b. Issue a ~~revised~~ certificate of need based upon a revised application.

(1) The commissioner may issue a decision ~~conditionally~~ approving ~~a project for~~ a certificate of need ~~provided that the HSA and applicant agree to specified revisions~~ based upon a revised application. Rationale shall be set forth for each revision proposed by the commissioner. ~~The decision shall also specify that the application shall be denied or remanded if the applicant or HSA reject the revisions.~~

HE 85 + FoF 30

(2) If the commissioner proposes a revision of the project, notice shall be mailed to the applicant and the HSA so informing them. Within 30 days after receipt, the applicant and the HSA shall inform the commissioner in writing as to whether or not they accept the revision.

(3) Upon the request of the HSA and the applicant, during the 30 days, the commissioner may amend his ~~final~~ decision by modifying the revisions as proposed ~~with the approval of the HSA and the applicant~~.

(4) The 30 day period in which reconsideration can be requested pursuant to Minn. Stat. S 145.838, subd. 2, or judicial review pursuant to Minn. Stat. SS 15.0424 and 145.838, subd. 3, shall commence to run after receipt by the commissioner of the written notice specifying whether or not the HSA and applicant accept the revisions ~~proposed by the commissioner~~, or if no notice is received, at the end of the 30 day period provided for in ~~section b~~ 7 MCAR S 1.663 H.3.b.(2).

(5) If the HSA and applicant accept the revision, the commissioner shall issue a certificate of need and notify the HSA and ~~SPA~~ Department of Energy, for Planning and Development.

(6) If the applicant or the HSA rejects the revision, the project shall be considered by the commissioner

solely based upon the merits of the application and the record as proposed prior to the rejected revision, without prejudice due to rejection of the revision.

c. Deny a certificate of need. If a project is denied, the commissioner shall set forth in writing rationale for the action and notify the applicant, the HSA and the ~~SPA~~ Department of Energy, Planning and Development. If the commissioner's decision is consistent with the HSA recommendation, the commissioner may adopt the findings and conclusions of the HSA by reference.

d. Remand the application to the HSA.

(1) A remand may occur if, during the review of the HSA record, the commissioner finds that one or more of the following conditions exist and determines that a remand will materially aid in the decision-making process.

(a) Findings of fact were not supported by the record;

(b) Findings of fact were based on inaccurate information in the record;

(c) Significant issues relating to review criteria and other provisions of rules were not addressed by the HSA;

(d) Significant evidence within the record was not addressed by the HSA;

(e) Conclusions were not supported by findings of fact;

(f) Conclusions were based on inaccurate findings of fact;

(g) Significant conclusions were not drawn from findings of fact; ~~or~~

(h) The recommendation was not supported by the conclusions~~.~~; or

(i) The existence of circumstances which arose under 7 MCAR SS 1.661 E.2. and 1.663 H.2. added per F&F 31

(2) The commissioner shall provide the HSA and the applicant with written rationale for the remand action and

instructions for further HSA review.

(3) Within 60 days of receipt of the remand, the HSA shall comply with the commissioner's instructions, hold another public hearing to review the project and forward a recommendation to the commissioner and the SPA Department of Energy, Planning and Development.

I. Determination by the commissioner: life support transportation service projects. For projects subject to review under the Act and also subject to review under the process described in Minn. Stat. S 144.802 for the licensure of life support transportation services, the commissioner shall make a certificate of need decision as provided in 7 MCAR S 1.663H.3. If the HSA submits a certificate of need recommendation and indicates that the life support transportation service licensure recommendation will be submitted separately, ~~and~~ the decision of the commissioner to issue a certificate of need in such a case shall not constitute a decision by the commissioner to issue a life support transportation service license.

7 MCAR S 1.664 Post determination actions.

A. Post determination appeals.

1. If the decision of the commissioner is consistent with the recommendation of the HSA, any person aggrieved by the decision may seek judicial review pursuant to Minn. Stat. S 145.838, subd. 3.

2. If the decision of the commissioner is contrary to the recommendation of the HSA, any person may, pursuant to Minn. Stat. S 145.838, subds. 2 and 3, either request the commissioner to reconsider his decision or seek judicial review.

a. A reconsideration request shall be submitted to the commissioner in writing within 30 days after receipt of the decision by either the HSA or the applicant. The request shall address the applicable condition specified in Minn. Stat. S 145.838, subd. 2(a) to (d). Within 30 days after receiving the reconsideration request, the commissioner shall determine whether to reconsider his decision.

b. If the commissioner determines his decision should

be reconsidered, the matter shall be remanded to the HSA. The HSA shall conduct a new public hearing. The record of the second hearing shall include the record of ~~the~~ each previous hearing~~(s)~~ on the application. The HSA shall issue a new recommendation within 60 days of receipt of the remand from the commissioner. } FoF 35.

c. If the commissioner determines that his decision should not be reconsidered, the HSA or the applicant may within 30 days request an administrative hearing pursuant to Minn. Stat. S 145.838, subd. 2.

3. Any aggrieved person may seek judicial review of the commissioner's decision rendered pursuant to Minn. Stat. S 145.838, subd. 1 or of the hearing examiner's decision rendered pursuant to Minn. Stat. S 145.838, subd. 2 by instituting an action pursuant to Minn. Stat. S 15.0424.

B. Amendment of certificate.

1. After a certificate of need has been issued and before completion of the project, an applicant may find it desirable or necessary to modify the approved project. The types of changes in or modifications to a project are described in 7 MCAR S 1.664 B.2., 3., and 4. When ~~more than one type of~~ a proposed change or modification ~~is proposed~~ falls into more than one of the types prescribed below ("immaterial," "minor," "significant"), the change shall be reviewed according to the ~~type of change~~ category which is most stringent. The effect of those changes on the issued certificate of need are as follows: form change

a. Changes and ~~modification~~ modifications which are immaterial in nature or result (see 7 MCAR S 1.664 B.2.) shall not require any additional certificate of need review.

b. Changes and modifications which are minor in nature or result (see 7 MCAR S 1.664 B.3.) shall not be made unless the commissioner, after review and recommendation by the HSA, issues an amended certificate of need. The review conducted by the HSA and commissioner shall be limited to determining whether or not the changes or modifications are minor as defined in 7 MCAR S 1.664 B.3., that the changes or modifications fall within the

scope of the project as initially approved for a certificate of need, and that the evidence supporting the certificate of need as initially issued supports the changes or modifications.

c. Changes and modifications which are significant in nature or results (see 7 MCAR S 1.664 B.4.) require the submission of a new application and require a full certificate of need review.

2. The following are immaterial changes:

a. Changes in spatial allocation or design;

b. Change in architectural plans to correct a facility's structural deficiencies or to comply with governmental rules or regulations;

c. An increase of less than 10% in the capital expenditure of the project, excluding inflation costs not projected at the time of application for a certificate of need; or

d. Other changes in project detail which will nevertheless result in the implementation of the project as approved.

3. The following are minor changes:

a. An increase of at least 10% but ~~not more~~ form less than 20% of the capital expenditure of the project, excluding inflation costs not projected at the time of application for a certificate of need;

b. Deletions of portions of the originally approved project;

c. Change in financing mechanism which increases the cost of financing; HE 87

d. Change in the selection of health services equipment, if not technologically different from that approved in the certificate; or

e. Change in bed capacity of a facility in a manner which increases the total number of beds, or distributes beds among various categories, by fewer than ten beds or ten percent of the licensed bed capacity, whichever is less.

4. The following are significant changes:

a. An increase equal to or in excess of 20% of the capital expenditure of the project, excluding inflation costs not projected at the time of application for a certificate of need;

b. Change in the type or scope of health service which was originally approved in the certificate;

c. Change in the selection of health services equipment, if technologically different from that approved in the certificate;

d. Change in the geographical location, if such change is relevant to the commissioner's reasons for approval of the certificate of need project; or

e. Change in bed capacity of a facility by more than ten beds or ten percent of the licensed bed capacity; or

f. Changes in the project which raise new material issues not previously considered by the HSA or commissioner related to:

(1) Guidelines, criteria or goals of comprehensive health planning in the applicable HSP, AIP or the State Health Plan;

(2) The quality of care as reflected in survey reports from the Department of Health and in other quality assurance programs recognized in federal and state laws;

(3) The proposed operating cost compared with similar services in similar health care facilities; or

(4) Unnecessary duplication of health care facilities and health services as reflected in governmentally issued or sponsored planning documents, studies or guidelines.

5. The applicant, prior to implementing any minor change in the project, shall submit a written request for an amended certificate to the HSA.

a. The request shall contain a narrative comparison of the approved project and the proposed changes, a description of the cost implications and rationale for the proposed changes.

b. Within 30 days, the HSA shall review the request and forward all information submitted, a recommendation and

HE 89. + Fnd F 37

rationale to the commissioner.

c. Within 30 days of receipt of the HSA recommendation, the commissioner shall review the applicant's request and the recommendation of the HSA and notify the applicant and the HSA in writing of the decision and reasons therefor.

6. The issuance of an amended certificate of need shall not result in the extension of the 18 month period which the applicant has to commence the project under the original certificate of need.

7. If a proposed amendment is not approved, the applicant shall either proceed under the certificate of need as initially issued or shall proceed through a full certificate of need review as a new applicant.

C. Expiration of certificate.

1. Notification of termination date. Pursuant to Minn. Stat. S 145.839, each certificate of need or waiver shall specify the termination date ~~pursuant to Minn. Stat. S 145.839~~.

2. Renewal of certificate or waiver.

a. If a project which had been granted a certificate of need or waiver has not commenced within 18 months, the applicant may submit information to the HSA and commissioner which updates the application and may request renewal of the certificate or waiver for a period up to 18 months.

b. Within 30 days of receipt of the request for renewal of the certificate of need or waiver, the HSA shall submit a recommendation to the commissioner as to whether the project or the reasons for approving the project have ~~changed~~ materially changed or been materially affected since the issuance of the certificate or waiver. If neither the project nor the reasons for approving the project have changed, renewal of the certificate ~~of~~ or waiver shall be recommended.

c. Within 30 days of receipt of the HSA recommendation regarding renewal, the commissioner shall determine whether renewal shall be granted based upon the HSA recommendation regarding renewal. Renewal may be granted for a period up to 18

months.

3. In the case of a construction project, the commissioner shall use all of the following criteria in determining whether the project has commenced:

HE 90 - F&P 33

a. Whether final working drawings and specifications have been approved by the Minnesota Department of Health;

b. Whether construction contracts have been let;

c. Whether a timely construction schedule has been developed stipulating dates for the beginning, various stages and completion of construction;

d. Whether all zoning and building permits have been secured;

e. Whether significant physical alteration of the site has been made and is continuing in accordance with the construction schedule; and

f. Whether other factors related to the above conditions exist.

4. In the case of a project solely involving the acquisition of equipment, the commissioner shall consider the following factors in determining whether the project has commenced:

a. Whether a final purchase order or lease arrangement for all component parts of the equipment has been executed; and

b. Whether the equipment has been delivered and installed or a firm delivery date has been set and a specific schedule has been established for commencing procedures.

5. In the case of offering of a service which does not require facility construction or equipment acquisition, the commissioner shall consider the following factors in determining whether the project has commenced:

a. Whether the new service has been introduced within the facility; and

b. Whether appropriate personnel, as set forth in the application, have been identified and an employment arrangement has been executed for commencing services on a specific schedule.

D. Transfer of certificate or waiver.

1. A certificate of need or waiver shall not be transferred independently of the project with which it is associated. A certificate of need or waiver and the associated project shall not be transferred without the prior approval of the commissioner. A transfer shall be approved by the commissioner if the information submitted pursuant to this section indicates that there will be no material changes in the project as originally approved in the certificate of need or waiver that has been issued.

2. An entity proposing to purchase or otherwise acquire the project and associated certificate of need or waiver shall apply for a transfer by submitting the following information to the HSA and the commissioner:

a. A statement that it agrees to be bound by all the terms and conditions of the certificate of need or waiver originally granted for the project;

b. The financial aspects portion of a certificate of need application or waiver request; and

c. A list of any changes or modifications it proposes to make in the project.

3. Within 30 days after receipt of this information, the HSA shall review the transfer request and shall submit its recommendation to the commissioner. Within 30 days after receipt of the recommendation, the commissioner shall inform the entity requesting the transfer, the HSA and the ~~SPA~~ Department form of Energy, Planning and Development as to whether or not the transfer has been approved and the reasons for the decision.

E. Periodic report.

1. Within 60 days after completion of a project for which a certificate of need was issued or a waiver granted, the applicant shall submit actual capital expenditure information related to the project to the commissioner and the HSA. The information submitted shall compare the estimated costs as outlined in the application with actual costs. A breakdown of costs, as specified in 7 MCAR S 1.663 A.4.b.(1)(a), shall be submitted.

2. If a discrepancy of more than 5% exists between estimated and actual costs in any of the reported line items or the total project cost, the applicant shall explain why the discrepancy occurred and indicate the additional impact on operating costs and patient charges resulting from the additional capital expenditures related to the project.

3. Completion of a project shall mean the earlier of the following:

a. The last payment for construction costs and other fees related to the project is made, not including debt service related to the project; or

b. The involved service is used for its intended purpose.

4. If the involved service is used for its intended purpose before the last related payment is made, an interim report shall be submitted utilizing actual and projected expenditures. In this case, the final report shall be submitted within 60 days after the last payment is made. Additional periodic reports may be required in connection with a revision to a project according to 7 MCAR S 1.663 F.

5. The requirements of this section shall apply to certificates of need and waivers issued or granted since August 1, 1979. If the project was completed prior to the effective date of these rules, the report shall be submitted within 60 days after the effective date of these rules.

~~F. Investigations. For the purposes of enforcement of the Act, the commissioner shall have access to all financial and other records of any entity subject to the Act.~~ deleted per HF93

7 MCAR S 1.665 Applications from health maintenance organizations.

A. An HMO shall be subject to certificate of need review, unless exempt under 7 MCAR S 1.665 C., if it proposes, or undertakes on behalf of an inpatient health care facility, a project involving:

1. Any erection, building, alteration, reconstruction, modernization, improvement, extension, lease, equipment purchase

or other acquisition related to inpatient institutional health services which requires, or would require if purchased, a total capital expenditure in excess of $150,000, and which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance;

2. The obligation of any capital expenditure related to a change in the bed capacity of a health care facility by more than ten beds or more than ten percent of the facility's total licensed bed capacity, whichever is less, over a two year period following the most recent bed capacity change, in a way which:

a. Increases or decreases the total number of beds;

b. Redistributes beds among various categories; or

c. Relocates beds from one physical facility or site to another.

3. The obligation of any capital expenditure which is associated with:

a. The addition of an institutional health service which was not offered within the previous twelve months; or

b. The termination of an institutional health service.

4. The addition of an institutional health service which was not offered during the twelve month period before the month in which the service would be offered, and which entails annual operating costs of at least $75,000; or

5. Acquisition of an existing health care facility if the institutional health services or bed capacity, according to 7 MCAR S 1.665 A.2., will be changed as a result of the acquisition.

B. The following entities may qualify for exemption from certificate of need review if the conditions of 7 MCAR S 1.665 C. are met.

1. An HMO;

2. A combination of HMOs;

3. A health care facility which primarily serves inpatients if it is:

a. Owned, or proposed to be owned, by an HMO ~~or HMOs~~; or

F&F 35

b. Governed by a controlling body which is composed of over fifty percent principal officers or board members of the HMO ~~or HMOs~~; or FoF 35

4. A health care facility, or a portion of a health care facility, leased by an HMO ~~or HMOs~~ for a term of at least 15 years.

C. The conditions which must be met to qualify for exemption are:

1. The applicant shall be "qualified" under Title XIII of the Public Health Services Act, 42 ~~U.S.C.~~ S United States Code, Section 300e or the applicant shall satisfactorily document to the commissioner that the HMO ~~or HMOs have~~ has substantially fulfilled the requirements of Title XIII of the Public Health Services Act, 42 ~~U.S.C.~~ S United States Code, Section 300e. FoF 35

2. At least 50,000 persons shall be enrolled in the pertinent HMO~~(s)~~ and shall have reasonable access to the proposed project; and FoF 35

3. At least 75 percent of the potential patients shall be enrolled in the pertinent HMO~~(s)~~. FoF 35

D. The following procedures shall be followed in applying for exemption of an HMO project from certificate of need review.

1. An application for exemption shall be submitted to the commissioner, HSA and ~~SPA~~ Department of Energy, Planning and Development. The application shall describe the project for which an exemption is sought and shall contain information demonstrating that the HMO meets the conditions for exemption specified in 7 MCAR S 1.665 C. form

2. The HSA or the commissioner, in order to make a recommendation or to make the final determination, may request additional clarifying information about the project. Any information requested shall be pertinent to the provisions of 7 MCAR S 1.665 B. and C. Failure to supply the information in a timely manner shall constitute sufficient grounds for determining that the entity is not eligible for exemption.

3. Within 30 days after the receipt of the request, the HSA shall forward its recommendation and all evidence to the

commissioner. Within 30 days of the receipt of the HSA recommendation, the commissioner shall notify the HMO and the HSA of the decision to grant or deny the exemption and the reason therefor. The commissioner shall approve an application for exemption if the applicable requirements of 7 MCAR S 1.665 B. and C. have been met or will be met on the date the proposed activity will be undertaken.

E. The project granted exempt status may not be sold or leased, a controlling interest in a project may not be acquired ~~and~~ or a health care facility described in 7 MCAR S 1.665 B.3. and 4. may not be used in a manner other than proposed in the project, unless:

~~a.~~ 1. The commissioner issues a certificate of need approving the sale, lease, acquisition, or use; or

~~b.~~ 2. Upon request, the commissioner grants exempt status to such entity.

F. 7 MCAR SS 1.661 through 1.664 shall apply to the review of a certificate of need application submitted by an entity listed in 7 MCAR S 1.665 B. for a non-exempt project. Notwithstanding the general review criteria in 7 MCAR S 1.663 E., if an entity listed in 7 MCAR S 1.665 B. applies for a certificate of need, the commissioner shall approve the project if he finds that:

1. Approval of the project is required to meet the needs of the members of the HMO and of the reasonably anticipated new members of the HMO; and

2. The HMO is unable to provide, through services or facilities which can reasonably be expected to be available to the HMO, its health services in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO and which makes these services available through physicians and other health professionals associated with it. In assessing the availability of these services from other providers, the HSA and commissioner shall consider only whether the services from these providers:

a. Would be available under a contract of at least

five years duration;

b. Would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

c. Would cost no more to the HMO than if the services were provided by the HMO; and

d. Would be available in a manner which is administratively feasible to the HMO applicant.

G. Any party aggrieved by a decision of the commissioner pursuant to 7 MCAR S 1.665 D. may seek judicial review of the commissioner's decision by instituting action pursuant to Minn. Stat. S 15.0424.

[Repealer clause. State Planning Agency rules 10 MCAR SS ~~1.202~~ 1.201 to 1.210 (formerly SPA 201 to 210) are hereby ~~repeal~~ repealed.]

~~* The reader is advised to refer to the definition of "construction or modification" pursuant to 7 MCAR S 1.661 B.7.~~

~~* Minn. Stat. S 145.835, subd. 4. Waivers.~~
~~A proposed construction or modification may be granted a waiver from the requirements of section 145.834 by the commissioner of health if, based on the recommendation of the health systems agency, the commissioner determines that: (a) The proposed capital expenditure is less than three percent of the annual operating budget of the facility applying for a waiver, and the expenditure is required solely to meet mandatory federal or state requirements of the law; or (b) The construction or modification is not related to direct patient care services such as parking lots, sprinkler systems, heating or air conditioning equipment, fire doors, food services equipment, building maintenance, or other constructions or modifications of a like nature.~~

~~** Minn. Stat. S 145.833, subd. 5(a)(2).~~
~~Subd. 5 "Construction or modification" means:~~
~~(a) Any erection, building, alteration, reconstruction, modernization, improvement, extension, lease or other~~

~~acquisition, or other purchase, lease or other acquisition of diagnostic or therapeutic equipment, by or on behalf of a health care facility which:~~

~~(2) Changes the bed capacity of a health care facility in a manner which increases the total number of beds, or distributes beds among various categories, or relocates beds from one physical facility or site to another, by more than ten beds or more than ten percent of the licensed bed capacity, whichever is less, over a two year period.~~

ATTACHMENT

RECOMMENDED PROCEDURE FOR HSA CONSOLIDATED REVIEW

OF

LIFE SUPPORT TRANSPORTATION SERVICE PROJECTS

Relevant Provisions of Certificate of Need Act and Rules

Minn. Stat. S 145.836 APPLICATION FOR CERTIFICATE OF NEED. Subdivision 1. Application procedure. Applications for certificate of need shall be submitted to the health systems agency serving the area in which the proposed construction or modification is to take place. Prior to acting on the application and within ten days of receipt, the health systems agency shall send a copy to the commissioner of health and to the state planning agency with a recommendation that the application be considered either complete or incomplete. The commissioner of health shall determine that the application is initially complete or incomplete within ten days of receipt of a recommendation from a health systems agency. If the application is incomplete, it is not to be considered to be submitted to the health systems agency or the commissioner and it shall be returned stating the specific needs to be met in order for the application to be considered complete.

7 MCAR S 1.663 B. Determination of completeness.

1. Within ten days of the receipt of an application the HSA shall review the application's contents and forward a recommendation to the commissioner and SPA as to whether it is complete. If the recommendation states that the application is incomplete, the HSA shall identify the sections which it found to be incomplete, and explain why it concluded that they were incomplete. A determination of incompleteness may occur under the following conditions:

a. The items specified in 7 MCAR S 1.663 A.4 have not been fully addressed or the information needs clarification.

b. The information provided raises additional questions which must be answered in order for the HSA and commissioner to perform their review under the Act and these

rules.

2. Within ten days of receipt of the recommendation from the HSA, the commissioner, after reviewing the application in conjunction with the HSA recommendation and comments, shall notify the applicant, HSA and SPA in writing as to whether the application is complete. If the application is declared incomplete, the applicant shall be informed what additional information must be submitted.

a. If the applicant submits the required additional information to the HSA, SPA and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the application may be found to be complete without being deferred to another cycle of reviews.

b. If the required information is submitted after five working days, but within 60 days of receipt of the commissioner's determination, the complete review will be made according to the schedule specified pursuant to 7 MCAR S 1.663 A.1. The result of this clause is that the application is considered for completeness in the next cycle of the commissioner's completeness determination process.

c. If an applicant has not fully responded to a request for additional information within 60 days of the request, the incomplete application shall be returned to the applicant.

3. A determination that an application is complete shall mean only that information has been given pertaining to each component part of the application as prescribed in 7 MCAR S 1.663 A.4. Determination that the application is complete shall carry no implication with respect to the quality of the information nor shall it preclude the HSA or the commissioner from requesting additional clarifying information during the review period.

4. The 60 day review period on the HSA level shall commence on the date that the HSA receives the notice from the commissioner that the application has been determined to be complete.

Minn. Stat. § 145.837, Subd. 2. Review procedures. In reviewing complete applications, the health systems agency shall:

(1) Hold a public hearing;

(2) Provide notice of the public hearing by publication in a legal newspaper of general circulation in the area for two successive weeks at least ten days before the date of such hearing and notify affected persons which shall include at least the applicant and other persons subject to review, contiguous health systems agencies, the health care facilities located in the health service area and which provide institutional health services, and the rate review agency;

(3) Allow any interested person the opportunity to be heard, to be represented by counsel, to present oral and written evidence, and to confront and cross-examine opposing witnesses at the public hearing;

(4) Provide a transcript of the hearing at the expense of any individual requesting it, if the transcript is requested at least three days prior to the hearing;

(5) Make written findings of fact and recommendations concerning the application. The commissioner of health shall promulgate by rule the required findings of fact which shall address the criteria specified in subdivision 1, and the provisions of the National Health Planning and Resources Development Act, 42 U.S.C., Section 300k, et seq. The findings of fact and recommendations shall be available to any individual requesting them; and

(6) Follow any further procedure not inconsistent with sections 145.832 to 145.845 or sections 15.0411 to 15.052, which it deems appropriate.

Within 60 days after the commissioner has determined the application to be complete, the health systems agency shall make its recommendation to the commissioner of health. The health

systems agency shall either recommend that the commissioner of health issue, deny or issue with revisions a certificate of need for the proposed construction or modification. The reasons for the recommendation shall be set forth in detail.

7 MCAR § 1.663 C. HSA hearing process and procedures for determining recommendations on certificate of need applications.

No proposal may be reviewed nor may any recommendation on an application be made by an HSA in a manner which does not comply with the Act or these rules.

1. Upon determination by the commissioner that the application is complete, the HSA shall schedule the date, time and place of a public hearing at which a determination will be made as to whether to recommend issuance of a certificate of need.

2. Notice of the hearing shall be published in a legal newspaper as required in Minn. Stat. § 145.837, subd. 2(2). The notice shall contain a brief description of the project and the date, time, and place of the hearing. A separate notification shall be mailed to all other affected persons, including at least the applicant, any contiguous HSA and all health care facilities located in the applicant's proposed service area. This separate notification shall contain information similar to that in the published notice, except that contiguous HSAs shall be requested to provide written comment prior to the public hearing or to appear at the public hearing to offer an opinion as to the need for the project and the factual basis for that opinion.

3. A hearing body shall conduct the public hearing. The chairman of the hearing body, or a member designated by the chairman, shall be the presiding officer and shall conduct the hearing and rule on all motions and on the admissibility of all evidence and testimony. The presiding officer shall designate a hearing secretary who shall tape record the proceedings and provide to the commissioner a verbatim transcript or a written summary of the hearing.

4. A majority of the members of the hearing body shall

constitute a quorum. No hearing may be held or recommendation made or other action taken unless a quorum is present.

5. The hearing body, if other than the governing body of the HSA, shall forward its recommendation, findings of fact, conclusions and all evidence to the governing body, which shall vote on the project as required in 7 MCAR § 1.663 C.7. The governing body shall not hear or receive evidence other than that forwarded by the committee unless it holds an additional hearing after first publishing a notice of hearing pursuant to the Act and 7 MCAR § 1.663 C.2.

6. All interested persons shall be given the opportunity to be heard, to be represented by counsel, to present any relevant oral or written evidence, and to examine and cross-examine witnesses. The applicant and any person who testifies orally or otherwise submits evidence or testimony at the hearing shall be subject to questioning by any member of the hearing body. All relevant evidence shall be heard and considered, and the inadmissibility of such evidence in a court of law shall not be grounds for its exclusion. The hearing may be recessed to another day if the hearing body finds that additional evidence or time is necessary. When the presiding officer determines that all available and relevant evidence has been heard, the hearing body shall then commence its deliberations.

7. The hearing body, if other than the governing body of the HSA, and the governing body, after receipt of a hearing body's recommendation and necessary deliberation, shall vote on the project as follows:

a. After a motion has been made with respect to the project, each member present and qualified to vote, including the chairman or presiding officer, shall vote, or abstain

(1) Within 30 days after receipt of the HSA recommendation, the applicant shall notify the HSA and the commissioner by certified mail as to whether it accepts or rejects the revisions.

(2) If the applicant does not respond or rejects the

revisions, the recommendation of the HSA to the commissioner shall remain as a recommendation for approval with revision including the findings of fact and conclusions which support revision of the application.

8. The recommendation of the HSA shall be forwarded to the commissioner and SPA in the format prescribed in 7 MCAR § 1.663 G.

9. If the applicant decides to withdraw from the review, it shall so inform the HSA and the commissioner in writing.

Relevant Provisions of Life Support Transportation Service Law (Minn. Stat. §§ 144.801-144.8091)

Minn. Stat. § 144.802 LICENSING

Subd. 3. (a) Each prospective licensee and each present licensee wishing to offer a new type or types of life support transportation service, to establish a new base of operation, or to expand a primary service area, shall make written application for a license to the commissioner on a form provided by the commissioner. The commissioner shall promptly send notice of the completed application to the health systems agency or agencies, the community health service agency or agencies, and each municipality and county in the area in which life support transportation service would be provided by the applicant. The commissioner shall publish the notice, at the applicant's expense, in the state register and in a newspaper in the municipality in which the service would be provided, or if no newspaper is published in the municipality or if the service would be provided in more than one municipality, in a newspaper published at the county-seat of the county or counties in which the service would be provided.

(b) Each municipality, county, community health service, and other person wishing to make recommendations concerning the disposition of the application shall make written recommendations to the health systems agency in its area within 30 days of the publication of notice of the application.

(c) The health systems agency or agencies shall:

~~(1) hold a public hearing in the municipality in which the services base of operation is or will be located;~~

~~(2) provide notice of the public hearing in the newspaper or newspapers in which notice was published under part (a) for two successive weeks at least ten days before the date of the hearing;~~

~~(3) allow any interested person the opportunity to be heard, to be represented by counsel, and to present oral and written evidence at the public hearing;~~

~~(4) provide a transcript of the hearing at the expense of any individual requesting it; and~~

~~(5) follow any further procedure not inconsistent with chapter 15, which it deems appropriate.~~

~~(d) The health systems agency or agencies shall review and comment upon the application and shall make written recommendations as to its disposition to the commissioner within 90 days of receiving notice of the application. In making the recommendations, the health systems agency or agencies shall consider and make written comments as to whether the proposed service, change in base of operations, or expansion in primary service area is needed, based on consideration of the following factors:~~

~~(1) the relationship of the proposed service, change in base of operations or expansion in primary service area to current health systems and annual implementation plans;~~

~~(2) the recommendations or comments of the governing bodies of the counties and municipalities in which the service would be provided;~~

~~(3) the duplication, if any, of life support transportation services that would result from granting the license;~~

~~(4) the estimated effect of the proposed service, change in base of operation of expansion in primary service area on the public health;~~

~~(5) whether any benefit accruing to the public health would outweigh the costs associated with the proposed service,~~

change in base of operations, or expansion in primary service area.

The health systems agency or agencies shall recommend that the commissioner either grant or deny a license or recommend that a modified license be granted. The reasons for the recommendation shall be set forth in detail. The health systems agency or agencies shall make the recommendations and reasons available to any individual requesting them.

Recommended Procedure for Consolidated HSA Review (Includes All the Requirements of Both Statutes and Assumes Certificate of Need Review Period Has Been Extended to 90 Days Pursuant to 7 MCAR S 1.663 B.

A. Submission of applications and determinations of completeness

The applicant shall submit a completed licensure application to the commissioner and should also submit a copy to the appropriate HSA. Simultaneously, the applicant should submit a completed certificate of need application to the appropriate HSA.

1. Within ten days of the receipt of the certificate of need application, the HSA shall review the application's contents and forward a recommendation to the commissioner and SPA as to whether it is complete. If the recommendation states that the application is incomplete, the HSA shall identify the sections which it found to be incomplete, and explain why it concluded that they were incomplete. A determination of incompleteness may occur under the following conditions:

a. The items specified in 7 MCAR S 1.663 A.4 have not been fully addressed or the information needs clarification.

b. The information provided raises additional questions which must be answered in order for the HSA and commissioner to perform their review under the Act and these rules.

2. Within ten days of receipt of the recommendation from the HSA, the commissioner, after reviewing the certificate of

need application in conjunction with the HSA recommendation and comments, shall notify the applicant, HSA, and SPA in writing as to whether both the licensure and the certificate of need applications are complete. If either application is declared incomplete, the applicant shall be informed what additional information must be submitted.

a. If the applicant submits the required additional certificate of need information to the HSA, SPA and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the certificate of need application may be found to be complete without being deferred to another cycle of reviews.

b. If the required certificate of need information is submitted after five working days, but within 60 days of receipt of the commissioner's determination, the complete review will be made according to the schedule specified pursuant to 7 MCAR S 1.663 A.1. The result of this clause is that the certificate of need application is considered for completeness in the next cycle of the commissioner's completeness determination process.

c. If an applicant has not fully responded to a request for additional certificate of need information within 60 days of the request, the incomplete certificate of need application shall be returned to the applicant.

d. The applicant should submit any additional information requested to complete the licensure application within the time frames specified in 2 a.-c. so as to assume a consolidated HSA hearing and consolidated determination by the commissioner.

3. If both applications are determined to be complete, the commissioner shall promptly send notice of the completed applications to the HSA(s), community health service agency or agencies, and each municipality and county in the area in which the life support transportation service would be provided by the

applicant. The commissioner shall publish this notice, at the applicant's expense, in the State Register, and in a legal newspaper of general circulation in the municipality in which the service would be provided. If no legal newspaper of general circulation is published in the municipality, or if the service would be provided in more than one municipality, the notice shall be published in a legal newspaper of general circulation published at the county seat of the county or counties in which the service would be provided.

4. A determination that a certificate of need application is complete shall mean only that information has been given pertaining to each component part of the application as prescribed in 7 MCAR S 1.663 A.4. Determination that the application is complete shall carry no implication with respect to the quality of the information nor shall it preclude the HSA or the commissioner from requesting additional clarifying information during the review period.

5. The 90 day review period on the HSA level shall commence on the date that the HSA receives the notice from the commissioner that the applications have been determined to be complete.

B. Any municipality, county, community health service agency, or other person wishing to make recommendations concerning the dispositions of the applications shall make recommendations to the HSA within 30 days of the publication of notice of the applications pursuant to A.3.

C. HSA hearing process and procedures for determining recommendations on consolidated review of certificate of need and life support transportation service licensure applications.

1. Upon determination by the commissioner that the applications are complete, the HSA shall schedule the date and time of a public hearing at which a determination will be made as to whether to recommend issuance of a certificate of need and licensure of a life support transportation service. The hearing shall be scheduled to be held in the municipality in which the service's base of operations is or will be located.

2. Notice of the hearing shall be published in the legal newspaper(s) in which notice of the applications was published pursuant to A.3. The notice shall contain a brief description of the project and the date, time and place of the hearing. A separate notification shall be mailed to all other affected persons, including at least the applicant, any contiguous HSA, and all health care facilities located in the applicant's proposed service area. This separate notification shall contain information similar to that in the published notice, except that contiguous HSAs shall be requested to provide written comment prior to the public hearing or to appear at the public hearing to offer an opinion as to the need for the project and the factual basis for that opinion.

3. A hearing body shall conduct the public hearing. The chairman of the hearing body, or a member designated by the chairman, shall be the presiding officer and shall conduct the hearing and rule on all motions and on the admissibility of all evidence and testimony. The presiding officer shall designate a hearing secretary who shall tape record the proceedings and provide to the commissioner a verbatim transcript or a written summary of the hearing. A majority of the members of the hearing body shall constitute a quorum. No hearing may be held or recommendation made or other action taken unless a quorum is present.

The hearing body, if other than the governing body of the HSA, shall forward its recommendation, findings of fact, conclusions and all evidence to the governing body, which shall vote on the project as required in 7 MCAR § 1.663 C.7. The governing body shall not hear or receive evidence other than that forwarded by the committee unless it holds an additional hearing after first publishing a notice of hearing pursuant to the Act and 7 MCAR § 1.663 C.2.

6. All interested persons shall be given the opportunity to be heard, to be represented by counsel, to present any relevant oral or written evidence, and to examine and cross-examine witnesses. The applicant and any person who

testifies orally or otherwise submits evidence or testimony at the hearing shall be subject to questioning by any member of the hearing body. All relevant evidence shall be heard and considered, and the inadmissibility of such evidence in a court of law shall not be grounds for its exclusion. The hearing may be recessed to another day if the hearing body finds that additional evidence or time is necessary. When the presiding officer determines that all available and relevant evidence has been heard, the hearing body shall then commence its deliberations.

7. The hearing body, if other than the governing body of the HSA, and the governing body, after receipt of a hearing body's recommendation and necessary deliberation, shall vote on the project as follows.

a. After a motion has been made with respect to the project, each member present and qualified to vote, including the chairman or presiding officer, shall vote, or abstain from voting, on the motion. The vote of each member, or the fact of his abstention, shall be recorded in the minutes of the hearing or meeting.

b. No member may vote on behalf of a member not present.

c. A motion for approval of a project shall not pass unless a majority of the members voting, including abstentions, vote in favor of the motion. Failure to obtain a majority vote in favor of approval shall constitute the recommendation of denial.

d. An approval of the certificate of need project with revisions may be recommended based upon findings of fact, conclusions and supporting evidence pursuant to 7 MCAR § 1.663 C.

(1) Within 30 days after receipt of the HSA recommendation, the applicant shall notify the HSA and the commissioner by certified mail as to whether it accepts or rejects the revisions.

(2) If the applicant does not respond or rejects the revisions, the recommendation of the HSA to the commissioner and

shall remain as a recommendation for approval with revision including the findings of fact and conclusions which support revision of the application.

8. The certificate of need recommendation of the HSA shall be forwarded to the commissioner and SPA in the format prescribed in 7 MCAR S 1.663 C.

9. The licensure recommendation of the HSA shall be to issue, deny or issue with modifications a life support transportation service license. The licensure recommendation shall contain the HSA's written and detailed comments as to whether the proposed service, change in base of operations, or expansion in primary service area is needed, based on consideration of the factors specified in Minn. Stat. S 144.804, subd. 3(d).

10. If the applicant decides to withdraw from the review, it shall so inform the HSA and the commissioner in writing.

OFFICE OF THE REVISOR OF STATUTES

Certificate of Approval of Adopted Rules

Agency: Department of Health

Rule Numbers: 7 MCAR SS 1.661-1.665

Rule Title: Implementing, Enforcing, and Administering the Minnesota Certificate of Need Act, Minn. Stat. SS 145.832-145.845, and Repealing State Planning Agency Certificate of Need Rules, 10 MCAR SS 1.201-1.210

Type of Rules: Permanent X

Temporary ____

Documents Incorporated by Reference:
Only those permitted by statute.

The attached Rules are approved as to form.

Steven C. Cross
Revisor of Statutes

Name: Roger J. Helder, Jr.

Title: Assistant Revisor

Phone: 297-2948

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

FINDINGS, CONCLUSIONS, AND ORDER ADOPTING RULES

The above-entitled matter came on for hearing before Jon L. Lunde, Hearing Examiner from the Office of Hearing Examiners, on the 9th day of June, 1981, at 9:30 a.m., and continuing through the morning of June 10, 1981, in Room 111, William Mitchell College of Law, 875 Summit Avenue, St. Paul, Minnesota, after proper notice required by Minn. Stat. § 15.0412 was served upon all persons, associations and other interested groups registered with the Commissioner of Health (hereinafter "Commissioner") for that purpose. Notice was also served upon other persons, associations and groups of which the Commissioner was aware of as possibly having an interest in the above-captioned rule. The proposed rules and Notice of Hearing were duly published in the State Register.

After affording interested persons an opportunity to present written and oral data, statements, and arguments, having heard and considered all of the testimony and evidence adduced and upon the records, files, and proceedings herein and applicable statutory standards or criteria, and confirming the need for and reasonableness of the above-captioned rules, the Commissioner makes and enters the following:

FINDINGS OF FACT

1. The Findings of Fact portion of the Report of the Hearing Examiner (herinafter "Report") dated August 6, 1981, is hereby adopted and made a part hereof except as noted in the following paragraphs.

2. Finding 6 of the Report (at 2) is amended to read as follows:

6. The Department complied with Minn. Stat. §§ 145.835, subd. 4, and 145.837, subd. 1. The provisions direct the Commissioner to promulgate rules, but only after consulting with the State Planning Agency (SPA) and the HSA, regarding the granting of waivers and governing health systems agencies (HSAs) in their certificate of need determinations respectively. Minn. Stat. § 145.845 specifies that rules regarding membership in HSAs shall be adopted by the Commissioner after consultation with the SPA. The Department also complied with this requirement. In addition, the Department has entered into a contract with the SPA as referenced in Minn. Stat. § 145.834.

The amendment consists of including a statement in the Finding to the effect that the Department had also complied with Minn. Stat. § 145.845, which required the consultation with the SPA prior to promulgating rules concerning membership of HSAs. This change was necessary because the Hearing Examiner had inadvertently left out reference to the Commissioner's compliance with this requirement.

3. The Hearing Examiner noted in Finding 8 (at 4) that the Department needs to comply prior to final adoption of these rules, with Minn. Stat. § 15.065 (1980) and with Minn. Laws 1981, ch. 360, § 14. Prior to noticing the rules for hearing, the issues raised by these statutory provisions were explicitly considered by the Department. Calculations by the Department established that the promulgation or implementation of the proposed rules would not trigger either of the financial thresholds specified. There are many reasons for this conclusion. They include the fact that in most instances any fiscal impact arises from the underlying Certificate of Need Act and not these rules per se. In addition, the waiver provisions established by the rules will actually result in reduced expenditures. The Commissioner therefore finds that neither Minn. Stat. § 15.065 (1980), nor Minn. Laws 1981, ch. 360, § 14, requires any further action by the Department.

4. Upon further review and at the suggestion of the Revisor of Statutes, 7 MCAR § 1.661 B.12.c. has been amended by making the statutory and rule references in it more specific. Not all of the provisions in the statutory and rule references were relevant requirements for membership of a project review committee. Therefore, by specifying exactly what subsections of the statutes and rules cited were relevant, the rule has been improved because it now expresses the requirements more clearly. Accordingly, the rule as amended now reads:

c. For HSAs other than the Metropolitan Council, a project review committee, the membership of which ~~conforms to~~ complies with the requirements of Minn. Stat. § 145.845 (2), (3), (4) and (5) and 7 MCAR § 1.661 C.2.b. (2).

5. Two changes were made in 7 MCAR § 1.661 B.25. The first one merely consists of rearranging the sentence structure so that the various phrases of the sentence are placed in a better order. The second change corrects the citation to federal law. The fact that the citation was not totally accurate could not have significantly misled anyone. Indeed, no one asked for clarification of the citation. Anyone who works in health planning knows what the State Health Plan is without having to refer to the federal law. Furthermore, the definition could have stood alone without any citation. It was placed in the rule merely as a point of reference and without any substance for the meaning of the rule. With these changes, the rule now reads:

25. "State Health Plan" means the document, developed by the SPA pursuant to 42 U.S.C. § 300m-3(c)(2)(A) and (B), which addresses statewide health needs and incorporates the HSPs of all Minnesota HSAs ~~pursuant to 42 U.S.C. 300k, Section 1524(c)(2)(A and B).~~

6. Minn. Rule 7 MCAR § 1.661 B.26. has been deleted in its entirety. The rule defined "SPA" as meaning the State Planning Agency. It has been deleted because the State Planning Agency has been abolished and all of its powers, duties, and functions have been transferred to the newly created Department of Energy, Planning and Development. Minn. Laws 1981, ch. 356, § 65, subd. 1. This transfer of authority, however, is a continuation of the authority of the State Planning Agency. Minn. Laws 1981, ch. 356, § 65, subd. 8.

7. All references in the rules to the State Planning Agency have been removed and replaced with Department of Energy, Planning and Development. These Findings will not list every specific rule in which the change was made.

8. Finding 31 in the Report (at 13) states that the Department had not demonstrated the authority to permit the Metropolitan Council to delegate responsibility to the Metropolitan Health Board. See 7 MCAR § 1.661 C.2.a. The proposed rule was an attempt to reflect Minn. Stat. § 145.833, subd. 7 (1980), which specifically provides for the Council to appoint a health board to advise it. The intent of the Department was not, however, to enable the delegation of final decision-making authority by the Metropolitan Council. Therefore, the

Commissioner accepts the Hearing Examiner's recommended deletion to correct the defect. Accordingly, 7 MCAR § 1.661 C.2.a. has been amended to read:[1/]

2. Membership for the HSA Governing Body.

a. Each HSA shall select from its membership a governing body to conduct its business and to carry out its duties and functions. The Metropolitan Council shall use its health board to advise it~~, and may delegate any of its functions and duties to the health board and its staff~~. The establishment of a governing body shall not prohibit any delegation of HSA duties and functions to staff except as provided in these rules. Documentation of any such delegation shall be filed with the Commissioner.

9. The Hearing Examiner found in Finding 33 (at 14) that the Department established the need for and reasonableness of 7 MCAR § 1.661 D.6. This rule requires that persons with a conflict of interest be excluded from thise counted for purposes of determining whether a quorum exists at any HSA meeting or hearing. However, the Hearing Examiner suggested, based upon the comments of several HSAs, that the possibility that such quorum requirements might not be met be addressed further in rule by the Commissioner. The Commissioner appreciates the suggestion of the Hearing Examiner, but declines to accept it for several reasons. One primary reason is that none of the HSAs who objected to the rule submitted any factual data, based upon their years of operational experience, which supported their view that the rule would have a deleterious effect. Furthermore, as the Department's Statement of Need and Reasonableness notes (at 34), the statute relies heavily upon the maximum degree of local participation possible. To alter the position taken in the conflict of interest area would be to retreat from the Legislature's concerns for significant local involvement in these types of decisions. HSAs which encounter difficulties with this rule have several options. A hearing could be reconvened at a later date at which a quorum would be available. Also, if HSA directors who could be a part of such quorums are repeatedly absent, the HSAs can make provisions for removal and replacement of such persons. To permit a deviation from the position demonstrated as necessary

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1/ In this section of the rules and in a number of others quoted herein, the Department had already amended the section as noted in the Post Hearing Supplemental Comments of Minnesota Commissioner of Health. The amendments were to some part of the section other than that reference herein. In those instances where the section was previously amended by the Post Hearing Supplemental Comments, the changes made therein will not be reflected here by underline and strikeout.

and reasonable, when these (and probably other) alternatives are available to the HSA, would lend credence to an approach effectively characterizing membership on an HSA board as a sinecure - an approach which the Commissioner rejects, especially in view of the aforementioned Legislative purpose of maximizing local participation.

10. Finding 35 of the Report (at 15) states that the Department established the need for and reasonableness of 7 MCAR § 1.661 E., as amended by the Department's post-hearing comments. It also suggests that the rule be further amended to provide that ex parte communications made a part of the record be subject to cross-examination by any party. The Commissioner appreciates the thrust of the suggestion, but feels that the Department's proposal, when read together with another section of the rules, generally addresses the procedural due process concerns raised. Ex parte communications which would find their way into the record would effectively be subject to cross-examination by affected parties under 7 MCAR § 1.663 H.2. This provision limits the Commissioner's consideration of material outside the HSA record to the assessment of the necessity of a remand. If, based upon such a communication, the Commissioner decided to remand the matter to the HSA for further consideration, parties affected thereby could plainly cross-examine the communication and its offeror. Thus, the Commissioner would never consider nonrecord material in his final decision-making process. This approach also deals with another issue. By tying decisive ex parte communications into the remand process, it assures a greater possibility of full local involvement, as encouraged by the purpose clause of the Act (Minn. Stat. § 145.832). Providing an opportunity for cross-examination at the Department of Health level would not be as consistent with the purpose clause of the Act as would providing the opportunity at the HSA level. Because of the foregoing, the rules as finally adopted will reflect the post-hearing submission of the Department, rather than the Hearing Examiner's recommendation.

11. The Hearing Examiner recommended in Finding 36 (at 15-16) that the Commissioner adopt, as a portion of the rule relating to ex parte communications, a provision permitting the filing of exceptions and argument with the Commissioner with respect to the HSA recommendation and evidence in the record if "all other parties" have notice of such communications.

Both suggestions would present serious policy and practical problems if adopted in rule. First, the process as established in the Certificate of Need Act both with respect to the amount of time that the Commissioner has to make his decision as well as with respect to the role of the Commissioner vis a vis that of the recommendation of the HSA leads to the conclusion that the submission of additional written argument to the Commissioner is neither necessary nor appropriate. The Commissioner has only 30 days in which to make his decision. Given that the Commissioner always has a number of HSA recommendations before him for review, and especially now in times of reduced staffing, the Commissioner cannot afford any decrease in the amount of time he has to review each certificate of need application. To allow additional submissions would result in a reduction of the Commissioner's review period because the comments would address the HSA record and recommendation. The Commissioner's review period would begin to run once the recommendation was issued. He simply could not wait to begin his review until after written comments were received even if that meant only a short delay of five or ten days.

With respect to the record, it is created during the HSA's 60 day review period. During that time the facts are established, and ample opportunity, before committees, at a hearing, and at any time during the review by written submission, is given to all interested persons to comment upon and argue about the impact and meaning of those facts as to whether they demonstrate a need for the project. From this record the HSA decides upon a recommendation to be submitted to the Commissioner. The Commissioner, however, does not merely determine whether the recommendation is supported by substantial evidence. Instead, the Commissioner conducts his own independent review of the record and reaches his own decision regarding issuance of the certificate of need. See 7 MCAR § 1.663 H.1. Because of this procedure, all of the arguments regarding the facts are in the record. There should be no need to merely repeat them anew to the Commissioner. Furthermore, argument on the recommendation of the HSA is not necessary because of the Commissioner's independent decision-making role.

Allowing the submission of comments to the Commissioner also poses serious practical problems with respect to identifying the "affected parties" who

are to receive notice of the submissions. The certificate of need review process is unlike judicial or contested case proceedings where the parties are clearly identified. Certainly, in these circumstances, the class of "affected parties" ought not to be so narrowly construed as to include merely the HSA and the applicant. In numerous situations, members of the public and other providers may have spoken to the merits of an application at the hearing and should reasonably be identified as "parties" for purposes of notice of communications received by the Commissioner after the close of the HSA record. There are also, however, an unknown number of persons who refrain from giving testimony at the HSA level for any of a variety of reasons but who might wish to communicate with the Commissioner about the content of any communication he may have received after the close of the HSA record. For example, a member of the public may have refrained from comment upon the merits of a proposal to build a full service hospital because he thought, based on the area's health systems plan and the positive recommendation of the HSA's project review committee (hearing body), that there was no need of further support. A communication could be received by the Commissioner which urges deletion of one or more of the services to be provided by the hospital, based on evidence in the record. Inasmuch as the member of the public had not been identified in the record as a "party," it would be almost impossible to specifically notify him of this communication. About the only way that notification of persons like him and all other "parties" could be made would be in the same manner as notification is made of the HSA hearing. This would seem to be ponderous, however, and at odds with the scheme laid out in the statute. The statute envisions a hearing on the merits to take place at the HSA level. It is plain that the debate about the merits is to take place within the HSA developed record. The statute does not contemplate a virtual replication of this process at the Department level; on the contrary, it is oriented against such an approach as discussed above.

It is also recognized that there are very few instances in which further argument from the parties at this level might have any public benefit. Plainly, when a party has slept on his rights and failed to take action on the notice provided by publication in conformance with the statute and rules, other parties and the general public should not be penalized by reopening the matter on the merits, even if limited to evidence clearly already in the record. Such a result would permit inappropriate strategic manipulation of the process by malevolently motivated

actions to produce patent inequity or an inappropriate curtailment of the procedural due process rights of the parties who have not slept on their rights.[2/]

For the above reasons then, the Commissioner declines to accept the Hearing Examiner's recommendation; the adopted rule contains the proposal by the Department found to have been necessary and reasonable by the Hearing Examiner.

12. Minn. Rule 7 MCAR § 1.661 G.1. has been amended to read:

G. Time Computation.

1. ~~In computing~~ Computation of any period of time prescribed or allowed by these rules ~~or by any applicable statute, the day of the act or event from which the designated period of time begins to run shall not be included~~ shall be controlled by Minn. Stat. §§ 645.15 and 645.151. ~~The last day of the period so computed shall be included, unless it is a Saturday, a Sunday or a legal holiday, in which event the period runs until the end of the next day which is not a Saturday, a Sunday, or a legal holiday. When the period of time prescribed or allowed is less than seven days, intermediate Saturdays, Sundays and legal holidays shall be excluded in the computation.~~

Because the Legislature acted during the 1981 session to make the provisions of Minn. Stat. ch. 645 applicable to rules as well as statutes (Minn. Laws 1981, ch. 253, § 35) there was no need to have a separate provision in the rules governing time computation which was similar to the standards specified in chapter 645. However, 7 MCAR § 1.661 G.2. is still necessary as it governs situations not covered by chapter 645.

13. The Hearing Examiner found in Finding 39 (at 17) that the Department's approach to dealing with evasions under the Certificate of Need Act was generally necessary and reasonable.[3/] The Commissioner agrees with the

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2/ Notwithstanding the foregoing, the rules do recognize certain narrow situations when additional information could be presented to the Commissioner for his review. Parties affected thereby should have notice of such information and the opportunity to cross-examine it or its offeror. These situations are specified in proposed 7 MCAR §§ 1.661 E.2. and 1.663 H.2. The Commissioner's review of such information would only be for purposes of determining the necessity for remand under 7 MCAR § 1.663 H.2. The remand, of course, would provide to any party and consistent with the Act's emphasis on local planning, notice of and opportunity to cross-examine such a communication at the local level.

3/ In his Finding 40, the Hearing Examiner found a portion of the evasion rule unreasonably vague. See discussion below in Commissioner's Finding 14 with respect to this issue.

conclusion of the Hearing Examiner that 7 MCAR § 1.661 H. is authorized, generally necessary and reasonable, and consistent with the Legislative intent of not combining separate and distinct sub-threshold projects only to subject them to the Act. The example chosen by the Hearing Examiner in support of his conclusion, however, needs some additional comment. The Commissioner agrees that the Hearing Examiner's example of a hospital in a particular year planning on remodeling its operating rooms, modernizing its cafeteria, and acquiring property for a parking lot is not subject to the Act so long as these actions were not part of an overall plan or joint undertaking and they did not exceed the jurisdictional threshold for a capital expenditure. Lest there be some misunderstanding, however, even a slight modification or addition to the example offered by the Hearing Examiner could result in a project reviewable under the Act. For example, if the purpose for remodeling the operating rooms, enlarging the cafeteria, and acquiring land for parking were to be able to meet the needs of patients in a new outpatient surgery program, and if the combined capital expenditure were in excess of $50,000, the project would be reviewable as an expansion or extension of health services under Minn. Stat. § 145.833, subd. 5(b). The Commissioner has no intention, however, of overreaching his statutory authority, and the Hearing Examiner's example, standing alone, constitutes a type of activity which is not reviewable under the Act. The Commissioner, therefore, adopts Hearing Examiner Finding 39, as clarified by the foregoing.

14. The Hearing Examiner found in Finding 40 (at 17-18) that proposed 7 MCAR § 1.661 H.1., which defines when projects will be determined to be single undertakings for purposes of Certificate of Need review, was, in part, unreasonably vague. The specific portion of § 1.661 H.1. objected to by the Hearing Examiner is the second clause of the rule (as modified by the Department's post-hearing submission at 12) which would characterize a project as a single undertaking "when component parts are so interdependent or interrelated that separate review would be inconsistent with the purposes of the Act." (The remainder of 7 MCAR § 1.661 H. was found to be reasonable and necessary in Hearing Examiner Findings 38 and 39.) The Commissioner has opted not to contest the Hearing Examiner's finding of vagueness. Instead, the Commissioner proposes to restructure and

clarify the rule to make it more specific, yet consistent with the approach of the rule as proposed. This restructuring would require deleting 7 MCAR § 1.661 H.1. as proposed and substituting the following:

H. Evasions

1. A project is a single undertaking when its component parts have been jointly planned, when financing arrangements are made to cover the entire project or when component parts are so interdependent or interrelated that separate review would be inconsistent with the purpose of the Act. No health care facility may divide a single project into separate components in order to evade the cost limitations of Minn. Stat. § 145.833, subd. 5. Division of a single project shall be deemed to have occurred if either of the following conditions exists:

a. Components which have been jointly planned are separated; or

b. Components which are so interdependent or interrelated that they could not feasibly be undertaken separately are separated.

p. 11, 12

The rule as restated repeats the essential language of the provision of statute implemented thereby (Minn. Stat. § 145.841) for purposes of contextual clarity. It then restates the language concerning joint planning, which was found to be necessary and reasonable by the Hearing Examiner. (Finding 39 at 17.) Lastly, the suggestion of the Hearing Examiner as to specific additional clarifying language relating to the infeasibility of separate undertakings is included. Absent the elimination of the phrase found to be unreasonably vague by the Hearing Examiner then, the rule is merely restated with the addition of language recommended by the Hearing Examiner. The necessity and reasonableness of this additional language is supported by the Department's comments in the hearing record and by the fact that the revised wording more clearly sets out the criteria which will be used to determine if an evasion has occurred.

15. Finding 41 (at 18) states that proposed 7 MCAR § 1.661 I., pertaining to the interpretation of rules, was made redundant, and thereby unnecessary, by the passage of Minn. Laws 1981, ch. 253, § 35. The Commissioner concurs with the Hearing Examiner and therefore has deleted proposed rule 7 MCAR § 1.661 I.

p. 12

16. At the suggestion of the Revisor of Statutes, the footnote in 7 MCAR § 1.662 A.1. has been deleted. The footnote advised the reader to refer to the definition of "construction or modification." Instead of the footnote reference,

the statutory and rule citation to the definition of "construction or modification" has been inserted in the rule itself. Reference to these definitions are necessary and reasonable in order to emphasize the substantive content of the defined term. For the purposes of the Certificate of Need law, "construction or modification" is a key term for correct interpretation of this section of the rules. By moving the reference to the term from footnote to rule, no substantial change is made in this rule. The rule now reads as amended:

> 1. If a person intends to embark upon a program of construction or modification* , as defined in Minn. Stat. § 145.833, subd. 5 and 7 MCAR § 1.661 B.7., prior to engaging in any predevelopment activities with respect to the program of construction or modification, that person shall submit a notice of intent to the appropriate HSA.

p. 12

17. Rule 7 MCAR § 1.662 B. permits the Commissioner, inter alia, to make a determination of the applicability of the Act on his own motion. The Hearing Examiner found that this provision was statutorily authorized, necessary, and reasonable. (Finding 46 at 20.) However, the Hearing Examiner suggested that the Department consider proposing an amendment to the Act to make more explicit the Commissioner's authority to initiate determination of applicability requests and that the Department further consider procedures making compliance with the statute more workable. The Commissioner appreciates both suggestions, and will take them under advisement for future action.[4/]

18. In Finding 50 (at 22) the Hearing Examiner suggested that proposed 7 MCAR § 1.662 C.5., dealing with factors to be considered in a determination of whether an acquisition of equipment by physicians is designed to circumvent the Act, be amended to include several additional factors. The Commissioner appreciates the Hearing Examiner's recommendation and accordingly has incorporated these factors into the rule as follows. The amendments noted below also include some minor grammatical changes which were necessary to clarify the rule.

4/ In recognizing the merits of the Hearing Examiner's suggestion, the Commissioner nevertheless rejects the Hearing Examiner's statement that the rule "ignores statutory language." Such a statement is contrary to the Hearing Examiner's findings that the rule is "within the Department's authority" (Finding 45 at 20) and that the statute is "properly construed" (Finding 46 at 20). The Commissioner adopts these latter findings but rejects the former.

5. The following direct or circumstantial evidence shall be considered in determining whether a proposed acquisition is designed to circumvent the Act:

a. The existence of an explicit agreement to circumvent the Act;

b. The projected proportion of patients who will use the equipment while also being inpatients or outpatients of a health care facility, if such inpatient use is not on a temporary basis, such as a result of a natural disaster, major accident or equipment failure;

c. The existence of a relationship between the requestor and a health care facility for purposes of making available the proposed equipment to the health care facility;

d. The needs of a health care facility to purchase such equipment if the proposed equipment were not acquired by the requestor;

e. The past occurrence of a denial of a certificate of need for the same or similar equipment to a health care facility the patients of which would receive health services from the requestor as a result of the proposed acquisition;

f. The financial ability of a health care facility to purchase or acquire the same or similar equipment, if patients of the health care facility would receive health services from the requestor as a result of the proposed acquisition.

g. The past or present existence of an intention to acquire such equipment, as expressed in its long range development or other plan, on the part of a health care facility, the patients of which would receive health services from the requestor as a result of the proposed acquisition;

~~e.~~h. The accrual to a health care facility of material benefit from the proposed acquisition ~~to a health care facility~~ and that, if the acquisition were made by the health care facility, the project would be reviewable under the Act; and

~~f.~~i. The existence of other information which shows that the acquisition of the equipment is designed to circumvent the Act.

amended P16

The necessity and reasonableness of the three additional types of circumstantial evidence are amply supported by the Department's comment in the hearing record, and specifically by the Department's arguments in favor of the need and reasonableness of subsection f. (now subsection i.). The fact that a certificate of need has been denied, the presence of intention to acquire similar equipment, and a facility's ability (or lack thereof) to purchase the equipment are plainly material considerations in connection with an administrative decision in this area.

19. The Hearing Examiner recommended in Finding 52 (at 23), in connection with the availability of waivers for real property acquisitions under

7 MCAR § 1.662 D.1.a., that the Department not substitute the word "site" for the term "real estate." The Hearing Examiner supported this recommendation by correctly noting the possibility that the acquisition of a site might well be a component part of a single undertaking, or construction or modification, and be thereby subject to full review because of the Act's prohibition of separating single projects into component parts in order to erode full review (Minn. Stat. § 145.841). The Commissioner agrees with the Hearing Examiner's conclusion, but believes that such an occurrence is not possible under the full rule relating to waivers, either when read alone, or when read in conjunction with the proposed rule on evasions. Rule 7 MCAR § 1.662 D.10. would prohibit separating a project into component parts if the result would be to render an otherwise reviewable project not subject to review under the Act. This provision addresses the concern of the Hearing Examiner, as shared by the Commissioner. The Commissioner, therefore, will retain the language referring to "site acquisitions" in the rule as last proposed.

✓ P. 17

20. The Revisor suggested that the footnote in 7 MCAR § 1.662 D.1.a. be deleted. The footnote merely quoted the text of 7 MCAR § 145.835, subd. 4. The Commissioner agreed with this recommendation in order to simplify the published text of these rules. The footnote did not have a substantial function in the rules and therefore deletion is not a substantial change.

✓ deleted P. 17

21. Analogous to the previous finding, the footnote in 7 MCAR § 1.662 D.1.c. has been deleted at the recommendation of the Revisor. This footnote quoted the statutory text of Minn. Stat. § 145.833, subd. 5(a)(2). In this case, the Commissioner has determined that it is appropriate to briefly describe the content of the statutory reference. By removing the footnote, the description is necessary in this rule because it makes the clause much more understandable but is not a substantial change because it merely summarizes what was in the footnote. Accordingly, the rule is amended to read:

> c. The proposed project is subject to Minn. Stat. § 145.833, subd. 5(a)(2)*, <u>which governs changes in bed capacity of a health care facility</u>, and is not reviewable under any other provisions of the Act or these rules.

so amended P. 17

22. The Hearing Examiner recommended in Finding 57 (at 24) that the Department delete the "substantially fulfilled" language from 7 MCAR § 1.662 D.2. or define the meaning of the term so that it is clear what is meant. The

Department disagrees with this recommended change on the basis of part of the reasoning described by the Hearing Examiner in Finding 57. He states:

> "When making a determination of whether the criteria have been met, of course, many factors must be balanced and weighed by the Commissioner, and 100 percent or absolute compliance with all the criteria is probably not necessary or possible in any given case."

The "substantially fulfilled" language clearly tells the public that the Commissioner will weigh and balance the evidence applicable to waivers rather than require absolute compliance with the criteria. Requiring total compliance with the criteria could result in having to deny some waiver requests which were otherwise meritorious solely because of some minor aspect which did not totally meet the criteria. The Commissioner proposed the "substantially fulfilled" language to avoid such results. Additionally, the meaning of "substantially fulfilled" does not require further definition. Minn. Stat. § 645.08(1) states that "words and phrases are construed . . . according to their common and approved usage." "Substantially" is defined in Black's Law Dictionary (4th ed.) as "essentially; without material qualification; in the main; in substance; materially; in a substantial manner."

It is needed and reasonable that the public be advised of the Commissioner's intention to apply the "substantially fulfilled" principle. This standard is of sufficient clarity so as to allow for consistent applicant.

23. The Hearing Examiner concluded in Finding 58 (at 24) that the last part of 7 MCAR § 1.662 D.2.a. must be clarified or deleted. The language in question provides that the inflation indicator applicable to facilities other than hospitals shall be "a comparable inflation indicator established by a governmental agency." As an alternative to the proposal presented at the public hearing, the Hearing Examiner recommended that the inflation indicator for hospitals might be the appropriate indicator for other health facilities as well. The Department agrees with the recommendation of the Hearing Examiner. The factors which contribute to the hospital inflation indicator are only minimally different than the contributing factors for other health facilities. Since there are no published inflation indicators currently available for facilities other than hospitals, the hospital inflation indicator is reasonable for all facilities. The need for this rule has been previously justified. Therefore, the Commissioner has changed 7 MCAR § 1.662 D.2.a. as follows:

a. The proposed project shall not result in an increase in patient charges of more than five percent over existing charges in either the average charge for all patients or the average charge for those patients who will benefit from the project; provided, for proposed waiver of changes in bed categories involving federal certification status of nursing homes, the proposed project shall not result in an increase in patient charges of more than 20 percent over existing charges in either the average charge for all patients or the average charge for those patients who will benefit from the project. The percentages shall be calculated after including any projected inflation increases based upon~~, for hospitals~~, the allowable increase limit established by the Commissioner pursuant to 7 MCAR § 1.504 ~~and for other health facilities, a comparable inflation indicator established by a government agency~~.

p. 18

24. The Hearing Examiner recommended in Finding 59 (at 25) that Minn. Stat. § 145.843 be mentioned in the criteria to be used for waiver determinations in 7 MCAR § 1.662 D.2. The Commissioner agrees that a waiver should not be granted when the conditions referenced in Minn. Stat. § 145.843 are met authorizing the denial of a Certificate of Need. It is reasonable and necessary to state the conditions under which such discretion will be exercised and the change would not be substantial. Therefore, the Commissioner proposes the following new clause, which will become 7 MCAR § 1.662 D.2.d.:

d. The applicant is not a health care facility against whom proceedings pursuant to section 144.55 or 144A.11 have been initiated. This factor shall not be considered if the proposed construction or modification is intended to correct, to the extent practicable, the causes of the violations.

p. 19

25. The Hearing Examiner recommended in Finding 60 (at 25) that 7 MCAR § 1.662 D.2.c. clarify the Commissioner's intention to grant a waiver when a facility does not have a long-range development plan if the other review factors are met. The Hearing Examiner pointed out that costs of long-range planning by nursing homes are disallowed by the Department of Public Welfare and the federal regulations related to health planning uses the "if any" language proposed here. For these reasons, the Commissioner agrees that it is necessary, reasonable and unsubstantial to change the rules as suggested by the Hearing Examiner. The modification to 7 MCAR § 1.662 D.2.c. is as follows:

c. The proposed project conforms to the facility's long-range development plan, if any, and to the guidelines, criteria and goals for such services in the applicable HSP, AIP and the State Health Plan.

p. 19

26. The issue of separate survey report submission for all facilities operated by an applicant is raised by the Hearing Examiner in Finding 74 (at 30).

One commentor was concerned that 7 MCAR § 1.663 A.4.i. may require an operator of several facilities to submit fourteen copies of the survey reports from each of the facilities. The Commissioner believes that it is clear that the proposed application contents refer only to "the health care facility" involved in the project. While it would be germane for the HSA or Commissioner to review the broader quality of care history of a health facility operator, the application contents is not intended to include, and does not request, the quality of care information from other facilities. If the Commissioner had desired submission of such survey reports from other health care facilities operated by the applicant, the language of 7 MCAR § 1.663 A.4.i. would have stated "any health care facility operated by the applicant" instead of the limiting language "the health care facility." Therefore, 7 MCAR § 1.663 A.4.i. is concluded to be clear and reasonable as proposed and no amendment is deemed necessary.

27. The Hearing Examiner suggested in Finding 78 (at 33) with respect to 7 MCAR § 1.663 C.2., that the Commissioner consider adding additional groups to the list of those who are to receive mandatory notice of the certificate of need hearing before an HSA when such notice would be consistent with the purposes of the Act. It was argued that organizations such as Human Services Boards and Public Health Nursing Services should receive notice of every hearing because they are involved, in one way or another, with the provision of health services. Application of this logic for mandatory notice would lead to providing notice to just about every existing health service provider. The list of potentially interested provider groups would be very long and providing notice to all of them could become very burdensome. Consequently, it is appropriate to limit mandatory notice to those directly affected by the Act, i.e., health care facilities. While these other groups may have some interest in a given certificate of need application, the connection is much more tangential and remote to the point that does not justify the extra burden or expense associated with providing mandatory notice. This limitation, however, does not mean that other health care providers will not be able to receive notice of the hearings if they are interested. Because the hearing notices must be published in local newspapers, non-health care facilities can monitor the papers for the notices. In addition, they can request the local HSAs to voluntarily notify them of all public hearings. The Hearing Examiner

points out in Finding 74 that the federal regulation 42 C.F.R. § 122.308(a)(2) requires all HSAs to send such notice to all parties who request to be informed of public hearings on Certificate of Need applications in their service area. The Commissioner believes that it is reasonable for this voluntary notice procedure to operate and that it is unnecessary to mandate notice to all health providers in the area.

no change p. 29

28. The Revisor of Statutes recommended that the attachment referenced in 7 MCAR § 1.663 D. be deleted. (The attachment set out a recommended process for consolidated reviews of life support transportation service projects under Minn. Stat. § 144.802 and the Act.) The Commissioner agrees that a similar function can be accomplished by making the recommended process available to the public without publication of the process with the rules. No substantial change is involved because the attachment was never proposed as a rule. Therefore, the attachment at the end of the rules, labeled "Recommended Procedure for HSA Consolidated Review of Life Support Transportation Service Project," is to be deleted and 7 MCAR § 1.663 D. is amended to read:

deleted p. 31

> D. Consolidated review of life support transportation service projects. If a project subject to review under the Act is also subject to review under the process described in Minn. Stat. § 144.802 for the licensure of life support transportation services, a single consolidated review of the project may occur in conformance with Minn. Stat. §§ 144.802 and 145.836 and the ~~recommended process described in the attachment~~ commissioner will make available to anyone who requests it a recommended process for consolidated review. In order to facilitate consolidated review of such projects, the HSA shall, upon agreement of the applicant pursuant to Minn. Stat. § 145.837, subd. 3, extend its certificate of need review period from 60 to 90 days to coincide with the 90 day life support transportation service licensure review period prescribed in Minn. Stat. § 144.802, subd. 3(d). Within that 90 day period, the HSA shall make both recommendations to the Commissioner. If mutual agreement pursuant to Minn. Stat. § 145.837, subd. 3, cannot be reached, the HSA shall attempt to make both the licensure and certificate of need recommendations within the 60 day period. If the HSA finds that making both recommendations within the 60 day period is not possible, it shall make the certificate of need recommendation within the 60 day period and a separate licensure recommendation within 90 days, as required by Minn. Stat. § 144.802, subd. 3(d).

p. 31

29. The Hearing Examiner recommended in Finding 84 (at 36) that the Department adopt two changes in 7 MCAR § 1.663 E.5.a. relating to consideration of the special needs and circumstances of medical teaching, research and referral facilities. The Commissioner agrees with the first recommendation, that is, to add the word "also" to the beginning of the second sentence of 7 MCAR § 1.663 E.5.a. so that it reads:

p. 36

5. Special needs and circumstances.

a. The special needs and circumstances of medical teaching, research facilities and referral facilities which provide a substantial portion of their services or resources, or both, to individuals outside of the health service area. Consideration shall also be given as to whether:

p.36

This change is needed, reasonable and not substantial. It clarifies that the special attributes of these health centers are related but not necessarily the same as the need for coordination with other facilities and contribution to the needs of area residents. These three principles must be weighed by the HSA and Commissioner in the findings and conclusions.

The second recommendation of the Hearing Examiner in Finding 84 was for the Commissioner to adopt Mayo Clinic's suggestion addition to 7 MCAR § 1.663 E.5.a. The language recommended by the Hearing Examiner is not the same as that proposed by Mayo Clinic; however, both proposals would be inconsistent with goals for comprehensive health planning. That is, the applicant in this case has a service area which includes a variable portion of a large number of other service areas, other states and, in the case of Mayo Clinic, other countries. To attempt to include the bed requirements or population of these outside areas would be improper extrapolation of the prospective health needs. The criterion, as proposed by the Commissioner, is necessary and reasonable without further change. It implements the statutory criterion on this subject as well as the purposes of comprehensive health planning.

30. The Hearing Examiner did not recommend any change in 7 MCAR § 1.663 H.3.b. relating to revisions; however, the Commissioner considers it necessary to clarify Finding 85 (at 37) so that there is no misunderstanding in the rulemaking record. The Hearing Examiner stated:

> "The Commissioner, in his post-hearing comments, agreed that if an HSA and applicant do not accept a Commissioner proposed revision, the project or proposal involved should be evaluated on its merits, and apparently agreed that the Commissioner has no authority to coerce changes in a facility's proposal by the issuance of a conditional Certificate of Need . . . . [T] he rule, as amended by the Commissioner, is a necessary and reasonable provision within his delegated authority. It properly deletes impermissible provisions and addresses the concerns raised by MHA/MAHA."

The Commissioner's post-hearing action to amend 7 MCAR § 1.663 H.3.b. was not based upon any belief that the rule as originally proposed was without authority and contained impermissible provisions nor that it was

designed to "coerce changes in a facility's proposal." The changes were designed merely to make the wording of the rule more consistent with the wording used in the Act. The substance of the action, whether it is called a revision or a condition, has not been changed. It must be recognized that a suggested revision will be based upon the record and its nature can be of at least two types. One type of revision could be merely a suggestion for improving the project's consistency with the relevant planning considerations as expressed and established in the record. Failure to agree to the revision will not necessarily result in the denial of a certificate of need. However, the Commissioner may also suggest a revision to the project because without it he may find it impossible to issue the certificate of need. Facilities will basically face the options of agreeing to the change and receiving a certificate of need or of disapproving the revision and perhaps having their application denied. This may be viewed as coercion, but it is far from it. Without the authority to suggest revisions, the Commissioner would have no choice but to deny projects a certificate of need, if the record warranted it, even in those instances where a revision to the application would make it acceptable. The facility denied a certificate of need would then have to revise its application and proceed through the entire certificate of need process again. Whereas under the revisions procedure, the Commissioner can express his concerns with the project the first time through the review process and give the facility an opportunity to make the changes necessary in order for the project to qualify for a certificate of need. An immense amount of time and resources for all concerned are thereby preserved.

The foregoing discussion is not intended to contradict the provision which was added after the hearing which states that if the applicant or HSA reject any revision proposed by the Commissioner that the project will nevertheless be considered on its merits without prejudice due to its rejection. The Commissioner remains committed to this provision, but the above comments are intended to make clear that there may be instances when a project will be denied after the rejection of a Commissioner proposed revision. The denial will be based upon the record when it establishes that the project does not merit a certificate of need notwithstanding that had the facility accepted the revisions a certificate could have been issued.

31. Minn. Rule 7 MCAR § 1.663 H.3.d. lists the circumstances under which the Commissioner could remand a certificate of need application back to an HSA for further consideration. However, 7 MCAR §§ 1.661 E.2. and 1.663 H.2. address situations in which the Commissioner may receive information (such as about a material misrepresentation) which is not in the record which justifies remanding the application. While it is possible that these situations might be covered in 7 MCAR § 1.663 H.3.d.(1)(a) through (h), that might not always be the case. Even if the existing criteria were sufficient, because a remand is clearly contemplated under the circumstances listed in 7 MCAR §§ 1.661 E.2. and 1.663 H.2., it is appropriate to specifically refer to them in the section on remand. Accordingly, 7 MCAR § 1.663 H.3.d.(1) has been amended to read:

> d. Remand the application to the HSA.
>
> (1) A remand may occur if, during the review of the HSA record, the Commissioner finds that one or more of the following conditions exist and determines that a remand will materially aid in the decision-making process.
>
> (a) Findings of fact were not supported by the record;
>
> (b) Findings of fact were based on inaccurate information in the record;
>
> (c) Significant issues relating to review criteria and other provisions of rules were not addressed by the HSA;
>
> (d) Significant evidence within the record was not addressed by the HSA;
>
> (e) Conclusions were not supported by findings of fact;
>
> (f) Conclusions were based on inaccurate findings of fact;
>
> (g) Significant conclusions were not drawn from findings of fact; ~~or~~
>
> (h) The recommendation was not supported by the conclusions~~.~~ ; or
>
> (i) The existence of circumstances which arose under 7 MCAR §§ 1.661 E.2. and 1.663 H.2.

added P. 40

Because the addition references other provisions of the rules dealing with remands, the change is not in any way substantial. It is also reasonable and needed as it acts as a good cross-reference within the rules which is always a helpful tool to readers.

32. The Hearing Examiner found in Finding 89 (at 40) that 7 MCAR § 1.664 B.4.f. was unreasonably vague and that to correct the defect the provision

had to be deleted or specific standards had to be adopted. The rule included in its list of items which would constitute a significant change in a certificate of need project any matter which raised new material issues not previously considered by the HSA or Commissioner. The Commissioner respectfully disagrees with the Hearing Examiner, because the standard of whether or not an issue had been previously considered is a clear, concrete, and easily ascertainable one. He has decided nevertheless that the best course of action is to adopt standards as suggested by the Hearing Examiner.

The Commissioner has decided to look to the purpose clause of the Act for assistance in establishing the standards to be used in determining the existence of materially new issues. It is reasonable to use the statutory purposes, found in Minn. Stat. § 145.832, subd. 1, as reference standards because these constitute the standards which the Legislature originally found to be relevant in determining what should be subject to the Act. Detail language has been added to the general standards as expressed in the Act to help delineate them.

The purpose clause, Minn. Stat. § 145.832, subd. 1, enumerates four fundamental topical purposes of the Act. A fifth purpose, "to provide an orderly method of resolving questions," is not relevant to the subject under consideration. The topical purposes relate to: promotion of comprehensive health planning, quality of care, lowest possible cost, and avoidance of unnecessary duplication. These four topical purposes are made more specific by use of language previously used in these rules. That is, comprehensive health planning is made more specific through language from 7 MCAR § 1.662 D.2.c.; quality of care is made more specific in language from the review criterion, 7 MCAR § 1.663 E.4.f.; lowest possible cost is further explained through language previously used in the review criterion, 7 MCAR § 1.663 E.4.c.(2); and unnecessary duplication is made more specific by use of language which describes important evidence found in 7 MCAR § 1.663 C.6.

For the foregoing reasons, the following modification has been made to 7 MCAR § 1.664 B.4. The change is needed as already found by the Hearing Examiner, it is reasonable because it is based upon the purposes behind the Act as implemented by other portions of these rules, and is a nonsubstantial change because it is a logical outgrowth of issues presented at the hearing and related to other portion of the rules. The rule therefore has been changed to read:

f. Changes in the project which raise new material issues not previously considered by the HSA or Commissioner: related to: p.44

(1) Guidelines, criteria or goals of comprehensive health planning in the applicable HSP, AIP or the State Health Plan;

(2) The quality of care as reflected in survey reports from the Department of Health and in other quality assurance programs recognized in federal and state laws;

(3) The proposed operating cost compared with similar services in similar health care facilities; or

(4) Unnecessary duplication of health care facilities and health services as reflected in governmentally issued or sponsored planning documents, studies or guidelines.

33. In Finding 90 (at 40) the Hearing Examiner questions the clarity of 7 MCAR § 1.664 C.3. as it relates to intent to require all six criteria to be met or whether one criterion would be sufficient in determining whether a project had commenced. It should be noted that the word "and" is intentionally used in 7 MCAR § 1.664 C.3.e. to show that all criteria will be used by the Commissioner. However, in response to the expressed concern about clarity, the word "all" has been added to 7 MCAR § 1.664 C.3. as indicated below.

3. In the case of a construction project, the Commissioner shall use all of the following criteria in determining whether the project has commenced: p.46

34. The Hearing Examiner stated in Finding 93 (at 42) that the Commissioner has insufficient authority relating to access to facilities' records to promulgate 7 MCAR § 1.664 F. While the Commissioner disagrees with this finding, he has opted not to contest it and instead will follow the Hearing Examiner's suggestion of deleting the rule. deleted p.48

35. There are a number of changes in the rules which correct typographical, grammatical, or similar errors or which are merely editorial in nature designed to make the rule read more smoothly. These changes are clearly nonsubstantial, because content is not being altered, and need no other comment to justify them, because these types of changes are inherently reasonable and needed. The amendments are as follows:

a. 7 MCAR § 1.661 B. is amended to read:

B. Definitions. The definitions contained in Minn. Stat. § 145.833 apply to the terms as used in these rules. Some of the terms

defined in Minn. Stat. § 145.833 are also defined in these rules in order to clarify certain sections or parts of the statutory language. Unless the context clearly requires otherwise, the following terms shall have the ~~meaning~~ meanings ascribed to them:

b. 7 MCAR § 1.661 B.5. is amended to read:

5. "Category," as used in Minn. Stat. § 145.833, subd. 5(a)(2), means classification of beds within a health care facility according to licensure (such as, general hospital, psychiatric, alcoholic, nursing home, boarding care home and supervised living) or classification of beds within a health care facility accoring to certification status under the provisions of Title XVIII of the Social Security Act as found in 42 ~~U.S.C. §~~ United States Code, Section 1395x(e), hospital; ~~§~~ Section 1395~~a~~x(f), psychiatric hospital; ~~§~~ Section 1395x(g), tuberculosis hospital; and ~~§~~ Section 1395x(j), skilled nursing facility; and in Title XIX of the Social Security Act in 42 ~~U.S.C. §~~ United States Code, Section 1396a(a)(28), skilled nursing facility; ~~§~~ Section 1396d(c), intermediate care facility; and ~~§~~ Section 1396d(d), intermediate care facility for the mentally retarded.

c. 7 MCAR § 1.661 B.7. is amended to read:[5/]

7. "Construction or modification" means:

a. Any erection, building, alteration, renovation, reconstruction, conversion of any existing building, modernization, improvement, expansion, extension or other acquisition by or on behalf of a health care facility which:

(1) Requires a total capital expenditure in excess of $150,000; ~~or~~ or

(2) Changes the bed capacity of a health care facility by more than ten beds or more than ten percent of the facility's total licensed bed capacity, whichever is less, over a two year period following the most recent bed capacity change, in a way which:

(a) Increases the total number of beds; or

(b) Changes the distrubution of beds among various categories; or

(c) Relocates beds from one physical facility or site to another.;

d. 7 MCAR § 1.661 B.7.c.(5) is amended to read:

(5) A material change in geographic source ~~or~~ of referrals to the facility;

5/ The word "or" was deleted in the Post Hearing Supplemental Comments of Minnesota Commissioner of Health at 52. It should not have been removed and is here being placed back into the rule.

e. 7 MCAR § 1.661 B.7.e. is amended to read:

e. Any reviewable predevelopment activity by or on behalf of a health care facility; or

f. 7 MCAR § 1.661 B.8. is amended to read:

8. "Direct patient care service" means any health service designed to provide diagnosis, treatment, nursing, preventive care, rehabilitative care or habilitative care to any person.

g. The definitions were listed in alphabetical order; however, "predevelopment activity" was inadvertently placed before "patient" in 7 MCAR § 1.661 B.18. and 19., respectively. These definitions are being reversed in order so as to preserve the alphabetical order.

h. 7 MCAR § 1.661 B.21.a. and b. is amended to read:

21. "Provider" means any person:

a. Whose primary occupation involves, or involved within the last 12 months previous to appointment to the HSA, provision of health services to individuals or the administration of health care facilities or other health service activities;

b. Who is, or was, within the 12 months previous to appointment to the HSA, employed by a health care facility as a health or mental health professional;

i. 7 MCAR § 1.661 B.21.d.(3) is amended to read:

(3) Issuing any policy or contract of a individual or group health insurance company, a health service plan or a health maintenance organization;

j. 7 MCAR § 1.661 B.22. is amended to read:

22. "Recommendation of the HSA" means the report of the HSA to the Commissioner which contains its recommendation as to what action should be taken with respect to judging if an ~~applications~~ application is complete or incomplete, if a project is subject to review, if a waiver should be granted or if a certificate of need should be issued. The recommendation includes submission to the ~~Commission~~ Commissioner of all information presented by the applicant and delineation of all rationales developed by the HSA to support its recommendation.

k. 7 MCAR § 1.661 C.2.b.(1) is amended to read:

(1) Be chosen by election or other appropriate method approved by ~~SPA~~ The Department of Energy, Planning and Development and consistent with provisions of 42 ~~U.S.C. § 300k, et seq.~~ United States Code, Section 300l-1 for a term of office not to exceed three years. No director may serve more than six consecutive years.

l. 7 MCAR § 1.662 D.1.a. is amended to read:

a. The proposed construction or modification falls within the situations described in Minn. Stat. § 145.835, subd. 4(a) or (b). Additional examples or items that come ~~with~~ within subd. 4(b) are business related equipment, telephone systems, energy conservation measures, warehouse storage, activities space, site acquisition and other projects of a like nature.

m. 7 MCAR § 1.662 D.10. is amended to read:

10. A project may not be separated into component parts if the granting of a waiver for one part would not subject the remaining parts to certificate of need review and if, when all parts are taken together, the project constitutes a single undertaking which is reviewable under the Act. If, however, the remaining component parts of a project would still be subject to review, a waiver may be requested for a specific component part of a project.

n. 7 MCAR § 1.663 A.3.b. is amended to read:

b. Nursing homes and boarding care homes; ~~and~~

o. 7 MCAR § 1.663 A.4.b.(2)(i) and (ii) are amended to read:

~~(i)~~(a) The requirements for cost allocation under Title XVIII of the Social Security Act, 42 ~~U.S.C. § 1395, et seq.~~ United States Code Section 1395x and 42 Code of Federal Regulations, Sections 405.401-405.406 and 405.453;

~~(ii)~~(b) The requirements for cost allocation under Title XIX of the Social Security Act, 42 ~~U.S.C. §~~ United States Code Section 1396a, ~~et seq.~~ and 42 Code of Federal Regulations, Sections 405.401-405.406 and 405.453;

p. 7 MCAR § 1.663 A.4.i. is amended to read:

i. A copy of all survey reports during the last three years of operation from the Minnesota Department of Health or from other quality assurance programs recognized in federal or state laws, such as the accreditation program of the Joint Commissioner on Accreditation of Hospitals.

q. 7 MCAR § 1.663 E.4.f. is amended to read:

f. The quality of care as reflected in the most recent survey reports from the Minnesota Department of Health and other quality assurance programs recognized in federal or state laws, such as the accreditation program of the Joint Commission on Accreditation of Hospitals.

r. 7 MCAR § 1.664 A.2.b. is amended to read:

b. If the Commissioner determines his decision should be reconsidered, the matter shall be remanded to the HSA. The HSA shall conduct a new public hearing. The record of the second hearing shall include the record of ~~the~~ each previous hearing~~(s)~~ on the application. The HSA shall issue a new recommendation within 60 days of receipt of the remand from the Commissioner.

s. 7 MCAR § 1.665 B. is amended to read:

B. The following entities may qualify for exemption from certificate of need review if the conditions of 7 MCAR § 1.665 C. are met.

1. An HMO;

2. A combination of HMOs;

3. A health care facility which primarily serves inpatients if it is:

a. Owned, or proposed to be owned, by an HMO ~~or HMOs~~; or

b. Governed by a controlling body which is composed of over fifty percent principal officers or board members of the HMO ~~or HMOs~~; or

4. A health care facility, or a portion of a health care facility, leased by an HMO ~~or HMOs~~ for a term of at least 15 years.

t. 7 MCAR § 1.665 C. is amended to read:

C. The conditions which must be met to qualify for exemption are:

1. The applicant shall be "qualified" under Title XVIII of the Public Health Services Act, 42 ~~U.S.C. §~~ United States Code Section 300e or the applicant shall satisfactorily document to the Commissioner that the HMO ~~or HMOs have~~ has substantially fulfilled the requirements of Title XIII of the Public Health Services Act, 42 ~~U.S.C. §~~ United States Code Section 300e.

2. At least 50,000 persons shall be enrolled in the pertinent HMO~~(s)~~ and shall have reasonable access to the proposed project; and

3. At least 75 percent of the potential patients shall be enrolled in the pertinent HMO~~(s)~~.

36. Pursuant to Minn. Stat. § 15.0412, subd. 4d(d), the Report has been made available for review to all affected persons upon request for at least five working days.

Based upon the foregoing Findings of Fact, the Commissioner makes the following:

CONCLUSIONS

1. The Conclusions contained in the Report are hereby adopted and made a part hereof except as noted in the following paragraphs.

2. The Hearing Examiner cited in Findings 31, 40, 58, 89, and 93 of his Report certain rules which were defective and therefore incapable of being adopted. Although the Commissioner respectfully disagrees with those findings, he has opted to change the rules to correct the defects as found by the Hearing Examiner in the manner suggested by him. These rules as modified are now valid and will hereby be adopted.

3. Any amendments and additions to the rules which were made after the Report was issued (a) do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of

Minn. Stat. § 15.0412, subd. 4e (1980) as amended by Minn. Laws 1981, ch. 253, § 11, and 9 MCAR § 2.111; and (b) are reasonable and necessary and supported by the record.

ORDER

NOW, THEREFORE, IT IS ORDERED that the above-captioned rules, implementing, enforcing, and administering the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845, repealing State Planning Agency Certificate of Need Rules, 10 MCAR §§ 1.201 to 1.210, and identified in the State Register as 7 MCAR §§ 1.661 to 1.665, are adopted this 6 day of November, 1981, pursuant to the authority vested in me by the Minnesota Certificate of Need Act.

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

George R. Petersen M D

GEORGE R. PETTERSEN, M.D.
Commissioner of Health

To: Ted Martinez
Date: 12/9/81
Re: Dept. of Health – Certificate of Need Rules

Rules as Adopted

p. 15 .662 C. 1. j.

Line 10 It appears "or" should be inserted between "proposed" and "existing"

p. 25 .663 A. 4. e. (1)

Line 22 This section appears to require the applicant to list the intentions of other institutions. The other institutions may not yet have formally filed notices of intention with the commissioner. Such notices are the only formal way for an applicant to learn other institutions' intentions. Could this rule require going beyond listing of formal intention notices?

HLTH-81-020-JL

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HEALTH

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.

REPORT OF THE CHIEF HEARING EXAMINER

The above-entitled matter came on for review by the Chief Hearing Examiner pursuant to the provisions of Minn. Stat. § 15.0412, subd. 4d (1980) which provides in part:

> If the [hearing examiner's] report contains a finding that the proposed rule is substantially different from that which was proposed at the public hearing, or that the agency has not met the requirements of section 15.0412, subdivisions 4 through 4f, it shall be submitted to the chief hearing examiner for approval. If the chief hearing examiner approves the finding of the hearing examiner, he shall advise the agency of actions which will correct the defects, and the agency shall not adopt the rule until the chief hearing examiner determines that the defects have been corrected. If the chief hearing examiner determines that the need for and reasonableness of the rule has not been established pursuant to subdivision 4, clause (c), and if the agency does not elect to follow the suggested actions of the hearing examiner to correct that defect, then the agency shall submit the proposed rule to the legislative commission to review administrative rules for the commission's advice and comment. The agency shall not proceed to adopt the rule until it has received and considered the advice of the commission; provided, that the agency is not required to delay adoption longer than 30 days after the commission's receipt of the agency's submission.

Based upon a review of the record in this proceeding, the Chief Hearing Examiner hereby approves the Report of the Hearing Examiner in all respects and specifically as to any finding of substantial change or of failure to comply with Minn. Stat. § 15.0412, subd. 4-4f (1980) or of failure to establish need for and reasonableness of the proposed rule.

In order to correct the defects enumerated by the Hearing Examiner, the agency shall either take the action recommended by the Hearing Examiner or reconvene the rule hearing if appropriate. If the agency chooses to reconvene the rule hearing, it shall do so as if it is initiating a new rule hearing, complying with all substantive and procedural requirements imposed on the agency by law or rule.

If the agency chooses to take the action recommended by the Hearing Examiner, it shall, prior to submitting the rules to the Attorney General for review, submit to the Chief Hearing Examiner a copy of the rules as initially published in the State Register, a copy of the rules as proposed for final adoption in the form required by the State Register for final publication, and a copy of the agency's Findings of Fact and Order Adopting Rules. The Chief Hearing Examiner will then make a determination as to whether the defect in regard to substantial change and the requirements of Minn. Stat. § 15.0412, subd. 4-4f (1980) have been corrected.

Should the agency make changes in the rules other than those recommended by the Hearing Examiner, it shall also, prior to submitting the rule to the Attorney General, submit the complete record to the Chief Hearing Examiner for a review in regard to substantial changes.

Dated: August 12, 1981, 1981.

DUANE R. HARVES
Chief Hearing Examiner

HLTH-81-020-JL

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HEALTH

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.

REPORT OF THE HEARING EXAMINER

The above-entitled matter came on for hearing before Jon L. Lunde, duly appointed Hearing Examiner, commencing at 9:00 a.m. on June 9, 1981, in Room 111, William Mitchell College of Law, 875 Summit Avenue, St. Paul, Minnesota, pursuant to an Order for Hearing dated April 10, 1981. The hearing continued through the morning of June 10, 1981. This is a rulemaking proceeding conducted pursuant to Minn. Stat. Chapter 15 to determine whether the Department of Health has authority to adopt the rules proposed and whether they are necessary and reasonable and may be adopted.

Richard A. Wexler, Assistant Attorney General, 136 University Park Plaza Building, 2829 University Avenue Southeast, Minneapolis, Minnesota, 55414, appeared as counsel on behalf of the Minnesota Department of Health (hereinafter the "Department"). The Department's witnesses were Daniel McInerney and Kent Peterson of the Department's Health Systems Division.

Approximately 50 people attended the hearing and 26 of them signed the Hearing Register. The hearing continued until all persons present had had an opportunity to be heard. Subsequent to the close of the hearing, but before the expiration of the 20-day comment period, 21 timely comments, including one Departmental comment, were filed with the Office of Administrative Hearings. Two additional comments were filed after the expiration of the designated comment period. The due date for this Report was extended by the Chief Hearing Examiner to August 6, 1981.

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

Pursuant to the provisions of Minn. Stat. § 15.0412, subd. 4d (1980), this Report has been submitted to the Chief Hearing Examiner for his approval. If the Chief Hearing Examiner approves the findings of this Report, he will advise the Department of actions which will correct the defects and the Department may not adopt the rule until the Chief Hearing Examiner determines that the defects have been corrected. However, in those instances where the Chief Hearing Examiner identifies defects which relate to the issues of need or reasonableness, the Department may either adopt the Hearing Examiner's recommendations to cure the defects or, in the alternative, if the Department does not elect to adopt the recommendations, it may submit the proposed rule to the Legislative Commission to Review Administrative Rules for the Commission's advice and comment. Provisions relating to this submission to the Commission may be found in Minn. Stat. § 15.0412, subd. 4d (1980).

If the Department elects to adopt the recommendations of the Hearing Examiner and makes no other changes and the Chief Hearing Examiner determines that the defects have been corrected, then it shall submit the rule to the Attorney General for review of form and legality. If the Department makes changes in the rule other than those recommended by the Hearing Examiner, then it shall submit the rule, with the complete record, to the Chief Hearing Examiner for a review of the changes before adopting it and submitting it to the Attorney General. Procedures relating to this subsequent review by the Chief Hearing Examiner are set forth in Minn. Stat. § 15.0412, subd. 4e (1980).

When the Department submits the rule to the Attorney General, it shall give notice on the day of submission to all persons who requested that they be informed of the submission to the Attorney General.

Based upon all the testimony, exhibits and written comments, the Hearing Examiner makes the following:

FINDINGS OF FACT

Procedural Requirements

1. On April 10, 1981, the Department of Health filed the following documents with the Chief Hearing Examiner:

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

2. On Monday, May 4, 1981, more than 30 days prior to hearing, a Notice of Hearing and a copy of the proposed rules were published at 5 State Register 1729 through 1758.

3. On May 6, 1981, more than 30 days prior to hearing, the Department mailed the Notice of Hearing to all persons and associations who had registered their names with the Department for the purpose of receiving such notice.

4. On May 14, 1981, more than 25 days prior to hearing, the Department filed the following documents:

(a) The Notice of Hearing as mailed.
(b) The Agency's certification that its mailing list was accurate and complete.
(c) The Affidavit of Mailing the Notice to all persons on the Agency's list.
(d) The Statement of Need and Reasonableness.
(e) The names of Department personnel to represent the Agency at the hearing together with the names of any other witnesses solicited by the Agency to appear on its behalf.
(f) A copy of the State Register containing the proposed rules.
(g) An Affidavit of Additional Notice.
(h) All materials received following a Notice of Intent to Solicit Outside Opinion published at 4 S.R. 585-586, on Monday, October 15, 1979.

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

5. The record remained open through June 30, 1981 for the receipt of written comments and statements, the period having been extended by order of the Hearing Examiner to 20 calendar days following the hearing.

6. The Department complied with Minn. Stat. §§ 145.835, subd. 4 and 145.837, subd. 1, requiring the Commissioner to consult with local health systems agencies (HSAs) and the State Planning Agency (SPA) in the promulgation of

these rules. In addition, the Department has entered into a contract with the SPA as required by Minn. Stat § 145.834.

7. The Minnesota Association of Health Care Facilities (hereinafter "MAHCF") raised three procedural issues in its posthearing comments. First, it alleged that the Department failed to give the notice required under Minn. Stat. § 15.0412, subd. 7 (1980), which provides as follows:

> If the adoption of a rule by an agency will require the expenditure of public moneys by local public bodies, the notice of the proposed rule as required by this section shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local public bodies in the state to implement the rule for the two years immediately following adoption of the rule if the estimated total cost exceeds $100,000 in either of the two years. For purposes of this section, local public bodies shall mean officers and governing bodies of the political subdivisions of the state and other officers and bodies of less than statewide jurisdiction which have the authority to levy taxes.

MAHCF stated that the number of reviews required by the Metropolitan Council, alone, might cost in excess of $100,000 in a given year and the Department should, therefore, have given its estimate of the costs required to implement the rule by local public bodies in its Notice of Hearing. The Notice of Hearing contained no estimate of these costs. However, there is no evidence that the Department did not consider the requirements of subdivision 7 and conclude that the costs of implementation would be less than $100,000 in each of the first two years. The general rule is that with respect to completed official acts, public officers are presumed, in the absence of affirmative evidence to the contrary, to have performed their duties in the time and manner required by law. The burden to overcome the presumption rests with the party alleging to the contrary. See, e.g., Walters v. Common School Districts 2550, ETC., 265 Minn. 284, 121 N.W.2d 605, 608 (1963). In this case, there is no evidence that the Department did not consider the costs of compliance with the rule by local public bodies and conclude that they were below the $100,000 threshhold nor is there any evidence that the costs to these bodies would, in fact, exceed $100,000 in any given year. MAHCF's mere speculation that cost to the Metropolitan Council alone "might very well exceed the $100,000 figure" is insufficient to overcome the presumption that the Department acted in the manner and form required by law. If MAHCF had evidence concerning costs, that evidence should have been presented at the hearing or the Department should have been questioned regarding those costs. However, that was not done and no procedural violation of subdivision 7 has been established.[1]

Although Minn. Stat. § 15.052, subd. 4, only requires the Chief Hearing Examiner to determine whether or not a new hearing is required because of an agency's failure to meet the requirements of § 15.0412, subds. 4 through 4f, a

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1 Even if costs were found to exceed $100,000 for purposes of subdivision 7, it is not clear that a violation occurred. No court has construed subdivision 7 and it is not immediately apparent that the adoption of new rules which, for the most part, codify existing practice and replace old rules, are within the notice requirement. Argument could be made that only the cost of new rules which impose new, different or additional requirements, come within the provision and that rules which merely update prior requirements and replace old rules are not within the provision.

new hearing may be required in the event that the notice provisions of subdivision 7 were not complied with because Minn. Stat. § 15.052, subd. 3, requires a hearing examiner to conduct only hearings for which proper notice has been given. Since the issue raised by MAHCF, if true, might require a rehearing on this matter, something more than a mere allegation or speculation that costs to local public bodies might exceed $100,000 in a particular year, is necessary to obtain the drastic relief available.

8. The other two procedural issues raised by MAHCF concern the Department's compliance with Minn. Stat. § 15.065 (1980), and Minn. Laws 1981, Chapter 360, § 14 (effective July 1, 1981). The former requires notice to house and senate committees of rules having a fiscal impact in excess of $100,000 annually before putting a rule into effect, and the latter requires consultation with the Legislative Advisory Committee and the Governor's approval prior to the promulgation or implementation of rules which will increase state expenditures by more than $50,000 during the 1981-83 biennium. The Department is not required to comply with § 15.065 prior to hearing but should do so prior to putting the proposed rules into effect. With respect to the 1981 amendment, which became effective after the hearing on these rules was held, the Department may also still comply with its requirments and should do so prior to implementing the rules.[2]

Statutory Authority

9. The Department's authority to adopt the rules proposed, as cited in the Notice of Hearing, derives from the provisions of Minn. Stat. § 145.832 et seq. (1980), the Minnesota Certificate of Need Act (hereinafter the "Act"). While the Act contains many specific mandates for particular rules, the general delegation of rulemaking authority is contained in the broad language of Minn. Stat. § 145.834, which provides in part as follows:

> 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.

The cited language is a sufficient and adequate delegation of authority for the adoption of Certificate of Need rules by the Department and, except as is specifically noted to the contrary elsewhere in this Report, authorizes the adoption of the rules proposed by the Department.

Introduction

10. In 1971, in order to control rising health care costs, the State adopted legislation regulating the development of health care institutions and the provision of health care services. That legislation, Minn. Stat. § 145.71 et

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[2] The 1981 amendment, while not in effect at the time of the hearing in this case, may require notice prior to hearing in future rulemaking proceedings. The statute uses the words "promulgate nor implement". The word "promulgate", itself, is an ambiguous one which can be construed to mean mere publication or pronouncement by an agency or it may be construed to mean adoption. If the former meaning was intended by this enactment, an agency would be required to consult with the Legislative Advisory Committee and obtain the Governor's approval for rules covered thereby prior to publication of its Notice and Order for Hearing. Assuming that the word "promulgation" means adoption, an agency would still be well advised to seek the Governor's approval prior to implementing expensive rulemaking proceedings.

seq., now repealed, placed various responsibilities in the State Planning Agency and the Commissioner of Health (hereinafter the "Commissioner") in the issuance of certificates of need to health care institutions. Rules implementing the law were adopted by the State Planning Agency. See, 10 MCAR §§ 1.201 to 1.210. Minn. Stat. § 145.71 et seq. was repealed by Minn. Stat. § 145.832 et seq. which placed greater authority in the Department of Health. The rules proposed repeal former rules of the State Planning Agency and are intended to implement the new Certificate of Need Act.

11. The Act, like its predecessor, contains the following introduction:

> The legislature finds that the unnecessary construction or modification of health care facilities increases the cost of care and threatens the financial ability of the public to obtain necessary medical services. The purposes of section 145.832 to 145.845 are to promote comprehensive health planning; to assist in providing the highest quality of health care at the lowest possible cost; to avoid unnecessary duplication by ensuring that only those health care facilities and services which are needed will be developed; and to provide an orderly method of resolving questions concerning the necessity of construction and modification of health care facilities.

The Act provides an outline of the situations when a Certificate of Need is required, applications that must be submitted, their review by the Department, waivers which are available, and preconstruction notices that must be filed so that the Department can determine the applicability of the Certificate of Need (CON) provisions to the particular undertaking involved. In addition, the Act deals with the involvement of local health systems agencies (HSAs) in the CON process. It applies to the construction or modification of medical facilities, the purchase of various types of equipment by them, and, in some cases, by physicians, and the provision of services by the institutions regulated.

12. The rules proposed for adoption, codified as 7 MCAR §§ 1.661 through 1.665, pertain to the Certificate of Need procedures imposed on the health care industry and implement the Act. The proposed rules were subject to detailed comments by HSAs, the Minnesota Hospital Association (MHA), the Minnesota Association of Homes for the Aging ("MAHA"), MAHCF, the Department, and other public and private persons.

Except where confusion would result, the rules are discussed sequentially, section by section, and all rules and proposed amendments not specifically addressed or discussed are found to be authorized and their need and reasonableness adequately supported by the evidence presented by the Department or in its Statement of Need and Reasonableness. Unless otherwise indicated, all amendments proposed are not considered substantial for purposes of 9 MCAR § 2.111, and Minn. Stat. § 15.0412, subd. 4d.

Definitions

13. 7 MCAR § 1.661 B.4. P. 2. "Capital expenditures" are defined in this Part. At the hearing, Departmental representatives testified that the proposed definition would include the purchase of an existing health care facility, even if the purchase does not involve a change in services or bed capacity. MAHCF challenged the reasonableness of such an interpretation and suggested that the purchase of an existing facility by another facility be excluded, or, at the very least, that the rules specifically state that such purchases are covered

to give affected persons reasonable notice of the applicability of CON procedures to such purchases.[3]

While MAHCF questioned whether the purchase of an existing facility is, in fact, a capital expenditure under generally accepted accounting principles, the Department is not required to make such a showing. All capital expenditures, whether or not capital expenditures under generally accepted accounting principles, are included except those which are not properly chargeable as an expense of operation and maintenance under generally accepted accounting principles. That is, the exception from capital expenditures is limited to those determined by generally accepted accounting principles and not the capital expenditures, themselves. Furthermore, while a cursory reading of the Act could support the conclusion that the purchase of existing facilities by other facilities is not intended to be within its scope, any lease "or other acquisition" by or on behalf of a health care facility in the threshhold amount of $150,000 is covered by the plain language of § 145.833, subd. 5(a).

14. The ordinary meaning of the verb "acquire" is "to get as one's own." Webster's New Collegiate Dictionary, p. 11 (1975). It is similarly defined in Black's Law Dictionary, p. 41 (1968), which reads:

> To gain by any means, usually by one's own exertions; to get as one's own; to obtain by search, endeavor, practice, or purchase; receive or gain in whatever manner; come to have. Clarno v. Gamble-Robinson Co. 190 Minn. 256, 251 N.W. 268, 269 (Emphasis added)

An acquisition is merely the act of acquiring and is usually construed as involving ownership and legal or equitable title. It clearly includes a purchase. 1 C.J.S. Acquire and Acquisition.

15. The words "lease or other acquisition" appearing in Minn. Stat. § 145.833, subd. 5(a), as part of the definition of a construction or modification, are new words which were not included in the original certificate of need law, Minn. Stat. § 145.71 et seq. Obviously, this language was added for some definite purpose but the legislative history of this langauge was not made a part of the record or discussed by the parties. Consequently, the language must be construed in order to arrive at the legislative intent.

As a general rule, an administrative agency's construction of a statute is to be accorded great deference, either where that construction is adopted simultaneously with the enactment of new legislation, or where the statutory language is ambiguous. See, e.g., Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 381 (1969); Buhs v. State Department of Public Welfare, 306 N.W. 2d 127 (Minn. 1981); and 82 C.J.S., Statutes, § 359. Contemporaneous administrative construction is given special deference because the agency is considered to have familiarity with the enactment and the Legislature's intent, but the weight accorded such construction is diminished where the interpretation is not of long standing, and the administrative interpretation is never conclusive.

16. In determining whether the purchase of an existing health care facility constitutes "a lease or other acquisition", and therefore, a "construction

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[3] The purchase of an existing facility by a person not already operating a health care facility may be excluded from review under the definition in § 1.661 B.17. defining "on behalf of."

or modification" for purposes of the Act, MAHCF raised several arguments. First, it pointed out that the review of such purchases is not required by federal law. In fact, such purchases are specifically excluded by 42 C.F.R. § 123.404(a)(1) which provides:

> Capital expenditures that exceed the expenditure minimum. The obligation by or on behalf of a health care facility of any capital expenditure (other than to acquire an existing health care facility) that exceeds the expenditure minimum for capital expenditures [must be covered by the State's CON procedures] (Emphasis added)

Whether or not the Act was adopted solely to bring Minnesota law into compliance with federal CON requirements, those requirements are relevant in arriving at a proper construction of the Act and in ascertaining legislative intent. The absence of a federal review requirement for the purchase of existing health care facilities coupled with the fact that the Act itself does not specifically mention such purchases is evidence that they were not intended to be covered. This evidence is corroborated by the absence of any legislative history supporting an intention to include such purchases under the Act.

17. MAHCF argued that application of recognized canons of construction also supports the conclusion that purchases of existing facilities do not constitute capital expenditures for a construction or modification. In their poshearing comments, Mr. Wildfang stated (p. 7):

> As applied to the definition of "construction or modification" found in § 145.833, Subd. 5(a), this rule [ejusdem generis] requires that the general phrase "or other acquisition" found in § 145.833, sub. 5(a) (which is the Commissioner's basis for the inclusion of purchases) is limited in its meaning to things of like nature to the specific words preceding it, i.e., "erection, building, alteration, reconstruction, modernization, improvement, extension". All of these words are consistent with the ordinary connotation of the term "construction or modification" in that each of the specific words contemplate adding something new to the health care facility or health care system. A purchase of an existing facility does not add anything new to the system, and therefore cannot be said to be "of like nature" to the preceding specific words. Therefore, under a proper construction of the Act, a purchase of an existing facility is not included in the statutory definition, and the Commissioner may not extend the scope of the Act by the adoption of a rule.
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> Even without using the rule of ejusdem generis, MAHCF believes a fair reading of the statutory definition fails to indicate any intent to include purchases of existing facilities. The word "purchase" is clearly and explicitly used in the same clause in relation to the acquisition of diagnostic or therapeutic equipment. If the legislature had really intended to include purchases of existing facilities, they could easily have done so by using the word in the statutory definition. The failure to do so must be regarded as an indication that there was no such intent. (Underlining theirs)

18. The ejusdem generis rule is only one rule of construction used by the courts in ascertaining legislative intent and is not controlling. The rule itself simply is that where words of a specific and limited meaning are followed by words of a general or generic meaning, the latter words are to be construed as applicable only to things of like nature to those specific words mentioned. It is based on the idea that the Legislature had in mind things of the same kind when using a general word, and was speaking of them all as a class. While

the rule is still viable, the Minnesota Supreme Court has noted that the legislative intent is usually directly contrary to the result obtained by application of the ejusdem generis rule. Orme v. Atlas Gas & Oil Co., 217 Minn. 27, 13 N.W.2d 757 (1944).

19. Although the Legislature did not use the word "purchase" in § 145.833, subd. 5(a), it is equally clear that some purchases would obviously be covered. A health care facility that purchased an adjacent building to be used as its administrative headquarters, as a cafeteria, a parking lot or other purpose would clearly be within the terms of the Act even though the word "purchase" is not used in the statute. Moreover, leases are specifically covered. The fact that leases are within the scope of the Act supports the conclusion that purchases are also witin its scope. While MAHCF might argue that leases, like acquisitions, are limited to those that add something new to the health care system, such an interpretation is not persuasive with respect to either. Words like modernization and improvement do not connote the adding of anything new to the health care system, except in the narrow sense that the component parts of a facility may be newer; and words like extension do not connote construction activities only.

In Orme v. Atlas Gas & Oil Co., supra, p. 764-65, the Minnesota Supreme Court discussed the ejusdem generis rule stating:

> The rationale of the rule of ejusdem generis is that all words in a writing should be given effect if possible; that where specific words enumerating members of a class are followed by general words capable of including the class and others, the former would be rendered meaningless if the latter were given their full and natural meaning, since the latter included the former, and that the incompatibility should be reconciled by construing the general words as referring to the same kind as those enumerated by the specific words, and thus give meaning to both.

In this case, giving the words "lease or other acquisition" their full and natural meaning does not render the "specific" words in the statute meaningless and there is no basis, therefore, for applying the rule. Leases and acquisitions are not of the same class as alterations, erections or improvements and it makes no sense to limit words of acquisition by words of construction as an application of the ejusdem generis rule would do. Therefore, the words "lease or other acquisition" should be construed in their general sense to include purchases of any kind. This comports with the rule that the word "other" be construed to mean something different from that which has been specified. 67 C.J.S., Other; Orme v. Atlas Gas & Oil Co., supra, at 763.

20. Even if it is true that the purchase of an existing health care facility does not add anything new to the health care system, it does add something new to the health care facility making the purchase, and the review of such purchases is consistent with the purposes of the Act. When one facility purchases another existing facility, for example, the purchase price does have a definite and pronounced effect on future rates as where nursing homes are involved. The Department's review of such purchases is consistent with the purposes of the Act in attempting to control rising medical care costs. The Act itself provides that the rate review agency is to receive notice of public hearings on CON applications. The Department of Public Welfare (DPW) would, in the review of purchases, be able to comment on the effect of a proposed purchase under this scheme and give valuable information on the effects of such a

purchase on nursing home rates under Rule 49 and perhaps on the reasonableness of the purchase price, itself. Notice to DPW is consistent with the Commissioner's review of purchases. Such a review is also consistent with the review criteria found in Minn. Stat. § 145.837, subd. 1, which requires consideration of a construction or modification in terms of the purchaser's long-range development plan and its solvency. In addition, it permits examination of the purchaser's past ability to meet the special needs of certain population groups, a finding the Commissioner must make under Minn. Stat. § 145.837, subd. 2.

The need to review purchases of one facility by another was summarized as follows by Pamela J. Parker of the Minnesota Board on Aging:

> While this review would probably be waived under most routine circumstances, the department's authority to review should be retained. Facility ownership is a primary factor in provision of qualify of care for residents. Fiscal, management and especially admission policies are controlled by facility ownership. When a facility ownership group aquires (sic) large numbers of existing nursing home beds, the effect of their particular policies expands to many more residents. Potential exists for creation of a monopoly or at the least, for a large amount of control over residents lives to exist in the hands of a few.
>
> Consumers groups are very concerned about this potential, in relation to issues presented in our previous comments about access to services. For example should a particular corporation buy several more facilities and impose their existing admissions requirements to restrict Medicaid admissions or more commonly to restrict admission of heavy care patients, access to services would be seriously impaired.
>
> In situations where a questionable record or harmful policies of a particular ownership group would be expanded to additional residents or where a massive number of beds would be controlled by one facility ownership group a forum for review should be available to analyze the impact on the service and the consumer.

21. For all these reasons, it is concluded that the Department's announced conclusion that such purchases are covered is not arbitrary or unreasonable and should be given deference in this case. While MAHCF labeled the Department's review of all purchases of existing health care facilities as becoming involved in a "morass" of difficult questions, the mere difficulty of the judgments that must be made in order to properly administer the Act is not good reason for refusing to make determinations which have been decided must be made. Furthermore, MAHCF's allegation that the rule, by excluding purchases by those who do not own other facilities, violates the Equal Protection Clause, was not persuasive because there are major differences between them which are relevant in the CON review process. For that reason, equal protection considerations do not affect the construction of Minn. Stat. §145.833, subd. 5(a).

22. 7 MCAR § 1.661 B.5. Under § 145.833, subd. 5(a), a construction or modification for purposes of the Act includes:

> (2) Changes in the bed capacity of a health care facility in a manner which increases the total number of beds, or distributes beds among various categories, or relocates beds from one physical facility or site to another, by more than ten beds or more than ten percent of the licensed bed capacity, whichever is less, over a two-year period.

To clarify this provision, the Department proposes to define "category". The word is defined on the basis of state licensure (e.g., psychiatric, nursing home, alcoholic, etc.), and on the basis of federal certifications (i.e., skilled nursing, intermediate care, hospital, etc.). MAHCF suggested that the

Department limit its definition of category to state licensure so that nursing homes would have flexibility in changing bed certification levels in order to respond to local needs without going through CON procedures. While there may be a need for flexibility, that need must be balanced against the purposes and policies of the Act, and since state licensure and federal certification categories are used in the state health plan, state health systems plans, and annual implementation plans, and since it is not possible to adequately examine the need for health care facility beds without knowing the specific categories involved, it is concluded that the rule proposed by the Department is necessary and reasonable.

In its posthearing comments, the Department proposes to amend the definition of the word "category" by adding the words "nursing home" in the first parenthetical in the rule, by deleting the citation to Title XIX of the Social Security Act, and by deleting the second parenthetical in the rule and replacing it with specific citations to the United States Code. The amendments merely clarify the meaning of the rule and give more specific citations to the federal statutes governing the certification status of beds and health care facilities. The citations added to this part were specifically authorized by the Chief Hearing Examiner's Order of May 27, 1981 and the changes involved are not substantial for purposes of 9 MCAR § 2.111.

23. 7 MCAR § 1.661 B.6. This Part defines "commissioner" as the commissioner of health or any duly authorized representative. MHA/MAHA objected to this definition and argued that it would allow the commissioner to improperly delegate his decision-making authority under the Act. MHA/MAHA cited Morgan v. United States, 298 U.S. 468 (1936), and KFC National Management Corp. v. NLRB, 497 F.2d 298 (2d Cir. 1974) for the proposition that those legally responsible for a decision must, in fact, make it, and that the Commissioner of Health is precluded from delegating his authority under the Act to subordinates. It suggested that the definition be amended accordingly. However, the cases cited do not prohibit the subdelegation of decision-making authority to designated subordinates, but respectively, restrict determinations upon evidence and argument to officers who have considered and appraised them, and prohibit delegation of final decision-making authority absent a statutory basis or internal agency procedural regulations. Furthermore, Minn. Stat. § 15.06, subd. 6(1), specifically authorizes the Commissioner to delegate to subordinates his statutory powers or duties provided that such delegation is made by written order filed with the Secretary of State.[4] Since compliance with Minn. Stat. § 15.06, subd. 6(1) must occur before a subordinate becomes a "duly authorized representative" of the commissioner, MHA/MAHA's argument is without legal basis and it is found, therefore, that the proposed definition is necessary and reasonable.

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[4] In State ex rel Independent School District No. 276 v. Minnesota Department of Education, 256 N.W.2d 619, 626 (Minn. 1976), the Minnesota Supreme Court recognized the validity of this statutory provision even though the requisite filing with the Secretary of State was not done. This decision is consistent with the current attitude allowing subdelegations. See, e.g., 1 K. Davis, Administrative Law Treatise § 3: 17 (1978).

24. 7 MCAR § 1.661 B.7. This part contains the definition of a "construction or modification" and is taken, in part, from Minn. Stat. § 145.833, subd. 5. MAHCF objected to the definition and its proclaimed coverage to purchases of existing health care facilities. As with the proposed definition of capital expenditure, MAHCF argued that purchases of existing health care facilities by other facilities should not be included within the definition of a construction or modification. This argument has already been discussed and rejected. The proposed definition is, therefore, found to be necessary and reasonable and within the Commissioner's authority.

25. 7 MCAR § 1.661 B.7.c. This Part pertains to those expansions or extensions of the scope of type of existing health care services which constitute a construction or modification for purposes of § 145.833, subd. 5(b). Since the initial definition covered insignificant activities and involved potentially unnecessary intrusions into the day-to-day management decisions of health care facilities which could lead to the review of projects intended to be unreviewable under the statute, the Department, in response to to comments by MAHCF and MHA/MAHA proposes to amend Part B.7.c. to clarify the factors to be applied to determine whether a proposed project is an expansion or extension. The new language, which is supported by both MAHCF and MHA/MAHA, more clearly indicates that only direct and material factors will be considered. The change is not substantial for purposes of 9 MCAR § 2.111 and is necessary and reasonable and should be adopted. As amended, the last sentence of the first paragraph of subpart c. will read: "Expansion or extension shall occur if at least one of the following factors is required by or a direct result of the proposed project . . ." In addition, in clauses 1 through 5 which follow, the word "material" is added so as to limit reviewable changes or increases to those which are material in nature. The Department has proposed other technical and grammatical amendments to Part B.7. which properly punctuate or clarify in minor detail the substance of the rule as originally proposed. Those other amendments to this Part are necessary and reasonable and not substantial for purposes of 9 MCAR § 2.111.

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26. 7 MCAR § 1.661 B.17. The definition of the phrase "on behalf of" as originally proposed by the Department was as follows: "'On behalf of' means in the interests of, at the behest of, or for the benefit of, a health care facility or other entity." It drew opposition from MHA/MAHA and the Metropolitan Medical Center, Inc. Two aspects of the definition were addressed. First, the inclusion of the phrase "or other entity" was cited as allowing unauthorized expansion of the scope of CON review to all entities, public or private, undertaking construction or modification as defined, while the Act addressed only activities on behalf of health care facilities. Recognizing the confusion which could arise from the use of the phrase "or other entity", the Department, in its posthearing comments, has proposed to delete it. Since the use of the words "or other entity" are inconsistent with the Act (Minn. Stat. § 145.833, subd. 5(a), limiting coverage to construction or modification "by or on behalf of a health care facility"), the Department's proposal to delete those words is necessary, reasonable and appropriate and does not involve a substantial change for purposes of 9 MCAR § 2.111. As amended, § 1.661 B.17. is proposed to read as follows:

delete (as amended) P.S.

"On behalf of" means in the principal interest of, at the behest of, or for the principal benefit of a health care facility.

27. In addition, MHA/MAHA and the Metropolitan Medical Center argued that the Department should limit the proposed definition to situations involving activities by an agent of a health care facility. This argument is based upon the distinction in usage between the phrases "on behalf of" and "in behalf of" as set forth in The American Heritage Dictionary of the English Language (1980) p. 119. The usage note therein indicates that 58% of the usage panel would restrict the phrase "on behalf of" to "as the agent of, on the part of" and the phrase "in behalf of" to the sense of "in the interest of, for the benefit of". The remainder of the panel would use the phrases interchangeably. The Department proposes to amend the definition of "on behalf of" to mean in the "principal" interest or benefit of a health care facility, thereby eliminating some of the unusual results which could occur under its definition as originally proposed. However, it refuses to limit the words "on behalf of" to an agency relationship. The Department feels that the Legislature intended that the Act apply to circumstances other than those where the project is merely "by" a health care facility. Of course, an agency relationship does make the activities "by a health care facility" even if they are undertaken by an agent. The Department further feels that it is the intent of the Act to apply to situations where a project is by a health care facility as well as to those where the degree of benefit or interest is principally that of a health care facility. Under the new definition, incidental benefits or interests are excluded from the phrase "on behalf of".

28. The words "on behalf of" and "in behalf of" have been construed by the courts in several cases, and in all cases known to the Hearing Examiner, the courts construed the words "on behalf of" as meaning an agency relationship, and the words "in behalf of" as meaning something broader. In White v. Transit Cas. Co., 402 S.W. 2d 212, 215 (Tex.Civ.App. 1966), the court held that the words "on behalf of" in an insurance contract meant an act by one person authorized to act for another. In that case, since the insured or someone acting on his behalf was required to give notice to the insurer (within a specified time period) of an accident, notice given by an injured party was not sufficient because the injured party was not acting on behalf of the insured. Similarly, in a case involving statutory interpretation, the court, construing the phrase "by and on his behalf" said:

'on his behalf,' when it refers to a candidate, means by someone who acts for him in the sense that an agent acts for and on behalf of his principal. The authority may be express or implied but it must exist; otherwise the disbursement is not made on behalf of the person sought to be charged.

Accord, Hicks v. Frager, 1 P.2d 1096, 1097, 118 C.A. Supp. 777 (1931). "In behalf of", on the other hand, means in the name of, on account of, or for the benefit, advantage, interest, profit, defense or vindication of another. Meyers v. State, 49 Tex. Civ. App. 336, 105 S.W. 48 (1907).[5]

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[5] Restatement of the Law 2d, Agency, § 1, p. 7 (1958) defines agency as "The fiduciary relation which results from the manifestation of consent by one person to another that the other shall act on his behalf and subject to his control, and consent by the other to so act." (Emphasis added)

29. In spite of this authority, the Hearing Examiner is not persuaded that the words "on behalf of" were intended to be limited to the relationship of principal and agent. The most persuasive reason for this conclusion comes from a comparison of the language found in Minn. Stat. § 145.72, subd. 3 and Minn. Stat. § 145.833, subd. 5(a). The former applied to health care facilities only and no mention was made of others acting "by or on behalf of" those facilities. That language was not added until the latter provision was adopted. In the contemplation of the law, the act of an agent is the act of the principal. Dun.Dig. (3rd Ed.) § 209. If that be true, an amendment to the former statute making it applicable only to agents of a health care facility would be a useless act of no legal consequence. It is presumed that the Legislature intends to make some change in the law by an amendment. Western Union Telegraph Co. v. Spaeth, 232 Minn. 128, 44 N.W.2d 440 (1950). It is also presumed that the Legislature does not pass useless, redundant or unnecessary laws. For that reason, it is concluded that by adding the words "on behalf of", the Legislature intended that something other than agents be covered by the Act and that the Commissioner's proposed definition is necessary and reasonable. Although there are a handful of decisions to the contrary, these decisions do not hold that the words in dispute are words of art having a well-settled legal meaning, and their interpretation has not been adopted in Minnesota. The Commissioner's use of a commonly accepted definition of the words, in view of all these factors, is within his discretion and should be accorded deference.

Health Systems Agency Membership.

30. 7 MCAR § 1.661 C. This section pertains to the membership of health systems agencies that conduct local review and make recommendations to the Commissioner. This Part was subject to no substantial adverse public comment and is found to be necessary and reasonable in its entirety. In response to comments from MHA/MAHA, however, the Department proposes to amend § 1.661 C.2.c. to delete the words "representatives of the interests of". This deletion makes the rule more consistent with the Act. It, like the other technical amendments proposed for this Part are necessary and reasonable and do not constitute substantial changes for purposes of 9 MCAR § 2.111.

31. 7 MCAR § 1.661 C.2.a. This section provides, in part, that the Metropolitan Council may delegate any of its functions and duties to the Health Board and its staff, and in an amendment to this Part, the Department proposes to approve delegations except those prohibited by the proposed rules. With respect to the proposed rule's purported authority to authorize delegations by the Metropolitan Council, this Part is found to be unauthorized. The Department cited no statutory authority under which it can authorize the delegation of authority by the Metropolitan Council to any of its subordinates or to restrict delegations otherwise authorized. Since the Department has not demonstrated authority to deal with delegations (§ 145.845 merely authorizing it to promulgate rules concerning membership of HSAs), the language authorizing delegations constitutes a substantive violation of Minn. Stat. § 15.0412, subd. 1, which requires the Commissioner to adopt rules only pursuant to authority delegated by law. To correct this defect, the second sentence containing the words "and may delegate any of its functions and duties to the health board and its staff" must be deleted.

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deleted p. 8

Conflicts of Interest.

32. 7 MCAR § 1.661 D. This Part deals with conflicts of interest that can arise when members of HSAs have an interest in matters being considered. The rule is clearly necessary because the HSAs, themselves, are composed of health care consumers and health care providers. The rules generally provide that individuals with a conflict of interest must report that conflict as soon as it becomes apparent and may not, after that, participate in or vote on any issue being considered. Such a person may thereafter participate only to the extent permitted to other members of the public. All conflicts must be declared in writing to the HSA, and those individuals who have declared a conflict of interest must be identified in the HSA's recommendations. For purposes of determining whether or not a quorum exists, persons with a conflict must be recorded as being absent rather as abstaining due to a conflict. The Central Minnesota Health Systems Agency (CMHSA) suggested that the rule could be more specific with respect to that point in time when a conflict of interest must be declared and questioned whether individuals with a conflict should be required to be absent from the hearing. Since a conflict of interest may not be "apparent" at any particular point in time, the proposed rule requiring that it be declared before the HSA begins its review of the application or when the conflict becomes apparent to the member is necessary and reasonable.

33. Section 1.661 D. requires that persons with a conflict of interest be excluded from those counted for purposes of determining an HSA quorum. CMHSA, the Southeastern Minnesota Health Systems Agency, and the Metropolitan Council all suggested that this provision be deleted, citing the frequency of such conflicts and the difficulties that already exist because of the attendance patterns of Board members. The impossibility of meeting quorum requirements in a particular case, or the delays caused by an overly stringent rule excluding those with a conflict for purposes of computing a quorum, were not addressed by the Department. Prolonged delays should be avoided and provision should be made for proceeding with HSA action where a quorum is impossible or nearly impossible to otain. It is suggested, therefore, that the Commissioner consider these circumstances in his final version of the rules. Relief could be provided by requiring that a minimum number of Board members act on an application, as an alternative to the proposed quorum rule, or by providing an exception to the rule in cases of actual or practical impossibility.

In spite of the problems that might be caused by this Part, it is a necessary and reasonable exercise of the Commissioner's discretion. Since the Act requires maximum participation at the local level, the rule, by treating those with a conflict of interest as absent and not countable, for purposes of determining a quorum, reasonably promotes full attendance by HSA board members. Furthermore, contrary to CMHSA's observation, those members are not required to be totally absent from any proceedings, but if they are present, they must appear as would other members of the public.

In order to clarify this Part, the Department has proposed some minor technical changes to the language of the rule. These changes are necessary and reasonable and do not constitute substantial changes for purposes of 9 MCAR § 2.111.

Ex Parte Communications

34. 7 MCAR § 1.661 E. This Part limits ex parte communications during the review process. However, exception is made in the rule for communications between government officials to investigate possible misrepresentation, inaccuracy or omission of relevant information. According to the Department's Statement of Need and Reasonableness (hereinafter the "Statement"), the exception is based upon Minn. Stat. §§ 15.0424 to 15.0426 which pertain to the judicial review of administrative decisions. However, Minn. Stat. § 15.0424, subd. 6, limits judicial review to the record except where alleged irregularities in procedure before the Agency (not shown in the record) are alleged. No one questioned this rule at the hearing, or in posthearing comments, and permitting ex parte communications to determine inaccuracies, or the omission of relevant information, is an appropriate administrative responsibility so long as proper notice of the information obtained is given to the parties affected by its consideration, and an opportunity is given to respond to it.

The rule limits ex parte communications except those between the Department, the SPA and the HSA to determine if the facts found are, in fact, true, or whether other information bearing on the case should be in the record. This is much broader than a court's review under Chapter 15, but the Department does have a different role in implementing the statute than the Court does in reviewing disputes which arise under it. Consequently, while extra record communications are permitted and administrative notice of facts not of record may be taken, all information so considered or acquired must be made part of the record with notice to the parties involved.

35. In its posthearing comments, the Department proposes to amend Part E.3. to read as follows:

> Ex parte communications received by the HSA, SPA or commissioner shall not be considered in the review of the project and shall not be part of the record, except as provided under 7 MCAR § 1.661 E.2. (New language underlined)

✓ so amended p. 10

This amendment implies that permitted ex parte communications will be made part of the record thereby giving notice to interested parties. This is an essential amendment which necessarily protects the interests of the parties by letting them know the facts upon which decisions are made. The amendment is necessary and reasonable and not substantial for purposes of 9 MCAR § 2.111. However, it is recommended that Part E.2. be further amended to read as follows:

> Ex parte communications received by the HSA, SPA or commissioner shall not be considered in the review of the project and shall not be part of the record. However, ex parte communications under 7 MCAR § 1.661 E.2. will be made part of the record and any party affected thereby may request an opportunity to rebut or challenge the substance of such communications.

this language not used See p. 10

The suggested amendment clarifies the rights of the parties and guarantees a meaningful procedure consistent with due process considerations. Merely making ex parte information part of the record does give notice to affected parties of the reasons for action but is meaningless if they are not guaranteed the right to meet, question and cross-examine it.

36. The Department's Statement (p. 35) indicates that a communication is not ex parte if both parties have notice of it. MAHCF, which generally praised

the rule proposed, suggested that it be amended so that comments to the Department on the HSA recommendation and the evidence in the record be permitted to be filed so long as all other parties have notice of such comments. Such a provision is recommended. In contested cases, Minn. Stat. § 15.0421 provides that once the recommendation of a hearing examiner is issued, an opportunity must be afforded by the Agency to each party adversely affected to file exceptions and present argument to it. While additional evidence may not be presented under § 15.0421, arguments may be submitted. Similarly, after an HSA recommendation is submitted to the Department, the parties adversely affected by its recommendation should be able, within a specified time period, to file exceptions and argument with the Commissioner. An amendment to the rule permitting the filing of such exception and argument, but no additional evidence, would not constitute a substantial change for purposes of 9 MCAR § 2.111. Insofar as MAHCF's suggestion would allow the submittal of different evidence to the Commissioner, their recommendation should not be adopted. If the evidence is relevant and material, it should have been presented to the HSA and considered by them; if additional evidence is necessary or discovered later, the parties should be permitted only to request that the matter be remanded.

not amended except as previously noted p. 10

Extension of Review Period.

37. 7 MCAR § 1.661 F. This Part permits the time periods for review prescribed in the Act and under the rules to be extended by the mutual agreement of all parties upon proper notice. It also specifies that time periods under the Act, and in the rules, are deemed directory and not mandatory. In Benedictine Sisters Benev. Assn. v. Pettersen, 299 N.W.2d 738 (Minn. 1980), the Minnesota Supreme Court held that the time limits contained in the former Certificate of Need Act were not mandatory but merely directory. Since abuses of time limitations has not been a problem in the Certificate of Need process, and since the provisions of the Certificate of Need Act have been found to be directory and not mandatory, the Department's proposed rule is authorized, necessary and reasonable.

In its posthearing comments, the Department proposes to recodify Part F.4. (making time limits directory) to 7 MCAR § 1.661 G.3. In addition, the Department has proposed some technical amendments to § 1.661 G. pertaining to time computation. Those amendments are necessary, reasonable, and not substantial for purposes of 9 MCAR § 2.111.

p. 10, 11

p. 11

Evasions

38. 7 MCAR § 1.661 H. This Part implements Minn. Stat. § 145.841 which prohibits a health care facility from separating portions of a single proposed construction or modification into components in order to evade the cost limitations contained in the Act and which trigger CON reviews. Generally speaking, an evasion occurs under the rule when the component parts of a project have been jointly planned, when financing arrangements are made to cover an entire project, or when component parts are so "interdependent or interrelated that separate review would be inconsistent with the purposes of the Act." MHA/MAHA objected to the first two tests for an evasion. Their first concern is that two totally separate undertakings in a given time period may be considered by the Department as an evasion under the Act solely because the individual projects were jointly planned.

In its posthearing comments, the Department replied to the criticism of the joint planning test as follows (p. 11):

> The Act is clearly intended to treat joint planning as a single undertaking. The Act, is most fundamentally, a health planning law, and it would be inconsistent with the Act to somehow rationalize that when component parts are jointly planned, they are not a single undertaking. Obviously, many construction or modification projects have many phases; however, the joint planning of the phases is the basic thrust of the Act.

However, the Department did agree to delete the reference to joint financing. In addition, with respect to the long-range development plan of the health care facility, such a plan, or the annual capital expenditure budget, will not "in and of itself" constitute a single undertaking. The words "in and of itself" were replaced for the word "necessarily" that was originally proposed. This is not a substantial change for purposes of 9 MCAR § 2.111.

change made A-12

39. The Legislature clearly did not intend that separate and distinct sub-threshhold projects be combined by the Department in order to subject them to Certificate of Need requirements. Thus, for example, if a hospital in a particular year planned on remodeling its operating rooms, modernizing its cafeteria, and acquiring property for a parking lot, it seems clear that these are separate undertakings not subject to the Act if below the threshhold amounts. A close reading of § 1.661 H.1. does not lead to a contrary conclusion since those three undertakings certainly would not be component parts of a single project. On the contrary, as noted in the Department's posthearing comments, a construction in phases of a single project will constitute a single undertaking because that project is jointly planned even if built in several phases. The rule does not permit separate undertakings which are not components, even if jointly planned, to be combined to create a single project out of what are actually multiple projects. Rather, it permits jointly planned components to be treated as a single undertaking as the Department's Statement says. For that reason, the proposed rules pertaining to evasion, as amended by the Department's posthearing comments, are found to be necessary and reasonable except as is noted below.

40. MAHCF objected to the language which would make multiple projects a single undertaking when they are so interdependent or interrelated that separate review would be inconsistent with the purposes of the Act. In view of the penalties which can be imposed upon a health care facility for non-compliance, MAHCF argued that this test of a single undertaking was unreasonably vague.[6] The penalties for violation of the Act do make it imperative that those activities constituting a single undertaking be defined with as much clarity as possible. The proposed rule providing that component parts "are so interdependent or interrelated" so as to constitute a single undertaking when "separate review would be inconsistent with the purposes of the Act" is unreasonably vague. The public should not be put in a position of determining what is, or is not, consistent with the Act since the interpretation of the Act is the responsibility

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[6] A health care facility which fails to obtain the requisite Certificate of Need can be refused licensure for any portion of its premises found to violate the Act, and any facility in violation of the Act is ineligible for apply for or receive public funds until the requisite Certificate has been issued.

of the Department. Under Minn. Stat. § 15.0411, subd. 3, rules must be adopted by each agency which makes specific the law enforced by them. The language MAHCF opposes fails to attain requisite specificity and constitutes a substantive violation of law. There is no evidence that the Department could not make more specific criteria for determining a single undertaking, and that part of the rule pertaining to interdependent or interrelated items is unnecessarily vague. To correct this defect, the Department must delete this language or state under what circumstances a review of interdependent or interrelated projects is consistent with the Act. For example, the rule could state that projects are interdependent or interrelated when they cannot feasibly be undertaken separately. If the rule is not clarified, health care facilities who, even in good faith and in a bona fide belief that they were complying with the law, could be severely and unjustifiably sanctioned for a violation.

41. 7 MCAR § 1.661 I. This Part pertains to the interpretation of the rules and specifies that they shall be governed by the provisions of Minn. Stat. Chapter 645, except insofar as Chapter 645 is in conflict with the definitions or other provisions of the Act or the rules. Since the time that this Part was initially proposed, Laws 1981, Chapter 253, § 35, was enacted, adding a new provision, Minn. Stat. § 645.001. It provides that the provisions of Chapter 645, unless specifically provided to the contrary by law or rule, govern all rules becoming effective after June 30, 1981. The enactment of this law appears to make Part I. redundant and unnecessary. Therefore, it is suggested that it be deleted from the rules when adopted by the Department.

deleted p. 12

Determination of Applicability and Waivers.

42. 7 MCAR § 1.662 A. This Part requires a facility to submit a Notice of Intent to the applicable HSA (or SPA) when a health care facility intends to embark upon a construction or modification project. The notice must be submitted before any predevelopment activities are undertaken. MAHCF and Forest View Community Homes, Inc. queried whether the rule created a Catch-22 situation in that the contents of the required notice require a facility to undertake prohibited predevelopment activity. In its posthearing comments, the Department stated that predevelopment activities necessary to file the required notice of intent are not prohibited. Furthermore, to clarify the fact that rule does not require a Notice of Intent until there is a "firm intent" to proceed with a project, the Department has proposed clarifying language. As amended, it will read:

> If a person intends to embark upon a program of construction or modification, prior to engaging in any predevelopment activities with respect to the program of construction or modification, that person shall submit a notice of intent to the appropriate HSA.

so clarified p. 12

This amendment clarifying the scope and applicability of the Part is necessary and reasonable and does not constitute a substantial change for purposes of 9 MCAR § 2.111. Furthermore, while a facility may have a firm intention to proceed with a project from the very beginning, they obviously may proceed with necessary predevelopment activities necessary under the rule to enable them to file the required Notice of Intent. The Department has verified this construction and it is the only construction that would otherwise avoid an absurd result.

43. Section 1.662 A.2. requires that the Notice of Intent be submitted in writing to the HSA at least 60 days prior to the submission of an application for a Certificate of Need and prohibits an HSA from accepting or acting upon an application for a CON until proper notice has been given. This provision received the endorsement of CMHSA and was subject to no adverse public comment. Since the Notice of Intent creates a basic regimenting and ordering of the review process, it is necessary that it be submitted a reasonable period of time prior to the submission of a CON application. Therefore, it is concluded that this provision is necessary and reasonable.

MAHCF raised the issue whether a Notice of Intent was required from all facilities intending to embark upon a program of construction or modification prior to engaging in specified predevelopment activities. While the definition of predevelopment activities under Minn. Stat. § 145.833, subd. 4, is restricted to predevelopment activities in connection with new institutional health services, the Department persuasively argued that the predevelopment activities referenced in Minn. Stat. § 145.835, subd. 1, are broader than the predevelopment activities defined in the Act. Therefore, it is concluded that § 1.662 A. is necessary and reasonable. The Department has broad rulemaking authority to administer the CON Act and may, under that authority, adopt reasonable procedural requirements in connection with the review and approval of CON applications and construction and modification projects undertaken by regulated facilities.

44. Part A.4. specifies the contents required of each Notice of Intent. The information required from a facility is not burdensome, is consistent with § 145.835 and is necessary to implement an orderly review procedure. The information requested under the rule is the same information which has been obtained by the Department for the past six years. For these reasons, this Part is found to be necessary and reasonable in its entirety.

In its posthearing comments, the Department has proposed some technical, grammatical and language changes to § 1.662 A. The proposed changes are necessary and reasonable and do not constitute substantial changes for purposes of 9 MCAR § 2.111. p12,13

45. 7 MCAR § 1.662 B. This Part pertains to the determination by the Department of the applicability of Certificate of Need procedures to the undertakings listed in a facility's Notice of Intent. The rule permits the Commissioner, on his own motion, to make a determination and permits any person directly affected to request such a determination. Requests for a determination may be made regardless of whether or not a Notice of Intent has been submitted by the facility involved. This Part implements Minn. Stat. § 145.835, subd. 2, which provides that any person "directly affected by the proposed construction or modification may, at the time of submission of the notice to the health systems agency, request a written determination by the commissioner of health as to whether the construction and modification is subject to the provisions" of the Act and whether a Certificate of Need must be obtained.

MHA/MAHA challenged the proposed rule as exceeding the statutory authority of the Department because it would allow any person directly affected by a proposed construction and modification to make a request for a determination of applicability regardless of whether a Notice of Intent has been submitted and regardless of the time when that request was made. Essentially, their

argument is that Minn. Stat. § 145.835, subd. 2, is mandatory and precludes the Department from making written determinations when no Notice of Intent has been filed or when the request for determination is not submitted at the same time as the Notice of Intent. Adoption of MHA/MAHA's construction of the Act would severely frustrate the intent and purposes of the Act and render determinations of applicability virtually meaningless.

It is clearly the intent of the Legislature to allow any person directly affected by a proposed construction or modification to request a written determination of the applicability of CON procedures or for the Commissioner to initiate his own determination. This is evidenced by the use of the permissive word "may" rather than the mandatory word "shall" in the controlling statute. The temporal language "at the time of submission of the notice" if construed as mandatory, would frustrate the ability of the Commissioner to effectively implement, enforce and administer the Act because it would allow those subject to the Act to circumvent applicability determinations by merely failing to submit the required Notice of Intent. Furthermore, persons directly affected by the project for which a Notice may be required would have no way of knowing that the applicant intended to file its Notice and would be unable, therefore, to file a request "at the time of" its submission. Clearly, adoption of MHA/-MAHA's construction would make it virtually impossible for a person directly affected by a proposed construction or modification to make the request authorized by the statute. For that reason, it is determined that the rule, as proposed, is necessary and reasonable to effectuate the purposes of the Act and within the Department's authority. North Shore Fish & Freight Co. v. North Shore Business Men's Trucking Ass'n., 195 Minn. 336, 263 N.W. 98 (1935).

46. While Part B.1. has been found proper, a rule which ignores statutory language does raise serious questions, and the mere fact that a statute is properly construed as directory does not mean that its provisions should be wholly disregarded. Therefore, the Department is urged to seek an amendment to Minn. Stat. § 145.835, subd. 2, which would more closely conform it with the rule. In addition, the Department is urged to consider procedures which would make compliance with the staute workable.

47. 7 MCAR § 1.662 B.2. This Part authorizes the HSA or the Commissioner, when necessary in order to make an informed determination on the issue whether a proposed construction or modification requires a Certificate of Need, to request additional information about the proposed undertaking from the applicant, and an applicant's failure to provide the same is grounds for determining that a Certificate of Need is required. This is a necessary and reasonable provision if the Commissioner is to make an informed decision on the necessity for a Certificate of Need for a particular undertaking.

Physicians Equipment Acquisition.

48. 7 MCAR § 1.662 C. This Part is based on Minn. Stat. § 145.835, subd. 3, which requires a doctor or group of doctors proposing to purchase or otherwise acquire diagnostic or therapeutic equipment requiring an expenditure in excess of $150,000, to notify the HSA and the Department of the proposed acquisition prior to its purchase. Under the statute, the Commissioner has 60 days after receipt of the Notice, to determine whether or not the proposed acquisition is "designed to circumvent the provisions" of the Act. The proposed rule

specifies the information the Notice must contain, specifies a 20-day time period for the Commissioner to determine whether or not the information submitted in the Notice is complete, and if not, enables the Commissioner to request additional information, and specifies that the 60-day statutory time period does not commence to run until the Commissioner determines that the Notice is complete. The rule also establishes the time period during which the HSA may submit its comments or request that a hearing be held. Additionally, in determining whether a proposed acquisition is "designed to circumvent" the Act, the factors to be considered by the Commissioner are listed. These include material benefits to a facility, the facility's needs in the event the particular purchase is not made, and other relevant information tending to establish the existence of a design to circumvent the provisions of the Act.

The Minnesota Medical Association (MMA), through its attorneys, William J. Keppel, and Charles L. Sweeris, and the Minnesota Radiologic Society, through its attorney, Warren P. Eustis, vigorously protested the adoption of this Part on the grounds that the proposed rules are inconsistent with statutory provisions with respect to the type of notice required, the time period in which the Commissioner must determine whether an acquisition is designed to circumvent the Act, and the circumstances under which a physician's purchase is subject to the Act.

49. The Commissioner has authority to promulgate rules necessary to implement, enforce and administer the Act under Minn. Stat. § 145.834. Clearly, therefore, he has authority to specify what the notice required of physicians regarding capital expenditures for the acquisition of diagnostic or therapeutic equipment must contain and when that notice is deemed complete. The rules, which are designed in order to enable him to make an informed decision as to the necessity for the purchasers of such equipment to obtain a Certificate of Need, are necessary and reasonable. Obviously, in order to implement the stated purposes of the Act, the Commissioner must have enough information to make an informed decision as to the applicability of the Act to a particular purchase. Furthermore, the Commissioner has authority to determine when he has been notified and when notice is effective. The proposed rules do not make a notice under this Part effective until it is complete and set up a reasonbly short period of time during which the Commissioner must request supplemental information. The rules are not inconsistent with the statute, and, indeed, are necessary in order for the Commissioner to perform his specified duties.

The Department, in its posthearing comments, does not dispute the fact that the ultimate determination that must be made by the Commissioner when a physician, or group of physicians, proposes to purchase covered diagnostic or therapeutic equipment is whether or not the purchase is "designed to circumvent" the provisions of the Act. The rule specifying the factors that will be considered in making that determination is not unreasonable, and the factors to be considered are not irrelevant for purposes of making that ultimate conclusion. While MMA argued that the notice required by Minn. Stat. § 145.835, subd. 3, is a "simple" notice deliberately designed so that acquisitions by physicians would be routinely approved within 60 days unless the agency can show that the acquisition is designed to circumvent the Act, there is nothing in the language of the statute indicating that such purchases should be routinely approved or that the notice required should be simple. In fact, the

notice required by the proposed rules is not difficult and is limited to the kind of information the Commissioner must have in order to make an informed decision. Furthermore, as was correctly pointed out by the Department in its posthearing comments, the existence of a design to circumvent the Act, like the existence of a conspiracy, will require, in most cases, that circumstantial evidence pointing to the existence of such a design, be examined. The Department has specified, in Part C.5., some of the kinds of circumstantial evidence that will be examined by the Commissioner in making the determination whether or not a design to circumvent the Act exists.

50. The Department proposes that Part C.5. be amended to make it clear that the existence of an explicit agreement to circumvent the Act will be considered as evidence along with other direct or circumstantial evidence showing that an equipment acquisition is designed to circumvent the Act. Other specific or circumstantial evidence to be considered includes the benefits derived by the facility and the needs of the facility at the time the purchase is actually made. These are relevant factors to be considered. Consequently, it is determined that the Part, as proposed, is necessary and reasonable, and that the amendments offered clarifying what direct or circumstantial evidence will be considered in determining whether there is a design to circumvent the Act do not constitute substantial changes for purposes of 9 MCAR § 2.111.

amended p.16

However, it is recommended that Part C.5. be amended by adding other factors that should be examined. They include whether the facility involved has been denied a Certificate of Need for the purchase involved, and the facility's financial ability to make the purchase and whether the purchase is consistent with the facility's health care plan.

Waivers.

51. 7 MCAR § 1.662 D. Minn. Stat. § 145.835, subd. 4, authorizes the issuance of a waiver of the application for a Certificate of Need if (a) the capital expenditure is less than 3 percent of the facility's annual operating budget, and is required solely to meet federal or state requirements, or (b) the Certificate of Need is not related to direct patient care. In addition, the Commissioner is authorized by statute to grant waivers in other situations not inconsistent with the Act or federal law.

Part D.1. authorizes waivers under clauses (a) and (b) but only if the construction and modification involved meets the additional criteria specified in Part D.2. While MAHCF questioned the Commissioner's authority to impose additional criteria for the issuance of waivers authorized by statute, the Commissioner clearly has discretion in issuing or not issuing waivers under the statute. In exercising that discretion, he may, therefore, impose those conditions that he deems necessary. He is not required to grant waivers and his imposition of additional criteria is not prohibited.

52. In response to comments from MHA/MAHA, the Department proposes to delete the words "real estate" and substitute the word "site" so that site acquisitions are eligible for a waiver under Part D.1.a.. The purpose of this change is to set apart real estate acquisitions by health care facilities made for investment purposes from real estate acquisitions purchased as a site in connection with a construction or modification as defined in the Act. It is clear that real estate acquisitions solely for the purpose of investment are not subject to the Act, and facilities acquiring real estate for purposes of

investment should not, therefore, need to obtain a waiver. However, it is not clear that site acquisitions should be subject to waiver where the site is acquired in connection with a construction or modification. On the contrary, it appears that the acquisition of a site would only be part of a single undertaking, and one component of the building of a new addition and may likely be a component of a construction or modification. If that is true, it is recommended that real estate acquisitions not be replaced with site acquisitions. While the amendment proposed is necessary and reasonable and not substantial for pur poses of 9 MCAR § 2.111, it is suggested that the Commissioner reconsider the granting of waivers for site acquisitions which may be but one component of a single undertaking which would otherwise be a reviewable construction or modification under the Act. amended p.17

53. Part D.1.c. permits waivers of CON review for changes in bed certifications when the project is not otherwise reviewable under the Act and the criteria of Part D.2. are met. MAHCF, which believes that changes in certification levels should not be subject to CON review, supported the waiver provision for such changes. In its posthearing comments, the Department also proposes to delete from this Part the last criteria for waiver (§ 1.662 D.1.c.(3)) because it is duplicative of the other criteria that must be met under Part D.2.b. and c. The amendment proposed by the Department is necessary and reasonable and does not constitute a substantial change for purposes of 9 MCAR § 2.111. deleted p.18

54. Parts D.1.b., d., and e. permit the waiver of CON review when the proposed project consists solely of the acquisition of diagnostic or therapeutic equipment to replace existing equipment, when the project is solely to conduct reviewable predevelopment activity under § 1.661 B.18.a., or when the proposed project consists solely of the acquisition of an existing facility reviewable under § 1.661 B.7.a.(1) (a capital expenditure of more than $150,000) and the change is not otherwise reviewable under the Act or the rules. Waivers of these situations, subject to the criteria specified in Part D.2., were shown to be necessary and reasonable.

Additional Waiver Criteria.

55. Part D.2. lists the additional criteria that must be met before the various kinds of waivers may be granted. D.2.a., as originally proposed, established a five percent increase in patient charges, exclusive of adjustments for inflation, as the threshhold amount over which a waiver would not be granted. MAHCF objected to the five percent figure because, with respect to nursing homes, few, if any, are sold without a change in patient charges of at least five percent. Furthermore, since the Department presented no facts justifying the use of a five percent figure where the sales of nursing homes are involved, MAHCF challenged the reasonableness of the rule as proposed. While the five percent figure may be somewhat arbitrary when applied to the purchae of an existing facility, the Commissioner is not required to grant waivers at all in this situation, and in order to implement the policy of providing health care at the lowest possible cost, he can determine that any change in rates resulting from a purchase of more than five percent, exclusive of inflation factors, should be reviewed. If this results in the review of most purchases, it simply means that the Commissioner has determined that most purchases should be reviewed if rate changes of five percent or more are involved. Since he is not required to grant any waivers for the review of these matters, his decision to

review those in excess of five percent is not arbitrary, and the rule in that respect is necessary and reasonable.

56. With respect to the reclassification of nursing home beds, the Commissioner has determined, however, that the five percent figure is not realistic, and in the Department's posthearing comments, it is proposed that Part D.2.a. be amended to provide that a proposed waiver of changes in bed categories involving the federal certification status of nursing homes, the proposed project can be granted a waiver if it does not result in an increase in patient charges of more than 20 percent over existing charges rather than the five percent figure otherwise applicable. The 20 percent figure for this one type of construction or modification is necessary and reasonable because the difference between skilled nursing care rates and intermediate care rates in the state during 1979 and 1980 for both profit and non-profit nursing homes amounted to slightly more than 20 percent. This provision was supported by MAHCF and is necessary and reasonable and does not to amount to a substantial change for purposes of 9 MCAR § 2.111. amended p. 18

57. Part D.2.a. which specifies additional criteria that must be met before a waiver will be granted for the various kinds of constructions and modifications covered by the Act provides that those criteria must be "substantially fulfilled." MAHCF questioned the use of this term because it is not defined and its meaning is unclear. It is difficult to understand how the five percent or 20 percent limitation on changes in patient charges can be substantially fulfilled. It is also difficult to comprehend when an applicant has substantially fulfilled the requirement that he document that the project is not unnecessarily duplicative, will be adequately utilized and will result in effective and efficient operations in conformity with plans and guidelines. The Hearing Examiner agrees with MAHCF that the "substantially fulfilled" language in Part D.2.a. and Part D.1. seems to unnecessarily confuse the language of the rule. When making a determination of whether the criteria have been met, of course, many factors must be balanced and weighed by the Commissioner, and 100 percent or absolute compliance with all the criteria is probably not necessary or possible in any given case. However, it does not follow that because the Commissioner must weigh and balance the evidence applicable to waivers that the "substantially fulfilled" language should be included in the rule. Therefore, while it is not bound to do so, it is recommended that the Department delete the substantially fulfilled language from the rule or define the meaning of the term so that it is clear what is meant. Unnecessary ambiguities in the rule can only lead to inconsistent applications of the rule and unfettered discretion in the reviewing authority. The potential for arbitrary actions should be eliminated as much as possible. not deleted p. 17, 18

58. Part D.2.a. also indicates that the inflation indicator applicable to facilities other than hospitals shall be "a comparable inflation indicator established by a governmental agency." This unspecific language must be changed because the failure to specify which governmental agency's inflation indicator will be used permits the Department to use different inflation indicators from different government agencies for different applicants or to change them from time to time. Because it permits arbitrary and inconsistent determinations of inflation indicators at the unfettered discretion of the Commissioner, it constitutes a substantive violation of Minn. Stat. § 15.0411, subd. 3, requiring

rules to make specific the law enforced. To correct this defect, the provision must be clarified or deleted.

deleted p. 18

It would seem that the inflation indicator established pursuant to 7 MCAR § 1.504, applicable to hospitals, might be the appropriate inflation indicator for purposes of this Part It is difficult to understand why the inflation indicator for one facility should be different than the inflation indicator for other facilities. If there is a discernible difference, then the rule should specify with particularity the inflation indicator to be used for facilities other than hospitals, and how it will be calculated.

59. Part D.2.a., pertaining to the criteria for the granting of waivers, does not specifically mention Minn. Stat. § 145.843, which permits the Commissioner to deny certificate of need to facilities involved in license suspension or revocation proceedings. It would appear that if a Certificate of Need would not be granted to a facility under that provision, that a waiver should not be granted either. Since the statute gives the Commissioner discretion in the implementation of that provision, it is recommended that the rules state when that discretion will be exercised.

See added p. 19

60. Part D.2.c. requires that the proposed project conform to the facility's long-range development plan and to the guidelines, criteria and goals of other existing plans. MAHCF questioned the reference to the facility's long-range development plan as a criteria for the granting of a waiver because many nursing homes do not have such a long-range development plan. The requirement that the project conform to a long-range development plan is taken directly from the review criteria for applications for certificates of need under Minn. Stat. § 145.837, subd. 1(b). The Department did not respond to MAHCF's comment on this point, but it is apparently the intention of the rule that a waiver is available even where a facility does not have a long-range development plan if the other criteria are met. If this is the intention of the Department, they could clarify this part by adding the words "if any" immediately after the words "the proposed project conforms to the facility's long-range development plan. . . ." This is particularly appropriate for nursing homes whose costs of long-range planning are disallowed by the Department of Public Welfare in determining their nursing home rates. Federal regulations (42 C.F.R. § 123.412(a)(2)) use the same "if any" language proposed here.

added p. 19

61. Part D.3., as originally proposed, required that the request for a waiver be submitted by the applicant at the same time as the submission of a Notice of Intent would have been submitted. Since the Department did not intend to prohibit an applicant from requesting a waiver simply because the applicant did not submit the request for a waiver along with the Notice of Intent, in its posthearing comments, it proposes to amend the rule by adding the following language after the first sentence:

> In situations in which the applicant has previously submitted a notice of intent alone, nothing shall preclude the applicant from submitting an amended or updated notice of intent concurrently with the waiver request. The waiver request . . .

so amended p. 19

The amendment proposed by the Department to Part D.3. is necessary and reasonable and does not constitute a substantial change for purposes of 9 MCAR § 2.111.

62. Under Part D.7., emergency waivers are permitted when the project proposed results from fires, floods or other disasters. Under D.7.d., such waivers are available only when adequate facilities are not available to people who previously used the facility damaged and the repair does not exceed the guidelines and goals for such services in the applicable health system's plans or the state health plan. MAHCF challenged the conditioning of emergency waivers stating in its posthearing comments as follows (p. 16):

> Again, in this provision the Commissioner is attempting to significantly restrict the availability of waivers beyond what is contained in the statute, see, § 145.835, Subd. 5. Under this proposal, a facility that has one wing destroyed by a tornado, might not be able to rebuild it, or even clean up the debris, if it happens to be in an area that the HSA believes is "over-bedded". (Emphasis theirs)

In its Statement (p. 53), the Department explained the necessity for this provision as follows:

> 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 the 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 would still be adequately cared for and the purposes of the Act would only be met by a routine Certificate of Need review."

Under Minn. Stat. § 145.835, subd. 5, the Commissioner is authorized to grant emergency waivers for repairs resulting from damage from fire or other disasters. However, as is indicated with the use of the discretionary word "may", the Commissioner does have a considerable degree of discretion in implementing and administering the Act to regulate the issue of waivers in emergency situations, and has the discretion to impose reasonable conditions on the granting of such waivers.

63. Like the owners of non-conforming uses, the owners of facilities covered by the Act have no absolute right to rebuild their facilities when they are damaged by fire or other disaster. The Commissioner's proposed rule limits such rebuilding to that which is consistent with the plain purposes of the Act and protects health service needs and is, therefore, a necessary and reasonable exercise of his delegated discretion.

Review Process Procedures and Criteria, § 1.663.

64. 7 MCAR § 1.663 A. This Part requires the Commissioner to adopt a schedule of dates when CON applications may be submitted. The schedule must permit applications to be filed at least every 30 days. MHA/MAHA expressed concern that the Commissioner might establish categories of applications resulting in a particular type of application not being acceptable for an extended period of time. In its posthearing comments, the Department disavowed any intention to permit the categorization of applications or an alternating scheduling process. In order to clarify his intent, the Commissioner proposed to amend this part to make it clear that all types of applications may be submitted no less frequently than every 30 days. The amendment proposed to this Part is necessary and reasonable to clarify the Commissioner's intent and does not constitute a substantial change for purposes of 9 MCAR § 2.111.

amended p. 21

65. Parts A.2. and A.3. specify that there shall be four different forms of application to be developed by the Commissioner and that each applicant for a Certificate of Need must submit 14 copies of the appropriate application

form. CMHSA questioned the necessity for 14 copies and suggested, in the alternative, that 30 copies would be preferable being the number of its board members, and questioned the necessity for different application forms, pointing out that this could result in potential confusion in the review process. The Department is requiring 14 copies of the application to be submitted so that there is one copy for each of the 11 members of the typical project review committee, one copy for the HSA staff, one for the Commissioner and one for the SPA. The Department feels that providing additional copies would be unduly burdensome to the applicant, and that HSAs can, if more copies are needed, make their own. Furthermore, the Department selected four different types of applications because of the basic differences between the types of health care facilities governed by the Act. Different forms were felt to be needed because of the different operating costs, methods for examining of revenue, methods for describing areas served, patient origin, and other factors. The Department's rationale for the number of copies of the form to be submitted and for selecting the different kinds of forms will be used for different kinds of health care facilities is necessary and reasonable and particularly within their discretion. As Roger Moore, Executive Director of Forestview Community Homes, Inc. noted, it makes no sense to require the same information from a six-person group home that a large hospital or nursing home would have to provide.

66. 7 MCAR § 1.663 A.4. Pursuant to the Commissioner's authority to prescribe the format for the Certificate of Need application, the Commissioner has proposed § 1.663 A.4., which lists the information that must be included in all application forms. MAHCF questioned the Commissioner's authority to request some of the information specified and challenged the reasonableness of requesting other information. For example, it argued that the Commissioner is not authorized to require a CON applicant to report the effect of a proposed project on the general solvency of an applicant as required by Part A.4.b.(1)(b). However, under Minn. Stat. § 145.836, subd. 2(d)(3), the anticipated effect of a construction or modification on the general solvency of an applicant is required information that must be included in an application.

67. In its posthearing comments, the Department proposes to amend 7 MCAR § 1.663 A.4.b.(2)(i) and (ii) to incorporate by reference the federal statutory provisions pertaining to cost centers. The Chief Hearing Examiner approved this incorporation and the use of the citations to federal laws and regulations in these rules. For that reason, the amendment to this section is necessary and reasonable and may be adopted. so amended p. 23, 24

68. In addition, in response to comments from MAHCF and MHA, the Department proposes to amend § 1.663 A.4.d.(1) which formerly required a 20-year projection of the population and groups to be served by a proposed project. Since some projects have a useful life of less than 20 years, the 20-year projection in all cases would be unreasonable. Consequently, the rule is being amended to make it clear that the projection shall be for the anticipated life of the project or 20 years, whichever is less. This is a necessary, reasonable and insubstantial amendment to the rules as originally proposed.

69. Parts A.4.d.(3) and (4) require each applicant to report on the impact of the proposed project upon the health needs of people who have traditionally experienced difficulty in obtaining access to health care and to describe its performance during the past five years in meeting its obligations under federal

regulations or state rules regarding the provision of uncompensated care, community services, or access to programs receiving federal financial assistance. In addition, the applicant must report the extent to which Medicare-Medicaid and medically indigent persons are served by the applicant and the range of methods by which a person may have access to its services.

This rule, as proposed, received a great deal of support from consumer groups throughout the state advocating that it be adopted as written. Support was voiced by the Minnesota Board on Aging, the Central Minnesota Legal Services Community Legal Education Program, the Minnesota Senior Federation, the Anoka People's Alliance for Change, Minnesota Citizens Acting Together (Minnesota COACT), and several of its local chapters. These public comments demonstrate the need and reasonableness of including the provisions proposed by the Department and the legal requirement and justification for including them. While MHA/MAHA felt that consideration of these criteria would single out some facilities for discriminatory treatment, that argument lacks merits where the consideration of access to medical care facilities and a facility's past practices in meeting the needs for access, especially for the elderly and the handicapped, is a highly pertinent part of the CON review process. Consequently, the rule, as originally proposed, should be adopted.

70. Under § 1.663 A.4.e.(2), an applicant must report, as part of its report on the facility's relationship to other facilities, the occupancy or utilization rates of similar existing institutions during the past five years. MHA/MAHA objected to this section as proposed because it could result in a determination that an application is incomplete for failure to provide data relating to occupancy and utilization rates of similar existing institutions even where that data is unobtainable. In order to avoid that result, the Department proposes to amend this Part to require an applicant to report information on the occupancy or utilization rates of similar existing institutions if such information is accessible to the applicant. While this does not relieve the applicant of attempting to locate and secure the information required, the amendment is necessary and reasonable because it will prevent the rejection of a Certificate of Need for failure to report information for reasons beyond the control of the applicant. The amendment is consistent with Minn. Stat. § 145.836, subd. 2(f), which requires that a facility report that information only "so far as is known." The amendment proposed, which avoids an unreasonable result and makes the rule more consistent with the statute, is not substantial for purposes of 9 MCAR § 2.111.

amended p. 25.

71. Section 1.663 A.4.f. contains additional information an applicant must submit as part of its application. This Part requires a description of consumer choice plans and programs in which the Applicant participates and the current and five-year projected number of consumers involved in those plans and programs and the methods of public information regarding cost and quality of health services. Understandably, MHA/MAHA questioned this part as vague and unclear. In order to clarify the scope and intent of the rule, the Commissioner proposes to amend it. As amended, the type of information sought is clarified and made more specific consistent with the stated purpose of the Act to assist in providing the highest quality of health care at the lowest possible cost. The informational request included in this Part is reasonable and necessary and consistent with § 1.663 E.3.b. which includes such information in the

amended p. 25, 26

ultimate evaluation of the project. To the extent that facilities engage in methods, procedures or plans which promote price competition in the provision of health services, review of such information is reasonably germane to an evaluation of a proposed project in order to serve the purposes of cost containment and the avoidance of unnecessary duplication of facilities and services, goals which are central to the Act. The types of consumer choice health plans in which an applicant participates, the number of consumers who currently use and who are expected to use those plans, and the procedures by which the price and quality of the health services available will be made known to potential customers is a factor which should be considered in the CON review process, and the amendment which clarifies the reporting data on this aspect of an applicant's operations is necessary and reasonable and does not constitute a substantial change for purposes of 9 MCAR § 2.111.

72. Part A.4.i., as originally proposed, required that an applicant submit a copy of all survey reports from the Department, as well as voluntary survey groups, related to the quality of care provided by the facility during the last three years. MAHCF objected to this provision, stating that there was a general agreement among long-term care professionals and health department regulators that an accurate evaluation of the quality of care furnished by any particular facility is not available at this time. It also expressed concern about the use of surveys by voluntary survey groups. MHA/MAHA also raised questions as to the duplication involved under the rule by requiring both a copy of survey reports from the Minnesota Department of Health and the Joint Commission on Accreditation of Hospitals (JCAH) since they both utilized substantially equivalent criteria. It further argued that quality of care considerations are properly reviewable under the Act only to determine increases or improvements in the previously certified quality of care.

Since one of the purposes of the Act is to "assist in providing the highest quality of care", information from documented public quality of care surveys may be considered in the Certificate of Need review where, as here, the Commissioner has determined that such a review is appropriate. The Commissioner's rejection of MHA's argument to limit the quality of care review only to increases or improvements, is a reasonable exercise of his discretion, and consistent with his specific responsibilities under Minn. Stat. § 145.837, subd. 2(5)

73. The Commissioner agreed, however, that the survey reports submitted should be limited to those that are based on verifiable evidence and accepted standards for quality judgments. Consequently, he proposes to amend § 1.663 A.4.i. to provide that survey reports from the Minnesota Department of Health "or from other quality assurance programs recognized in federal or state laws, such as the Joint Commission on Accreditation of Hospitals" may be considered. so amended p. 26, 27 The proposed amendment is within the authority granted the Commissioner and is necessary and reasonable because it clarifies the rule, eliminates the requirement for filing duplicative reports, and ensures that the reports submitted have a recognized degree of reliability and are based on verifiable evidence. The amendment, as proposed does not constitute a substantial change for purposes of 9 MCAR § 2.111.

It should be pointed out, however, that this rule does not preclude independent survey groups, not recognized by federal or state law, from appearing

at the HSA hearing and offering any evidence they have pertaining to the quality issues which may be raised by a particular application. The rules, as proposed, do not preclude such testimony and the necessity for offering it was highlighted by Pamela Parker, a long-term care ombudsman for the Minnesota Board on Aging, and is implicit in the comments submitted by other consumer groups.

74. Forestview Community Homes, Inc. raised one issue with respect to this provision that has not been addressed by the Department. They were concerned whether a six-person group home would be required to file 14 copies of the survey reports from each of the homes operated or whether surveys only for the home involved in the proposed construction or modification would be required. This is an important point for those persons who operate several separate facilities, each of which is separately surveyed. In order to clarify the intent of this rule prior to final adoption, it is recommended that this issue be clarified.

no clarification but see F of F 24

75. Part A.4.k. requires that an applicant describe the relationship of the project to the health systems plan (HSP), the annual implementation plan (AIP), and the state health plan. MHA/MAHA argues that the use of the state health plan, here and in other parts of the rule, is unauthorized. Their argument is based on the proposition that Minn. Stat. § 145.837, subd. 2(6), prohibits the Commissioner from utilizing the state health plan. The essence of their argument is that since Minn. Stat. 145.832, subd. 1, provides that decisions regarding proposals subject to the Act should be based on the maximum possible participation on the local level that it is inconsistent with the Act for the Commissioner to use the state health plan, which is not a local health planning document; and therefore, its inclusion as a criterion of review is inconsistent with the Act and unauthorized.

The inclusion of the state health plan as a criterion for review is consistent with the stated purpose of the Act to promote comprehensive health planning. The Act does not seek to limit planning functions to the local level, but to maximize participation at the local level in the decision-making process. In order to effectuate the planning purposes of the Act, it is reasonable and necessary, if not essential, that the state health plan be included as a criterion for review. Although the review criteria set forth in Minn. Stat. § 145.837, subd. 1, do not mention the state health plan, those criteria are minimal criteria which must be considered by the Commissioner, as is indicated by the use of the words "at least" in specifying the criteria which must be considered. In implementing the rule, it is clear that the Commissioner can require that additional criteria be considered. Since there is a close interrelationship between the state health plan and the various health systems plans, and since the State Planning Agency itself may act as the HSA where none exists (indicating that in some areas of the state there is no HSA or no local health systems plan), it is concluded that inclusion of the state health plan in the review process is necessary, reasonable and authorized. This is consistent with the general rule that absent words of limitation, mere legislative silence should not be construed to limit an agency's discretion or to preclude the Commissioner from utilizing a state-wide planning document when comprehensive health planning is one of the specific purposes of the Act and

where the Commissioner is authorized to implement and administer such comprehensive health planning policies. Furthermore, Minn. Stat. § 145.837, subd. 2(5), requires that the Commissioner adopt rules governing findings of fact that should be made in each Certificate of Need application. The rules must require that the findings of fact "address the criteria specified in subdivision 1, and the provisions of the National Health Planning and Resources Development Act, 42 U.S.C. § 300k, et seq." Federal regulations implementing that Act, at 42 C.F.R. § 123.412(a)(1), require consideration of state health plans in evaluating Certificates of Need.

Determination of Completeness.

76. 7 MCAR § 1.663 B. This Part pertains to the determination of completeness procedures set out in Minn. Stat. § 145.836, subd. 1. Before review of a Certificate of Need application is commenced, an initial determination must be made that the application is complete. Section 145.836 and proposed rules require that the applications contain specified information. If the application is incomplete, § 145.836, subd. 1, requires that it not be considered but be returned to the applicant "stating the specific needs to be met" to be considered complete. In implementing this procedure, the Commissioner has proposed two rules which were vigorously challenged by MHA/MAHA. First, the Commissioner proposes the following language as justification for a determination of incompleteness in Part B.1.b:

> The information provided raises additional questions which must be answered in order for the HSA and Commissioner to perform their review under the Act and these rules.

In addition, upon receipt of any additional information requested, the Commissioner proposes Part B.2.a. to read as follows:

> If the applicant submits the required additional information to the HSA, SPA and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the application may be found to be complete without being deferred to another cycle of reviews.

MHA/MAHA commented on Part B.1.b. as follows:

> This process allows the Commissioner to inquire of the applicant until he (the Commissioner) is satisfied. The effect of this provision is to make indefinite and vague the determination of completeness of a CoN application. The reference of the Commissioner to additional questions which must be answered in order to perform the review under these rules is equally vague and without limitation. This proposed revision would allow the Commissioner and the HSA to raise questions ad infinitum before proceeding with the review.

Furthermore, MHA/MAHA argued that the Parts cited above are inconsistent with § 145.836. The inconsistency was characterized as follows (p. 21-22):

> The inconsistency has two facets. First, it is possible for the Commissioner to find that the initial application, as well as each subsequent submission of further information, raises additional questions. Such determinations could cause an application to be perpetually incomplete, and the applicant could never be sure that the information provided at any point would make the application complete. Second, it arguably would be impossible for the Commissioner ever to state the specific needs to be met for an application to be made complete. If an application was initially incomplete, the Commissioner could not be sure that new questions would not arise upon the provision of further in-

formation. Thus, even if the Commissioner tried to state exactly the needs to be met in order for the application to be made complete, he would logically be unable to do so (Emphasis theirs).

77. The rule permits the Commissioner, in their view, to engage in a kind of "fishing expedition" that has been, according to them, specifically prohibited by the Courts in investigatory proceedings. In response to these objections, the Commissioner now proposes to amend § 1.663 B.1.b. to provide as follows:

> The information provided raises definite questions directly relevant to the proposed project and which are critical and essential in order for the HSA and Commissioner to perform their review under the Act and these rules.

So amended P. 27

The use of broad discretionary language, such as "other information the Commissioner deems necessary or advisable" is, as a general rule, impermissible because it subjects the public to the unfettered discretion of the administrative officer. In some cases, however, a provision of that nature is necessary. Such is the case here. In its posthearing comments (p. 36), the Department noted that certain applications, such as those involving new medical technology, cannot receive prompt and complete review without additional information explaining that technology and its relationship to health planning and health costs. The amendment is necessary and reasonable and does not constitute a substantial change for purposes of 9 MCAR § 2.111. It serves to focus the scope of any additional information request with the requirement of definite questions of direct relevance to the proposed project and which are "critical and essential" in order for the HSA and the Commissioner to perform their review under the Act and the rules. This imposes some standard on the types of additional information the Commissioner requests and avoids the exercise of unfettered discretion.

Although MHA/MAHA characterized the Commissioner's request for additional information as an impermissible "fishing expedition", specifically prohibited by the Courts, it should be pointed out that the review of an application for a Certificate of Need is not an investigatory proceeding as characterized by MHA, but is more akin to the application for a license or permit and is regulatory rather than investigatory in nature. The information an administrative agency may request from an applicant for a permit, license, certificate of convenience and necessity or other authorization to undertake regulated activities has always been construed broadly to effectuate public policies and protect the public interest. To the extent that the Commissioner's duties could be analogized to an agency's investigatory power, Professor Davis makes it quite clear that the investigatory power does, indeed, permit agencies to virtually engage in fishing expeditions. Thus, he has stated as follows:

> The breadth of an investigation is for the investigators to determine. The breadth of a subpoena or of a search made in records may be excessive, but the test is relevanced to the specific purpose, and the purpose is determined by the investigators. The statement by the 9th Circuit seems about as good a general statement as any: "The only limitation upon the scope of the administrator's inquiry is that the records demanded be reasonably relevant to the matter in issue." 1 K. Davis, Administrative Law Treatise, Section 3.06, p. 189 (1958).

The necessity for the rule authorizing the Commissioner to request additional information when the application raises questions which must be answered in

order to undertake a meaningful review, was verified by MHA itself when it noted (p. 22) that even if the Commissioner tried to state "exactly the needs to be met in order for the application to be made complete, he would logically be unable to do so." This very observation points out the difficulty in establishing all the information which must be submitted for every kind of possible construction or modification and the necessity for having a procedure for obtaining additional information in unusual cases. While it is possible that the Commissioner might make a second determination of incompleteness, it is doubtful that that situation would ever occur.

HSA Hearing Procedures

78. 7 MCAR § 1.663 C. This Part governs the procedures applicable to HSA hearings on complete Certificate of Need applications. Under Part C.2., notice of the hearing must be published in a legal newspaper describing the project and the place of hearing, and a separate notification must be mailed to other affected persons, including at least the applicant, any contiguous HSA and all health care facilities located in the applicant's proposed service area. The Brown-Nicollet Human Services Board and the Brown County Public Health Nursing Service both suggested that mandatory notice should also be required to be given to local county boards, human services boards, local boards of health organized under the Community Health Service Act, community mental health boards and community social service boards. All these groups are involved, in one way or another, in the provision of health services, especially those pertaining to the mentally ill, mentally retarded and chemically dependent. The Department did not respond to these written comments, and it is suggested that the Department consider adding additional groups where it determines that mandatory notice to them is consistent with the purposes of the Act. However, the rule, as proposed, is necessary and reasonable and may be adopted. If the Commissioner declines to require mandatory notice to the other groups, as suggested by these comments, nothing prohibits these groups from monitoring local newspapers or notifying their local HSA in an attempt to work out some informal notice procedure. The latter approach is specifically prescribed in 42 C.F.R. § 122.308(a)(2). no change See FoF 27

79. Part C.6., which pertains to the HSA hearing, provides that "[e]vidence presented in the form of governmentally issued or sponsored planning documents, studies and guidelines, such as the state health plan, shall be given substantial weight but shall not be considered conclusive." Both MAHCF and MHA/MAHA objected to the Commissioner's attempt to determine the weight an HSA should give to particular kinds of evidence. MHA also challenged the Department's statement that the HSA hearing is not a judicial hearing but is most closely analogous to a legislative-type hearing. Whether or not the HSA hearing is concerned with adjudicative facts or legislative facts, or a combination of both, the Department proposes, in its posthearing comments, to delete the language objected to and to substitute it with the following:

> Evidence presented in the form of governmentally issued or sponsored planning documents, studies and guidelines, such as the State Health Plan and health systems plans, shall be specifically considered.

So amended p. 30

This is a necessary and reasonable amendment and leaves the weighing of the evidence to the body holding the hearing as is traditional, and the amendment, for purposes of 9 MCAR § 2.111 is not substantial.

Review Criteria (Termination of Services)

80. 7 MCAR § 1.663 E. This Part pertains to the criteria for the review of Certificate of Need applications by the HSA and the Commissioner. Part E.1.d.(3) provides that if the project involves the reduction, elimination or relocation of a health service, consideration shall be given to the extent to which the project will affect certain priority population groups. MAHCF and MHA/MAHA both challenged the Commissioner's authority to review reductions or eliminations of health services and suggested that the quoted language be eliminated from the rule. In its posthearing comments (p. 41), the Department stated that the rule was not intended to bring reductions or eliminations of services under the Act and suggested an amendment to Part E.1.d.(3) to read as follows:

> If the project involves the reduction, elimination or relocation of a health service and the project is otherwise reviewable under the Act, consideration shall be given to the extent to which the project will affect the ability of affected members of these above priority groups to obtain needed health care. (New language underlined.)

So amended p. 33

The National Health Planning and Resources Development Act of 1974, as amended, 42 U.S.C. § 300k et seq. requires each state to administer a Certificate of Need program which conforms to certain prescribed standards. Under §§ 123.402(b), 123.403(a), and 123.412(a), each state's Certificate of Need program must contain procedures and review criteria based on the provisions of § 123.401 et seq. Federal regulations elaborating on the requirements of the Act are found in 42 C.F.R. §§ 122.301 et seq. and 123.401 et seq., 45 F.R. 69742 et seq., October 21, 1980. 42 C.F.R. § 123.412, specifies the criteria for state agency rule. Subsection (a)(5)(ii) gives the following as the required criteria:

> In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the need that the population presently served has for the service, the extent to which that need will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, to obtain needed health care.

It is clear throughout the Act that the Commissioner is to comply with Federal law and regulations pertaining to the Certificate of Need program, and in reviewing applications must make written findings of fact addressing the criteria specified in the provisions of the National Health Planning and Resources Development Act, itself. Thus, since Federal law requires the consideration of the effect on certain population groups of the reduction, elimination or relocation of a service, the Commissioner's proposed § 1.663 D.1.d.(3), which is nearly identical to that in the Federal regulation, is found to be within the scope of the authority delegated to the Commissioner, and a necessary and reasonable provision. The clarification made in the proposed amendment that the project be otherwise reviewable under the Act is not a substantial amendment for purposes of 9 MCAR § 2.111.

81. MHA/MAHA also objects to proposed Part E.1.d.(4) which specifies that the review criteria include the past performance of the applicant in meeting its obligations under Federal laws and regulations or state laws requiring the provision of uncompensated care and other services to specified population

groups. Again, the rule is nearly identical in language to the requirement of 42 C.F.R. § 123.412(a)(6)(ii), which provides:

> The performance of the applicant in meeting its obligation, if any, under any applicable federal regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving Federal financial assistance (including the existence of any civil rights access complaints against the applicant). . . .

The proposed rule, like that previously mentioned, is specifically required by federal regulations and the Commissioner's adoption of this criteria, as he is required to do, is necessary and reasonable and within the scope of the authority granted to him under the Act. While MHA/MAHA felt that adoption of this criteria would lead to discriminatory action against some facilities, it cannot be presumed that the Commissioner will engage in any unlawful discrimination against any facilities which is not otherwise required by law. However, the accessibility of health care services to specified population groups, is one factor that must be considered in the Certificate of Need process. Such a consideration is not only mandated by the law, but there is obviously a direct relationship between accessibility and the provision of services, and it is reasonable that the Commissioner seek to review these factors in relationship to the needs of the population served or to be served by a proposed or existing facility, and that facility's past practices.

82. Price competition among similar services is an additional review criteria specified in Part E.3.b. of the rules. Subpart b., as originally proposed, provided as follows:

> The existence of methods by which public information regarding cost and quality of health services will be provided to potential consumers and payors.

MHA/MAHA challenged this Part as unreasonably vague in conjunction with its comments on 7 MCAR § 1.663 A.4.d.(4)(a). They feel that there is no incentive by consumers to consider costs of health care services and, for that reason, the language of this Part has no relationship to the purpose of the Act in providing the highest quality of care at the lowest cost. In addition, they challenge the rule as so vague as to be meaningless and suggested that it be deleted. Federal regulations at 42 C.F.R. § 123.412(a)(17) and (18) require a consideration of the effect of competition on the supply of health services being reviewed, and improvements or innovations in the financing and delivery of health services which foster competition and which serve to promote quality assurance and cost effectiveness. Certainly, the degree of participation by the applicant in health plans that provide options and choices to the consumer, and which inform the consumer about health care costs and the quality of health care services will have a bearing on competition. Furthermore, in evaluating the competitive effects of a particular project, the procedures to be used by the applicant in notifying consumers and payors of the costs of their services, and the qualify of their services is material. Therefore, it is concluded that the Part is a necessary and reasonable exercise of the Commissioner's authority, and as amended to clarify the vagueness mentioned by MHA/MAHA, the rule should be adopted. The amendment, itself, does not constitute a substantial change for purposes of 9 MCAR § 2.111.

see new language p. 34, 35

83. 7 MCAR § 1.663 E.4.f. This Part requires that the quality of care furnished by a particular applicant, as reflected in the most recent survey

reports of the Minnesota Department of Health, be considered during the review process. MAHCF objected to the use of the Department's survey reports on the basis that they are not sufficiently reliable and accurate for use in making Certificate of Need determinations and that the provisions should, therefore, be deleted. One of the purposes of the Act is to provide the highest quality of care to residents in the state of Minnesota. In addition, pursuant to 42 C.F.R. § 123.412(a)(20), quality of care provided by facilities in the past must be one of the criteria examined during the Certificate of Need process. The Commissioner's intended use of his own survey reports is necessary and reasonable and based on verifiable information. The mere allegations of MAHCF that these reports are not precise or accurate enough to make Certificate of Need determinations was not supported by any evidence and it was not shown that the other survey reports the Commissioner proposes to use are any more accurate. The Commissioner has proposed to amend this Part, however, to permit, in addition to survey reports from the Department, quality assurance programs recognized in Federal or state laws. If the other surveys which may be considered under the rule are more accurate with respect to particular matters, no doubt the weight accorded to these other reports will be greater, and any deficiencies in the Department's survey reports can be overcome by the use of alternative reports or other evidence. Therefore, the rule, as amended in the Department's posthearing comments, is necessary and reasonable and does not constitute a substantial change for purpose of 9 MCAR § 2.111.

amended p. 35, 36

84. Consistent with Minn. Stat. § 145.837, subd. 1(i) and (j), and Federal regulations, Part E.5. provides that the HSA reviewing an application for a Certificate of Need give consideration to the special needs and circumstances of certain regional or national health centers such as the Mayo Clinic. The proposed rule, however, in listing specific factors to which consideration shall be given, mentions the extent to which the instruction, studies or consultation provided by the facility is coordinated with other facilities in the area, and whether the project contributes to the health service needs of the residents of the health service area. The Mayo Clinic suggested that the consideration of the extent to which their activities are coordinated with the activities of other facilities was inconsistent with the purposes of the Act and that this Part, on the whole, fails to adequately define the special needs and circumstances of such facilities. In response to these comments, the Department has proposed some minor language changes to this Part. Those changes are necessary, reasonable and insubstantial. While the Department did not delete that part of the rule which requires consideration of the extent of the coordination that might exist between the facilities, retention of that requirement is not unauthorized or unreasonable and is consistent with the purpose of the Act to promote comprehensive health planning.

changed p. 36

Although the rule, as written, is not unreasonable or unnecessary, the Hearing Examiner agrees with the Mayo Clinic that it seems to place more emphasis on coordination and the needs of the health service area residents than on the special needs and circumstances of unique medical institutions. The purpose of the rule should be to require consideration of unique medical institutions' special needs and circumstances. To put the purpose of the rule in proper perspective, it is suggested that the Department add the word "also" to the beginning of the second sentence of Part E.5.a. so that it reads:

added p. 36

Consideration shall also be given as to whether:

* * *

Additionally, it is recommended that the Department adopt the Mayo Clinic's suggestion and add the following provision to the end of Part E.5.a.:

(3) The bed requirements for the applicant's service area should be counted in the overall bed to population ratio for that area.

not added - see FoF 29

85. 7 MCAR § 1663 H. Minn. Stat. § 145.836, subd. 3, provides that a proposed project may be revised by the HSA, the Commissioner or the facility during the review of the application provided that the revision is within the scope of the construction or modification originally proposed and is acceptable to the facility and the HSA. That statutory provision is contained in 7 MCAR § 1.663 F. In Part H.3.b. of the same section, the Commissioner originally proposed, in implementing the statute, to provide for the issuance of a conditional approval of a Certificate of Need, conditioned on the HSA's and the applicant's consent to specified revisions. MHA/MAHA vigorously protested the issuance of conditional Certificates of Need because the conditioning of Certificates on the approval by the HSA and the applicant of specified revisions is directly contrary to legislative intent. The Commissioner, in his posthearing comments, agreed that if an HSA and applicant do not accept a Commissioner-proposed revision, the project or proposal involved should be evaluated on its merits, and apparently agreed that the Commissioner has no authority to coerce changes in a facility's proposal by the issuance of a conditional Certificate of Need. In order to conform the rules to the statute and legislative intent, and to clarify these matters, the Commissioner proposes to amend Part H.3.b. by deleting the language pertaining to the conditional approval of Certificate of Need and the denial of applications in the event proposed revisions were not accepted by the applicant or the HSA. He also proposes to add a new subpart (6), to specifically provide that if the applicant or HSA rejects any revision proposed by the Commissioner, the project will be considered on its merits without prejudice due to its rejection. The rule, as amended by the Commissioner, is a necessary and reasonable provision within his delegated authority. It properly deletes impermissible provisions and addresses the concerns raised by MHA/MAHA. Furthermore, the amendment is a logical outgrowth of issues presented at the hearing and is not a substantial change for purposes of 9 MCAR § 2.111.

deleted p. 39

added p. 39

86. Part H.2. pertains to the Commissioner's review of the Application and record presented to him by the HSA. MAHCF objected to that part of the rule which permitted the Commissioner to review information not included in the HSA record but only in order to "assess the necessity of a remand to the HSA for further consideration." MAHCF feels that this provision is directly contrary to Minn. Stat. § 145.838, subd. 1, which permits the Commissioner to review the HSA's recommendations, and "based on the record developed" by the HSA, either issue a Certificate, deny a Certificate or remand the application for further consideration and recommendations." MAHCF believes that going outside the record to determine the necessity for a remand to the HSA for further consideration, is not a determination based "on the record" and is, therefore, impermissible.

Professor Davis has considered the propriety of an agency's taking of official notice of facts not in the record and has stated the concerns which must be evaluated in determining the propriety of going outside the record in making administrative decisions. He said:

> Among all the major problems of administrative law, none is so much misunderstood as the problem of use of extra-record information or understanding in an adjudication. The problem is to reconcile the needs of procedural fairness with the need for adequate use of administrative expertness, including knowledge and experience of the agency staff and including the storehouse of information which is readily available to the typical agency.
>
> * * *
>
> The cardinal principle of fair hearing is neither that all facts should be in the record unless they are indisputable, nor that all facts used should be subject to cross-examination and rebuttal evidence, nor that "nothing can be treated as evidence which is not introduced as such,", but it is that parties should have opportunity to meet in the appropriate fashion all facts that influence the disposition of the case.

2 K. Davis, Administrative Law Treatise, § 15.14, p. 431-32 (1958). Thus, the problem with taking official notice of facts not "on the record" is that final decisions should be made only on evidence which the parties have had an opportunity to know and challenge. Obviously, if the Commissioner knows facts not in the record and which may substantially impact on the propriety of a proposed construction or modification in terms of its need or its costs, a Certificate should not be granted merely because those facts were not "on the record." Furthermore, since his remand to the HSA to consider those facts gives all parties an opportunity to address them, no prejudice results to the parties, themselves, other than the time it takes to engage in further proceedings, and the purposes of the Act are fully implemented. Courts and agencies frequently remand matters for further consideration where additional information is required. This information may need scrutiny as a matter of law or may be brought to the attention of the Court or the administrator by mere allegations of the parties. In reviewing the record submitted by an HSA, the statute directs the Commissioner, "based upon the record developed", to make a determination. That does not mean that he cannot take official notice of extra record facts known to him or his staff based on their years of experience and combined expertise, and such a conclusion is not supported by any authority. If the record is inadequate or incomplete or fails to address issues or facts the Commissioner officially notices, he can properly remand the matter for further consideration.

Post-determination Actions.

87. 7 MCAR § 1.664 B. This Part pertains to the amendment of a Certificate of Need. The rule was adopted so that it would be clear when changes in a proposed project could be made after the issuance of a Certificate of Need without the necessity for the issuance of a new Certificate of Need. The approach taken by the Department is to classify changes as immaterial, minor and significant. Immaterial changes require no additional Certificate of Need review, minor changes and modifications receive limited review, and significant changes require the submission of a new application and a full Certificate of Need review.

Part B.3.c. originally listed a change in financing mechanism as a minor change which would require at least a cursory review by the HSA and the Commissioner. At the suggestion and request of MHA/MAHA, the Department now proposes to amend it to provide that only changes in financing mechanism "which increase the cost of financing" are reviewable minor changes. This is a necessary and reasonable amendment to the rule as originally proposed and does not constitute a substantial change for purposes of 9 MCAR § 2.111.

amended p. 43

88. Part B.3.e. provides that a minor change includes changes in the bed capacity of a facility in a manner which increases the total number of beds or distributes beds among various categories by few than ten beds or ten percent of licensed bed capacity, whichever is less, as a minor change. MHA/MAHA objected to this provision as contrary to Minn. Stat. § 145.833, subd. 5(a)(2), which only subjects changes in bed capacity by more than ten beds or more ten percent of the licensed bed capacity over a two-year period to CON review. MHA/MAHA argues that it is unreasonable to subject a recipient of a Certificate of Need to further review where it proposes to change the bed capacity in a manner not reviewable under the Act simply because a pending Certificate of Need has not been fully completed. The Commissioner feels that an otherwise unreviewable change in bed capacity does affect the Certificate of Need because the Certificate may not have been approved if the information regarding the change had been on the original application and that the complete project, with the proposed change in bed capacity, deserves evaluation.

The Commissioner believes that if such changes had been proposed in the original application it may have had a material effect on its disposition. He argues that the rule is consistent with the purposes of the Act and the detailed application and review provisions, and that such changes should be given at least minimal scrutiny by the HSA and the Commissioner prior to approval. It is possible that modifications which are classed immaterial or minor would impact related portions of the project so that they would have materially influenced the original determination to issue the Certificate of Need. In recognition of this potential impact, it is necessary and reasonable that the Commissioner have access to information regarding the effect of project modifications occurring prior to completion in order to determine whether the proposed changes or modifications fall within the scope of the project as initially proposed and that the evidence supporting the Certificate of Need as initially issued supports the changes or modifications. For that reason, the rule is found to be necessary and reasonable and within the scope of the Commissioner's delegated authority.

It should be noted, however, that changes in bed capacity which are reviewable minor changes must be changes that are truly part of the project originally approved. Thus, where the project originally approved consists of changes in bed capacity, which is reviewable under the Act, any modifications to the originally proposed changes in bed capacity would be a reviewable minor change. The rule is also limited to changes in an "approved project." Changes in bed capacity which have no relationship to the project originally proposed and approved would not be reviewable under the Act and cannot be reviewed because it would permit the Commissioner to do indirectly what he cannot do directly. Gale v. Commissioner of Taxation, 228 Minn. 345, 37 N.W.2d 711 (1949). However, changes which are part of the project or the construction or modification

originally proposed and merely a component of the project originally proposed are reviewable minor changes.

89. Section 1.664 B.4. pertains to those changes in a project which are of a significant nature and which require a full Certificate of Need review, including the submission of a new application. Part B.4.f. provides that "changes in the project which raise new material issues not previously considered by the HSA or Commissioner" are significant changes for purposes of the rule. MHA/MAHA challenged this rule as impermissibly vague, ambiguous and non-specific, giving the Agency discretion to impose additional requirements not covered by standards or criteria. Consequently, they recommended that it be deleted.

As noted in the Commissioner's Statement (p. 107), the purpose of this provision was to describe conditions whereby any changes which raised new material issues not previously considered by the HSA or the Commissioner would always require a new Certificate of Need review. The need to review significant changes in a proposed project is clear. However, the Commissioner must adopt standards and criteria which give reasonable notice to regulated facilities of what changes require them to submit a new application. Part B.4.f. wholly fails to give any reasonable notice to regulated facilities of their obligation to submit a new application. What issues are new or material or whether those issues were considered by the HSA or the Commissioner cannot readily be determined, and reasonable minds could differ substantially in the interpretation of this rule. As such, the rule, as proposed, is unreasonably vague and fails to make specific the law administered by the Commissioner contrary to Minn. Stat. § 15.0411, subd. 3, defining a rule for purposes of the APA and constitutes a substantive violation of law. To correct this defect, this provision must be deleted or specific standards adopted.

specific standards adopted p. 44

90. Under Minn. Stat. § 145.839, a Certificate of Need expires if the construction and modification is not commenced within 18 months following the issuance of the Certificate. Section 1.664 C.3. lists six criteria the Commissioner will use in determining whether a project has commenced. MAHCF questioned whether this provision was intended to mean that all six criteria listed must be met or whether just one of the six criteria must be met for a project to be considered to have commenced. That issue should be clarified in the final version of the rules.

clarified p. 46

91. Minn. Stat. § 145.84 requires the Commissioner to adopt rules mandating that facilities, upon completion of a project, to furnish financial information comparing actual costs with estimated costs. Section 1.664 E.2. in implementing that provision requires facilities to explain discrepancies of more than five percent between actual and estimated costs and the effect of those additional costs on the facilities' operations and patient charges. MHA/MAHA objected to this Part because it fails to provide for the exclusion of inflation costs not projected at the time of application. It is not logical to assume that the Commissioner would be able to differentiate those cost discrepancies attributable to unprojected inflation and those attributable to other factors. Therefore, the provision, as proposed, is necessary and reasonable.

92. 7 MCAR § 1.664 E.5. This Part makes reporting requirements under the rule applicable to projects which have received Certificates of Need since August 1, 1979, the date the Act was adopted. MHA/MAHA suggested that this

section be deleted in its entirety. They argue that the requirement of retroactive periodic reporting imposed by this rule is beyond the authority granted the Commissioner and is an unreasonable type of "ex post facto" regulation. It is their position that projects which received Certificates of Need since August 1, 1979, and up to the effective date of the rules proposed by the Commissioner, are governed by the rules of the State Planning Agency which do not currently require periodic reporting. They further argue that if the Commissioner desired to obtain this information, temporary rules should have been adopted under Minn. Stat. § 15.0412, subd. 5.

The Department did not respond to this particular objection but its Statement (p. 116) notes that one of the purposes of requiring periodic reports is to supply the Department with a data base on capital expenditures and that requiring reports regarding capital expenditures after August 1, 1979 would provide the Department with the needed data base on capital expenditures and information on capital cost trends.

Retroactive rules, as noted by Professor Davis, are not necessarily prohibited. He has observed:

> Like retroactive statutes, retroactive rules are valid if they are reasonable but are invalid if their retroactivity is unreasonable in the circumstances. The constitutional prohibition of ex post facto laws has always been limited to criminal law and has never applied to civil legislation or regulations.

1 K. Davis, Administrative Law Treatise, § 7:23, p. 109 (2nd Ed. 1979). However, Davis has also noted, with respect to retroactive rules as follows:

> Although the argument is plausible that legislative rules may be retroactive whenever a statute may be, since the fairness or unfairness is the same, and judicial ideas of fairness are decisive, rules differ in two main respects - agencies have no powers except those conferred, and courts are reluctant to imply power to issue retroactive rules, and courts give greater deference to judgments of legislative bodies than to judgments of agencies. The ideal might be to tolerate retroactive rules only when they are specifically authorized by a statute, but courts' holdings fall well short of that ideal.

Id., p. 109. The Minnesota Administrative Procedure Act does not discuss an agency's authority to adopt retroactive rules. However, rules are defined in § 15.0411, subd. 3, as "every agency's statement of general applicability and future effect." The Minnesota Supreme Court has considered retroactive rules in one case. In Mason v. Farmers Ins. Companies, 281 N.W.2d 344 (Minn. 1979), the Court stated as follows (p. 348):

> In principle, rules may be made retroactive if it is reasonable to do so. See, Summit Nursing Home, Inc. v. United States, 572 Fed. 2d. 737 (Ct. Cl. 1978). But Minn. Stat. § 15.0413 does not specifically provide for retroactivity of this rule in this case; nor does the Minnesota Franchise Act nor the rule itself.

The rule proposed by the Department is not a prohibited ex post facto rule, and while it requires facilities to report to it on facts occurring in the past, it is not retroactive in the ordinary sense of that term. It does not impose any sanctions or remove any rights, benefits or privileges facilities otherwise enjoyed. On the contrary, it merely requires those facilities, in the future, to submit reports pertaining to past activities. If, for that reason, it is retroactive in some respect, that retroactivity is not prohibited. The Commissioner does have a legitimate need to obtain information on capital costs and capital cost trends, and the fact that temporary rules were not

adopted with respect to this issue is immaterial. Consequently, the rule, as proposed, is found to be necessary, reasonable and within the scope of the Commissioner's delegated authority.

93. 7 MCAR § 1.664 F. This Part provides that the Commissioner shall have access to all financial and other records of any entity subject to the Act. This provision was objected to by MHA/MAHA as outside the scope of the Commissioner's delegated authority. The Act nowhere provides that the Commissioner has a visitorial power to gain access to facilities' records. It cited no general authority to conduct investigations of that nature, and it has no cited subpoena power. In cases where agencies have undertaken investigations, statutory provisions have been included in their delegation of authority specifically permitting them to issue subpoenas or to examine records. See, e.g., Minn. Stat. § 256 B.27, subd. 3, and Minn. Stat. § 256B.27 (1980).

Proposed Part F. violates Minn. Stat. § 15.0412, subd. 1, requiring agencies only to adopt rules pursuant to delegated authority, and constitutes a substantive violation of the Minnesota Administrative Procedures Act. Therefore, it must be deleted. If the Commissioner feels that such investigatory power is necessary, proper statutory authorization must be obtained to have access to pertinent financial records necessary to determine compliance with the Act. deleted p. 48

94. The repeal of State Planning Rules upon the adoption of the rules proposed is authorized by Minn. Stat. § 145.834 and is clearly necessary and reasonable.

95. The incorporation by reference in the rules of various state and federal laws is authorized by an Order of the Chief Hearing Examiner on file herein and is necessary and reasonable and consistent with Minn. Stat. § 15.0412, subd. 4a. Furthermore, all repetition of statutory language in the rules proposed is essential and crucial for their understanding for purposes of Minn. Stat. § 15.0412, subd. 1.

Based on the foregoing Findings of Fact, the Hearing Examiner makes the following:

CONCLUSIONS

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

2. That the Department has fulfilled the procedural requirements of Minn. Stat. § 15.0412, subd. 4-4f (1980) and all other procedural requirements of law or rule.

3. That the Department has demonstrated its statutory authority to adopt the proposed rules and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 15.0412, subd. 4e and 15.052, subd. 3(4)(i) and (ii) (1980), except as noted at Findings 31, 40, 58, 89 and 93.

4. That the Department has documented the need for and reasonableness of its proposed rules with an affirmative presentation of facts in the record within the meaning of Minn. Stat. § 15.0412, subd. 4c (1980).

5. That the amendments and additions to the proposed rules which were suggested by the Department after publication of the proposed rules in the State Register do not result in rules which are substantially different from

the proposed rules as published in the State Register within the meaning of Minn. Stat. § 15.0412, subd. 4d (1980) and 9 MCAR §§ 2.110 A. and 2.111 (1980 Ed.).

6. That the Hearing Examiner has suggested action to correct the defects cited in Conclusion 3 as noted at Findings 31, 40, 58, 89 and 93.

7. That due to Conclusion 3, this Report has been submitted to the Chief Hearing Examiner for his approval pursuant to Minn. Stat. § 15.0412, subd. 4d (1980).

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

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

Based upon the foregoing Conclusions, the Hearing Examiner makes the following:

RECOMMENDATION

It is hereby recommended that the proposed rules be adopted except where specifically otherwise noted above.

Dated this 6th day of August, 1981.

Jon L. Lunde

JON L. LUNDE
Hearing Examiner

It is further ordered that NALAC mail all shareholders of NALAC a copy of all statements, amendments, or other material filed hereafter pursuant to Minn. Stat. § 60D.02, subds. 1 and 2 (1978) within five (5) business days after receipt by NALAC.

It is further ordered that Allianz shall reimburse NALAC for all expenses it reasonably incurs in mailing this Notice and Order for Hearing and in mailing all statements, amendments, or other material filed pursuant to Minn. Stat. § 60D.02, subds. 1 and 2 (1978), as ordered hereinabove. To guarantee payment of these expenses, Allianz is ordered to furnish the Insurance Commissioner with a bond in the amount of $5,000.00.

The hearing in this matter will be held for the purpose of determining whether the Commissioner should approve or disapprove the purchase by Allianz of NALAC, pursuant to the authority vested in the Commissioner by Minn. Stat. § 60D.02 (1978).

The hearing will be conducted pursuant to the contested case procedures set forth in Minn. Stat. §§ 15.0411 through 15.0422 (1978) as amended, and pursuant to the rules of contested case procedures adopted by the State Office of Hearing Examiners, 9 MCAR §§ 2.201-2.222.

Allianz, NALAC, shareholders of NALAC and any other persons whose interests may be affected may be represented in this proceeding by legal counsel, by a person of their choice, or by themselves if not otherwise prohibited as the unauthorized practice of law. Questions concerning issues, concerning informal disposition of these proceedings, or discovery should be directed to Special Assistant Attorney General Robert J. Clayton, 500 Metro Square Building, Seventh and Robert Streets, Saint Paul, Minnesota 55101, telephone (612) 296-9412.

October 4, 1979

Michael D. Markman
Commissioner of Insurance

Energy Agency
Data and Analysis Division

Notice of Intent to Solicit Outside Information Concerning the Agency in Its Preparation for the Hearing to be Held on NSP's Application to Modify Prairie Island's Spent Fuel Pool

Notice is hereby given that the policy analysis staff of the Minnesota Energy Agency is seeking information, opinions, and comments from sources outside the Agency in its preparation for the hearing to be held on NSP's application to modify Prairie Island's spent fuel pool. NSP seeks to increase the storage capacity by replacing current storage racks with racks containing more storage spaces. The Certificate of Need Hearing on NSP's application will be held pursuant to Minnesota Laws 116H.13 and 6 MCAR §§ 2.0601-2.0641. The policy analysis staff recognizes that many members of the public have difficulty in participating in Certificate of Need hearings which can be legalistic, confusing, and time-consuming. Therefore, the policy analysis staff is providing this opportunity for public information, opinions, and comments before the staff prepares its testimony and questions for hearing. Since the staff anticipates receiving diverse views on this application, no responder is assured that his view will be the position taken by staff. However, the staff will endeavor to assure that the concerns and questions of the public are addressed at the Certificate of Need hearing. The staff anticipates that public meetings to gather input will be held in Red Wing and St. Paul prior to the Certificate of Need hearing.

Anyone desiring to give information, opinions, or comments is asked to write to the Agency at the following address:

David W. Buller, Manager
Minnesota Energy Agency
980 American Center Building
150 E. Kellogg Blvd.
St. Paul, Minnesota 55101
Telephone : (612) 297-2335

Comments should be received by November 20, 1979.

Department of Health
Health Systems Division

Notice of Intent to Solicit Outside Opinion Concerning Rules Governing Certificates of Need for Health Care Facilities

Notice is hereby given, pursuant to the provisions of Minn. Stat. § 15.0412, subd. 6 (1978), that the Commissioner of Health is soliciting outside opinions concerning the promulgation of rules governing all aspects of the implementation, enforcement, and administration of Laws of 1979, ch. 323, the Minnesota Certificate of Need Act. These rules, when promulgated, will take the place of the existing Certificate of Need rules adopted by the State Planning Agency. In the meantime, the State Planning rules will remain in effect.

All interested parties desiring to submit data, views, opinions, comments or other related information concerning the amendment or revision of the Certificate of Need rules should write to or telephone Kent E. Peterson, Chief, Planning & Resources Control Section, Minnesota Department of Health, Division of Health Systems, 717 Delaware Street

Southeast, Minneapolis, Minnesota 55440, telephone (612) 296-5365. Evidence submitted for consideration should be pertinent to the matter at hand. Written material received by the Department of Health will become part of the hearing record.

Any materials submitted will be reviewed and considered by the Department of Health during the preparation of the proposed rules. Notice of the public hearing on the proposed rules will be published in the *State Register* and given to all interested parties who have registered with the Secretary of State's Office in accordance with the provisions of the Administrative Procedure Act.

In addition, please be advised that Minn. Stat. § ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five (5) days after he commences lobbying. A lobbyist is defined in Minn. Stat. § 10A.01, subd. 11 (1978) as amended by Laws of 1979, ch. 59 § 3, as any individual:

(a) Engaged for pay or other consideration, or authorized by another individual or association to spend money, who spends more than five hours in any month or more than $250, not including *his own* travel expenses and membership dues, in any year, for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials; or

(b) Who spends more than $250, not including *his own* traveling expenses and membership dues, in any year for the purpose of attempting to influence legislative or administrative action by communication or urging others to communicate with public officials.

The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, Saint Paul, Minnesota 55155, telephone (612) 296-5615.

September 28, 1979

George R. Pettersen, M.D.
Commissioner of Health

Minnesota State Retirement System

Special Meeting of the Board of Directors

Notice is hereby given that a special meeting of the Board of Directors of the Minnesota State Retirement System will be held on Friday, October 26, 1979, at 9:00 a.m. in the office of the System, 529 Jackson Street, St. Paul, Minnesota 55101.

Department of Personnel Social Security Retirement Division

Notice of Intent to Solicit Outside Opinion Concerning Proposed Revisions of Rule Relating to More Frequent Depositing of Social Security Contributions and Providing for Annual Reporting of Wages by Covered Public Employers

Notice is hereby given that the Minnesota Department of Personnel is considering the revision of the department's rule, 2 MCAR § 2.198, requiring more frequent depositing of Social Security contributions by covered public employers in order to comply with Federal Department of Health, Education and Welfare regulations, 20 CFR, Sections 404.1255 and 404.1255A.

The proposed amendments to the rule are authorized by Minn. Stat. § 355.05 which enables the department to promulgate such rules as it finds necessary or appropriate for the efficient administration of its Social Security functions. One proposed amendment prescribes the time and conditions for monthly depositing of Social Security contributions by covered public employers effective July, 1980. The other proposed amendment provides for annual reporting of wages, in lieu of quarterly reporting, with an effective date of January 1, 1981.

All interested or affected persons or groups may submit information on this subject. Written or oral information and comment should be addressed to: Mr. Harry Groschel, Director, Social Security Retirement Division, Room 656, Space Center Building, 444 Lafayette Road, St. Paul, Minnesota 55101.

All statements of information and comment must be received by November 2, 1979. Any written materials received by this date will become part of the record of any rules hearing held on this subject.

Barbara L. Sundquist
Commissioner of Personnel

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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.

ORDER FOR HEARING

To effectively implement the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832-145.845 (1980), the Minnesota Commissioner of Health deems it necessary to consider adoption of the proposed rules captioned above pursuant to the authority vested in him by the above-referenced Act.

NOW, THEREFORE, IT IS ORDERED this 10 day of April, 1981, that a public hearing on the proposed rules captioned above be held in Room 111, William Mitchell College of Law, 875 Summit, St. Paul, Minnesota, on June 9, 1981, commencing at 9:00 a.m., and continuing until all persons or representatives of associations or other interested groups have had an opportunity to be heard.

IT IS FURTHER ORDERED that notice of said hearing be published in the State Register and be given to all persons or representatives of associations or other interested groups who have registered their names with the Commissioner of Health for that purpose.

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

George R. Petterson M.D.

GEORGE R. PETTERSEN, M.D.
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

NOTICE OF HEARING

A public hearing concerning the proposed new rules captioned-above will be held in Room 111, William Mitchell College of Law, 875 Summit Avenue, St. Paul, Minnesota, on June 9, 1981, commencing at 9:00 a.m. Persons attending the hearing may park either on Summit Avenue or at the William Mitchell parking lot between Summit Avenue and Grotto, two blocks east of the school. The proposed rules may be modified as a result of the hearing process. Therefore, if you are affected in any manner by the proposed rules you are urged to participate in the rule hearing process.

Following the agency's presentation at the hearing, all interested or affected persons will have an opportunity to ask questions and make comments. Statements may be made orally and written material may be submitted. In addition, whether or not an appearance is made at the hearing, written statements or material may be submitted to Jon L. Lunde, Hearing Examiner, Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, telephone: (612) 296-5938, either before the hearing or before the close of the hearing record which shall remain open at least five working days after the hearing is adjourned. The Hearing Examiner may, at the hearing, order that the record be kept open for a longer period not to exceed 20 calendar days. All such statements will be entered into and become part of the record. For those wishing to submit written statements or exhibits, it is requested that at least two (2) copies be furnished. In addition, it is suggested, to save time and avoid duplication, that those persons, organizations, or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement in behalf of such interests. The rule hearing procedure is governed by Minn. Stat. §§ 15.0411-15.0417 and 15.052 and by 9 MCAR (Minnesota Code of Agency Rules) §§ 2.101-2.113. If you have any questions about the procedure, call or write the Hearing Examiner.

The statutory authority for the Commissioner of Health to adopt these rules is contained in Minn. Stat. § 145.834 (1980). In addition to this general directive to adopt such rules as are necessary to implement, enforce, and administer the Certificate of Need Act (hereinafter "Act"), Minn. Stat. §§ 145.832 to 145.845 (1980), specific areas authorized to be addressed by rules or procedures are contained in Minn. Stat. §§ 145.834, 145.835, subds. 4 and 5, 145.836, subd. 2, 145.837, subds. 1 and 2(5), 145.84, and 145.845 (1980). Furthermore, a general grant of authority to adopt procedural rules is contained in Minn. Stat. § 15.0412, subd. 3 (1980).

The new rules repeal the existing rules of the State Planning Agency, 10 MCAR §§ 1.201 to 1.210 (formerly SPA 201 to 210), which were promulgated pursuant to Minn. Stat. §§ 145.71 to 145.831 (1978), the Certificate of Need Act in effect prior to August 1, 1979, and constitute an entirely new set of rules intended for the implementation, enforcement, and administration of the existing Act. In doing so, the rules cover the following subjects:

1. General provisions regarding definitions, membership of the health systems agency and its governing body, conflicts of interest, ex parte communication, extension of the review period, computation of time periods specified in rules or the Act, evasions of the Act, and guide to interpreting the rules;

2. Rules governing the submission of the notice of intent, the determination of applicability of the Act to a project, the acquisition of equipment by physicians, and the granting of waivers to projects subject to the Act;

3. Rules governing the review process, procedures, and criteria including the submission and content of the application for certificate of need, the determination of completeness of the application, the Health Systems Agency hearing process, and procedures for reaching recommendations on certificate of need applications, the review criteria, the procedures for revisions of a project, the content of the hearing record, and the Commissioner's determination;

4. Rules governing consolidated review process and determination by the Commissioner of life support transportation service projects which are subject to both the Act and Minn. Stat. § 144.802;

5. Rules governing post-determination actions including reconsideration of the Commissioner's determination, amendment of an issued certificate of need, transfer of an issued certificate of need, expiration of a certificate of need, submission of periodic reports, and investigations;

6. Rules governing applications from health maintenance organizations including the basis of review, the entities which qualify for exemption from review, conditions for exemption, procedures, criteria for review, and provisions for judicial review.

A free copy of the rules may be obtained by contacting Kent Peterson, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440, telephone (612) 296-5365. Additional copies will be available at the hearing. If you have any questions about the rules, please contact Mr. Peterson.

Twenty-five (25) days prior to the hearing, a Statement of Need and Reasonableness will be available for review at the agency and at the Office of Administrative Hearings. This Statement of Need and Reasonableness will include all of the evidence which the agency intends to present at the hearing to justify both the need for and the reasonableness of the proposed rule. The agency intends to present only a summary of the Statement of Need and Reasonableness at the hearing; however, additional evidence may be submitted in response to questions raised by interested persons. You are therefore urged to both review the

Statement of Need and Reasonableness before the hearing and to attend the hearing. Copies of the Statement of Need and Reasonableness may be obtained from the Office of Administrative Hearings at a minimal charge. Additional copies will be available at the hearing.

Any person may request notification of the date on which the Hearing Examiner's Report will be available, after which date the agency may not take any final action on the rules for a period of five working days. Any person may request notification of the date on which the hearing record has been submitted or resubmitted to the Attorney General by the agency. If you desire to be so notified, you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the Hearing Examiner, in the case of the Hearing Examiner's Report, or to Mr. Peterson, in the case of the agency's submission or resubmission to the Attorney General.

Minn. Stat. ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five days after he or she commences lobbying. A lobbyist is defined in Minn. Stat. § 10A.01, subd. 11, (1980) as any individual:

a. Engaged for pay or other consideration, or authorized by another individual or association to spend money, who spends more than five hours in any month or more than $250, not including his own travel expenses and membership dues, in any year, for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials; or

b. Who spends more than $250, not including his own traveling expenses and membership dues, in any year for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials.

The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, St. Paul, Minnesota 55155, telephone: (612) 296-5615.

Dated: April 16, 1981

STATE OF MINNESOTA
COMMISSIONER OF HEALTH

s / George R. Pettersen, M.D.
GEORGE R. PETTERSEN, M.D.
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

NOTICE OF HEARING

A public hearing concerning the proposed new rules captioned-above will be held in Room 111, William Mitchell College of Law, 875 Summit Avenue, St. Paul, Minnesota, on June 9, 1981, commencing at 9:00 a.m. Persons attending the hearing may park either on Summit Avenue or at the William Mitchell parking lot between Summit Avenue and Grotto, two blocks east of the school. The proposed rules may be modified as a result of the hearing process. Therefore, if you are affected in any manner by the proposed rules you are urged to participate in the rule hearing process.

Following the agency's presentation at the hearing, all interested or affected persons will have an opportunity to ask questions and make comments. Statements may be made orally and written material may be submitted. In addition, whether or not an appearance is made at the hearing, written statements or material may be submitted to Jon L. Lunde, Hearing Examiner, Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, telephone: (612) 296-5938, either before the hearing or before the close of the hearing record which shall remain open at least five working days after the hearing is adjourned. The Hearing Examiner may, at the hearing, order that the record be kept open for a longer period not to exceed 20 calendar days. All such statements will be entered into and become part of the record. For those wishing to submit written statements or exhibits, it is requested that at least two (2) copies be furnished. In addition, it is suggested, to save time and avoid duplication, that those persons, organizations, or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement in behalf of such interests. The rule hearing procedure is governed by Minn. Stat. §§ 15.0411-15.0417 and 15.052

and by 9 MCAR (Minnesota Code of Agency Rules) §§ 2.101-2.113. If you have any questions about the procedure, call or write the Hearing Examiner.

The statutory authority for the Commissioner of Health to adopt these rules is contained in Minn. Stat. § 145.834 (1980). In addition to this general directive to adopt such rules as are necessary to implement, enforce, and administer the Certificate of Need Act (hereinafter "Act"), Minn. Stat. §§ 145.832 to 145.845 (1980), specific areas authorized to be addressed by rules or procedures are contained in Minn. Stat. §§ 145.834, 145.835, subds. 4 and 5, 145.836, subd. 2, 145.837, subds. 1 and 2(5), 145.84, and 145.845 (1980). Furthermore, a general grant of authority to adopt procedural rules is contained in Minn. Stat. § 15.0412, subd. 3 (1980).

The new rules repeal the existing rules of the State Planning Agency, 10 MCAR §§ 1.201 to 1.210 (formerly SPA 201 to 210), which were promulgated pursuant to Minn. Stat. §§ 145.71 to 145.831 (1978), the Certificate of Need Act in effect prior to August 1, 1979, and constitute an entirely new set of rules intended for the implementation, enforcement, and administration of the existing Act. In doing so, the rules cover the following subjects:

1. General provisions regarding definitions, membership of the health systems agency and its governing body, conflicts of interest, ex parte communication, extension of the review period, computation of time periods specified in rules or the Act, evasions of the Act, and guide to interpreting the rules;

2. Rules governing the submission of the notice of intent, the determination of applicability of the Act to a project, the acquisition of equipment by physicians, and the granting of waivers to projects subject to the Act;

3. Rules governing the review process, procedures, and criteria including the submission and content of the application for certificate of need, the determination of completeness of the application, the Health Systems Agency hearing process, and procedures for reaching recommendations on certificate of need applications, the review criteria, the procedures for revisions of a project, the content of the hearing record, and the Commissioner's determination;

4. Rules governing consolidated review process and determination by the Commissioner of life support transportation service projects which are subject to both the Act and Minn. Stat. § 144.802;

5. Rules governing post-determination actions including reconsideration of the Commissioner's determination, amendment of an issued certificate of need, transfer of an issued certificate of need, expiration of a certificate of need, submission of periodic reports, and investigations;

6. Rules governing applications from health maintenance organizations including the basis of review, the entities which qualify for exemption from review, conditions for exemption, procedures, criteria for review, and provisions for judicial review.

A free copy of the rules may be obtained by contacting Kent Peterson, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440, telephone (612) 296-5365. Additional copies will be available at the hearing. If you have any questions about the rules, please contact Mr. Peterson.

Twenty-five (25) days prior to the hearing, a Statement of Need and Reasonableness will be available for review at the agency and at the Office of Administrative Hearings. This Statement of Need and Reasonableness will include all of the evidence which the agency intends to present at the hearing to justify both the need for and the reasonableness of the proposed rule. The agency intends to present only a summary of the Statement of Need and Reasonableness at the hearing; however, additional evidence may be submitted in response to questions raised by interested persons. You are therefore urged to both review the Statement of Need and Reasonableness before the hearing and to attend the hearing. Copies of the Statement of Need and Reasonableness may be obtained from the Office of Administrative Hearings at a minimal charge. Additional copies will be available at the hearing.

Any person may request notification of the date on which the Hearing Examiner's Report will be available, after which date the agency may not take any final action on the rules for a period of five working days. Any person may request notification of the date on which the hearing record has been submitted or resubmitted to the Attorney General by the agency. If you desire to be so notified,

you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the Hearing Examiner, in the case of the Hearing Examiner's Report, or to Mr. Peterson, in the case of the agency's submission or resubmission to the Attorney General.

Minn. Stat. ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five days after he or she commences lobbying. A lobbyist is defined in Minn. Stat. § 10A.01, subd. 11, (1980) as any individual:

a. Engaged for pay or other consideration, or authorized by another individual or association to spend money, who spends more than five hours in any month or more than $250, not including his own travel expenses and membership dues, in any year, for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials; or

b. Who spends more than $250, not including his own traveling expenses and membership dues, in any year for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials.

The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, St. Paul, Minnesota 55155, telephone: (612) 296-5615.

Dated: April 16, 1981

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

George R. Petterson M D

GEORGE R. PETTERSEN, M.D.
Commissioner of Health

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

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

AFFIDAVIT OF MAILING

Linda Karivoski, wo jk being first duly sworn, deposes and says:

1. That on the 6th day of May, 1981, at the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached Notice of Hearing by depositing in the United States mail at said City of Minneapolis, a true and correct copy thereof, properly enveloped, wtih postage prepaid, to all persons and associations at the addresses listed on the Certificate of Agency's Mailing List attached and made a part hereof as Exhibit A; and

2. That on the 29th day of April, 1981, at the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached Notice of Hearing and proposed certificate of need rules by depositing in the United States mail at said City of Minneapolis, a true and correct copy thereof, properly enveloped, with postage prepaid, to all persons and associations at the addresses listed on Exhibit B, attached and made a part hereof.

Linda M. Karwoski

Subscribed and sworn to before
me this 12th day of May, 1981

Marie B. Tronicjak

MARIE B. TRONICZAK
NOTARY PUBLIC - MINNESOTA
HENNEPIN COUNTY
My Commission Expires Oct. 23, 1987

Exhibit A

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

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

CERTIFICATE OF AGENCY'S MAILING LIST

I, Lora Erickson, secretary to the Commissioner of Health, hereby certify that I am responsible for maintaining the list of all persons who register with the Department of Health for the purpose of receiving notice of rule hearings on proposed rules and amendments thereto on the subject captioned above pursuant to Minn. Stat. § 15.0412, subd. 4, and further certify that the list attached and made a part hereof constitutes the complete list of the persons, associations, and other interested groups who as of 11:45 AM, this 6 day of May, 1981, have so registered with the Department.

COMMISSIONER OF HEALTH
GEORGE R. PETTERSEN, MD

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STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

RECEIVED

MAY 14 1981

ADMINISTRATIVE HEARINGS

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 . . . . . page 2

B. Statement of Need . . . . . page 4

C. Compliance with Procedural Rulemaking Requirements . . page 6

1. Procedural Rulemaking Requirements of the Administrative Procedure Act . . . . page 6

2. Procedural Rulemaking Requirements of the Act . . page 10

3. Non-Mandatory Actions by the Commissioner . . page 10

D. General Statement of Reasonableness . . . . page 12

E. Rule-by-Rule Justification . . . . . page 15

7MCAR § 1.661 General Provisions . . . . page 15

7 MCAR § 1.662 Determination of Applicability and Waivers . . . . . page 39

7 MCAR § 1.663 Review Process, Procedures, and Criteria . . . . . page 57

7 MCAR § 1.664 Post Determination Actions . . . page 101

7 MCAR § 1.665 Applications from Health Maintenance Organizations . . . . . page 117

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 not 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

GEORGE R. PETTERSEN, M.D.

By Kent E. Peterson

Kent E. Peterson, Chief
Planning and Resources Control Section

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

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

AFFIDAVIT OF DELIVERY

Wayne Carlson, being first duly sworn, deposes and says:

That on the 1st day of May, 1981, at the City of Minneapolis, County of Hennepin, State of Minnesota, he served the attached Notice of Hearing on all members of the Minnesota Legislature as of the above-referenced date by delivering personally a copy for each Senator and Representative to the mail rooms for the Minnesota Senate and Minnesota House of Representatives in the State Capitol for placement in their respective mail boxes.

Wayne R. Carlson

Subscribed and sworn to before
me this 12th day of May, 1981

Marie B. Tomczyk

NOTARY PUBLIC - MINNESOTA
HENNEPIN COUNTY
My Commission Expires Oct. 23, 1987

have signed a separate pupil request form for guidance and counseling services only for whom request forms have been properly completed.

E. B. Submission of program and budget. On or before October 15 the public school district or intermediary service area shall submit to the Department of Education a program and budget of the guidance and counseling services that are being offered to the nonpublic school pupils for the current school year. The program and budget shall be on forms made available by the Department of Education and shall include:

1. Projected guidance and counseling services expenditures for salaries, supplies, equipment and other eligible expenses, which expenditures shall not exceed the amount allocated for guidance and counseling services to the public school district or intermediary service area by the Department of Education. The allocation for guidance and counseling services is determined by multiplying the total number of participating secondary pupils by the allocation available per pupil for guidance and counseling services as set forth in 5 MCAR § 1.0882 C. Pupils shall be counted as one pupil each.

2. Projected expenditures for guidance and counseling services administration, which expenditures shall not exceed an amount equal to five percent of the public school district's or intermediary service area's expenditures for guidance and counseling services for nonpublic school pupils and which shall be in addition to the guidance and counseling services allocation.

G. F. Year-end report. On or before July 15, following each school year, the public school district or intermediary service area shall submit to the Department of Education a year-end report of guidance and counseling services provided to nonpublic school pupils. The report shall be on forms made available by the Department of Education.

G. Nonpublic school files. The nonpublic school shall maintain on file for a period of three years all pupil request forms for guidance and counseling services. The forms shall be available for inspection by the department of education, the public school district or the intermediary service area.

Department of Health
Health Systems Division

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

Notice of Hearing

A public hearing concerning the proposed new rules captioned-above will be held in Room 111, William Mitchell College of Law, 875 Summit Avenue, St. Paul, Minnesota, on June 9, 1981, commencing at 9:00 a.m. Persons attending the hearing may park either on Summit Avenue or at the William Mitchell parking lot between Summit Avenue and Grotto, two blocks east of the school. The proposed rules may be modified as a result of the hearing process. Therefore, if you are affected in any manner by the proposed rules you are urged to participate in the rule hearing process.

Following the agency's presentation at the hearing, all interested or affected persons will have an opportunity to ask questions and make comments. Statements may be made orally and written material may be submitted. In addition, whether or not an appearance is made at the hearing, written statements or material may be submitted to Jon L. Lunde, Hearing Examiner, Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, telephone: (612) 296-5938, either before the hearing or before the close of the hearing record which shall remain open at least five working days after the hearing is adjourned. The Hearing Examiner may, at the hearing, order that the record be kept open for a longer period not to exceed 20 calendar days. All such statements will be entered into and become part of the record. For those wishing to submit written statements or exhibits, it is requested that at least two (2) copies be furnished. In addition, it is suggested, to save time and avoid duplication, that those persons, organizations, or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement in behalf of such interests. The rule hearing procedure is governed by Minn. Stat.

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. Strike outs indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." ADOPTED RULES SECTION — Underlining indicates additions to proposed rule language. Strike outs indicate deletions from proposed rule language.

§§ 15.0411-15.0417 and 15.052 and by 9 MCAR (Minnesota Code of Agency Rules) §§ 2.101-2.113. If you have any questions about the procedure, call or write the Hearing Examiner.

The statutory authority for the Commissioner of Health to adopt these rules is contained in Minn. Stat. § 145.834 (1980). In addition to this general directive to adopt such rules as are necessary to implement, enforce, and administer the Certificate of Need Act (hereinafter "Act"), Minn. Stat. §§ 145.832 to 145.845 (1980), specific areas authorized to be addressed by rules or procedures are contained in Minn. Stat. §§ 145.834, 145.835, subds. 4 and 5, 145.836, subd. 2, 145.837, subds. 1 and 2(5), 145.84, and 145.845 (1980). Furthermore, a general grant of authority to adopt procedural rules is contained in Minn. Stat. § 15.0412, subd. 3 (1980).

The new rules repeal the existing rules of the State Planning Agency, 10 MCAR §§ 1.201 to 1.210 (formerly SPA 201 to 210), which were promulgated pursuant to Minn. Stat. §§ 145.71 to 145.831 (1978), the Certificate of Need Act in effect prior to August 1, 1979, and constitute an entirely new set of rules intended for the implementation, enforcement, and administration of the existing Act. In doing so, the rules cover the following subjects:

1. General provisions regarding definitions, membership of the health systems agency and its governing body, conflicts of interest, ex parte communication, extension of the review period, computation of time periods specified in rules or the Act, evasions of the Act, and guide to interpreting the rules;

2. Rules governing the submission of the notice of intent, the determination of applicability of the Act to a project, the acquisition of equipment by physicians, and the granting of waivers to projects subject to the Act;

3. Rules governing the review process, procedures, and criteria including the submission and content of the application for certificate of need, the determination of completeness of the application, the Health Systems Agency hearing process, and procedures for reaching recommendations on certificate of need applications, the review criteria, the procedures for revisions of a project, the content of the hearing record, and the commissioner's determination;

4. Rules governing consolidated review process and determination by the commissioner of life support transportation service projects which are subject to both the Act and Minn. Stat. § 144.802;

5. Rules governing post-determination actions including reconsideration of the commissioner's determination, amendment of an issued certificate of need, transfer of an issued certificate of need, expiration of a certificate of need, submission of periodic reports, and investigations;

6. Rules governing applications from health maintenance organizations including the basis of review, the entities which qualify for exemption from review, conditions for exemption, procedures, criteria for review, and provisions for judicial review.

A free copy of the rules may be obtained by contacting Kent Peterson, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440, telephone (612) 296-5365. Additional copies will be available at the hearing. If you have any questions about the rules, please contact Mr. Peterson.

Twenty-five (25) days prior to the hearing, a Statement of Need and Reasonableness will be available for review at the agency and at the Office of Administrative Hearings. This Statement of Need and Reasonableness will include all of the evidence which the agency intends to present at the hearing to justify both the need for and the reasonableness of the proposed rule. The agency intends to present only a summary of the Statement of Need and Reasonableness at the hearing; however, additional evidence may be submitted in response to questions raised by interested persons. You are therefore urged to both review the Statement of Need and Reasonableness before the hearing and to attend the hearing. Copies of the Statement of Need and Reasonableness may be obtained from the Office of Administrative Hearings at a minimal charge. Additional copies will be available at the hearing.

Any person may request notification of the date on which the Hearing Examiner's Report will be available, after which date the agency may not take any final action on the rules for a period of five working days. Any person may request notification of the date on which the hearing record has been submitted or resubmitted to the Attorney General by the agency. If you desire to be so notified, you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the Hearing Examiner, in the case of the Hearing Examiner's Report, or to Mr. Peterson, in the case of the agency's submission or resubmission to the Attorney General.

Minn. Stat. ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five days after he or she commences lobbying. A lobbyist is defined in Minn. Stat. § 10A.01, subd. 11, (1980) as any individual:

a. Engaged for pay or other consideration, or authorized by another individual or association to spend money, who spends more than five hours in any month or more than $250, not including his own travel expenses and membership dues, in any year, for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials; or

b. Who spends more than $250, not including his own traveling expenses and membership dues, in any year for the

purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials.

The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, St. Paul, Minnesota 55155, telephone: (612) 296-5615.

April 16, 1981

George R. Pettersen, M.D.
Commissioner of Health

Rules as Proposed (all new material)

7 MCAR § 1.661 General provision.

A. Purpose.

1. These rules, 7 MCAR §§ 1.661 to 1.665, are intended to govern the implementation, enforcement and administration of the Minnesota Certificate of Need Act. The rules do not repeat provisions of the Act which are clear and complete without rules; therefore, the Act should be read with the rules. References to the Act are made in these rules in order to assist the public in cross-referencing the Act with the rules.

2. The commissioner has, within the limits of the Act, developed review procedures and criteria which involve a minimum period of time, require only essential information, and involve the least cost for the applicant, the health systems agency (HSA), and the department. These rules promote health planning cooperation by health care facilities and health systems agencies before the certificate of need review and encourage health system innovations and alternatives, as well as beneficial price competition.

B. Definitions. The definitions contained in Minn. Stat. § 145.833 apply to the terms as used in these rules. Some of the terms defined in Minn. Stat. § 145.833 are also defined in these rules in order to clarify certain sections or parts of the statutory language. Unless the context clearly requires otherwise, the following terms shall have the meaning ascribed to them:

1. "Act" means the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845.

2. "AIP" means annual implementation plan as defined in the Act, Minn. Stat. § 145.833, subd. 11.

3. "Application" means the submission by a person of the information required by 7 MCAR § 1.663 A. in requesting the issuance of a Certificate of Need.

4. "Capital expenditure" means any expenditure, regardless of type of financing mechanism, including gifts, donations and other philanthropic activities, utilized to purchase, acquire, renovate, remodel or substantially alter or modify real property, buildings, fixtures, equipment or a service. Whenever real property, buildings, fixtures or equipment are acquired by capitalized lease or any type of rental agreement, that capital expenditure for lease or rental agreement shall be the fair market value at the date upon which the agreement is executed. Expenditures which, under generally accepted accounting principles, are properly chargeable as an expense of operation and maintenance are not capital expenditures. Capital expenditures include the total of all anticipated expenditures for a single undertaking with interdependent or interrelated components whether or not any individual expenditure exceeds the threshold of the Act.

5. "Category," as used in Minn. Stat. § 145.833, subd. 5 (a) (2), means classification of beds within a health care facility according to licensure (such as, general hospital, psychiatric, alcoholic, boarding care home and supervised living) or 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 (such as skilled nursing care, intermediate nursing care and intermediate care for the mentally retarded and persons with related conditions).

6. "Commissioner" means the Commissioner of Health and includes any duly authorized representative of the commissioner.

7. "Construction or modification" means:

a. Any erection, building, alteration, renovation, reconstruction, conversion of any existing building, modernization, improvement, expansion, extension or other acquisition by or on behalf of a health care facility which:

(1) Requires a total capital expenditure in excess of $150,000; or

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(2) Changes the bed capacity of a health care facility by more than ten beds or more than ten percent of the facility's total licensed bed capacity, whichever is less, over a two year period following the most recent bed capacity change, in a way which:

(a) Increases the total number of beds; or

(b) Changes the distribution of beds among various categories; or

(c) Relocates beds from one physical facility or site to another.

b. Any capital expenditure in excess of $150,000 by or on behalf of a health care facility used to acquire diagnostic or therapeutic equipment. If the equipment is being updated rather than totally replaced, the capital expenditure will be based upon the cost of the equipment parts to be replaced, or added cost of manufacturer's labor and installation as well as any financing costs incurred according to generally accepted accounting principles.

c. Any expansion or extension of the scope or type of existing health service by a health care facility which requires a capital expenditure in excess of $50,000 during any consecutive 12 month period for that service. Change in scope or type of existing service means the difference between the range and nature of the present service and the range and nature of the services contemplated under the proposal. An expansion or extension does not occur if there is solely increased efficiency of operations or increased square footage or spatial allocation. Expansion or extension shall occur if at least one of the following factors is directly associated with the proposed project:

(1) An increase in volume of services provided;

(2) The ability to perform treatments or procedures not previously performed;

(3) An increase in personnel associated with the capital expenditure;

(4) A change in proportion of patient mix; or

(5) A change in geographic source or referrals to the facility.

d. Any establishment of a new health care facility.

e. Any reviewable predevelopment activity by or on behalf of health care facility.

f. Any establishment by a health care facility of a new institutional health service, other than a home health service, which is to be offered in or through that facility and which was not offered on a regular basis in or through that facility prior to the twelve months before that service which will be offered under the terms of the proposal.

8. "Direct patient care service" means any health service designed to provide diagnosis, treatment, nursing, preventive, rehabilitative or habilitative care to any person.

9. "Exemption" means the decision by the commissioner to authorize an HMO or health care facility to proceed with a project reviewable under the Act, without request for a waiver or application for a certificate of need.

10. "Evidence" means any exhibit, oral or written testimony or other data or information submitted to an HSA prior to the close of the public hearing for the purpose of affecting the determination of whether a certificate of need should be issued.

11. "Health Maintenance Organization" or "HMO" means any organization which operates or proposes to operate pursuant to Minn. Stat. §§ 62D.01 to 62D.29.

12 "Hearing body" means:

a. The governing body of an HSA;

b. In the case of the Metropolitan Council, the Metropolitan Health Board; or

c. For HSAs other than the Metropolitan Council, a project review committee, the membership of which conforms to the requirements of Minn. Stat. § 145.845 and 7 MCAR 1.661 C.2.b.

13. "HSA" means health systems agency as defined in the Act, Minn. Stat. § 145.833, subd. 7.

14. "HSP" means health systems plan as defined in the Act, Minn. Stat. § 145.833, subd. 10.

15. "Institutional health service" means any health service as defined in the Act, Minn. Stat. § 145.833, subd. 3, wherever and however that health service is provided.

16. "Long range development plan" means a health care facility's written description of its present and anticipated configuration of health services which is developed in consideration of the HSP for the health care facility's health service area.

17. "On behalf of" means in the interests of, at the behest of, or for the benefit of, a health care facility or other entity.

18. "Predevelopment activity" means any activity by or on behalf of a health care facility or any person which involves

architectural designs, plans, working drawings, specifications, feasibility studies, surveys, site acquisitions, contractual agreements, legal services, fund-raising and any other related pursuit and which occurs with intention to embark upon a program of construction or modification.

a. "Reviewable predevelopment activity" means any predevelopment activity which occurs with intention to offer or develop a new institutional health service if:

(1) The predevelopment activity would require an expenditure in excess of $150,000; or

(2) The predevelopment activity involves any arrangement or committment for financing the new institutional health service.

b. "Non-reviewable predevelopment activity" means any predevelopment activity not included in 7 MCAR § 1.661 B.18.a.

19. "Patient" means any person receiving care in a health care facility and is synonymous with the term "resident."

20. "Project" means the proposed construction or modification. Project is used synonymously with proposal.

21. "Provider" means any person:

a. Whose primary occupation involves, or involved within the last 12 months previous to appointment, provision of health services to individuals or the administration of health care facilities or other health service activities;

b. Who is, or was, within the 12 months previous to appointment, employed by a health care facility as a health or mental health professional;

c. Who has a fiduciary interest in or position with a health care facility or other entity which has the provision of health services as its primary purpose;

d. Who has, or has had within the twelve months previous to appointment a material financial interest (more than one-fifth of the person's gross annual income) from any one or a combination of the following:

(1) Fees or other compensation for research into or instruction in the provision of health care;

(2) Producing or supplying drugs or other materials, articles or devices for individuals in the provision of, research into, or instruction in health care;

(3) Issuing any policy or contract of individual or group health insurance, health service plan or health maintenance organization;

(4) Any other material financial interest in rendering of a health service; or

e. Who is a spouse of an individual described in items a., b., c. or d. above.

22. "Recommendation of the HSA" means the report of the HSA to the commissioner which contains its recommendation as to what action should be taken with respect to judging applications complete or incomplete, if a project is subject to review, if a waiver should be granted or if a certificate of need should be issued. The recommendation includes submission to the commission of all information presented by the applicant and delineation of all rationale developed by the HSA to support its recommendation.

23. "Region" means the geographic area designated by the Secretary of the United States Department of Health and Human Services upon recommendation of the Governor to be under the jurisdiction of an HSA for the purposes of health systems planning.

24. "Requestor" means a licensed medical doctor or a group of licensed medical doctors, however legally organized.

25. "State Health Plan" means the document, developed by the SPA, which addresses statewide health needs and incorporates the HSPs of all Minnesota HSAs pursuant to 42 U.S.C. 300k, Section 1524 (c) (2) (A and B).

26. "SPA" means the State Planning Agency established pursuant to Minn. Stat. §§ 4.10 to 4.17.

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

1. Membership of HSA. HSAs may specify in their corporate bylaws provisions regarding eligibility for membership, categories of members and similar items.

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2. Membership for the HSA governing body.

a. Each HSA shall select from its membership a governing body to conduct its business and to carry out its duties and functions. The Metropolitan Council shall use its health board to advise it, and may delegate any of its functions and duties to the health board and its staff. The establishment of a governing body shall not prohibit any delegation of HSA duties and functions to staff. Documentation of any such delegation shall be filed with the commissioner.

b. The membership of the governing body, and the health board of the Metropolitan Council shall, in addition to complying with the requirements of Minn. Stat. § 145.845:

(1) Be chosen by election or other appropriate method approved by SPA and consistent with provisions of 42 U.S.C. 300k, *et seq.* for a term of office not to exceed three years. No director may serve more than six consecutive years.

(2) Include only residents of, or individuals having their principal place of business in, the region in which the HSA has jurisdiction.

c. The membership of all HSA committees or subcommittees making recommendations to the governing board of an HSA or the Health Board of the Metropolitan Council on proposals for a certificate of need shall consist of a majority of consumers, and shall include representatives of the interests of providers.

D. Conflicts of interest.

1. No HSA member or other person who assists the HSA in the review of a project may participate at any level of review, formally or informally, in discussing or voting upon any project for a certificate of need if a conflict of interest exists. Persons having a conflict of interest, however, may participate in the proceedings in the same manner as any party who is not a member of a hearing body, or the Metropolitan Council.

2. A conflict of interest exists when a person:

a. Has a direct or indirect financial interest in the applicant;

b. Has a contract or has had within the preceding twelve months a contractual, creditor or consultative relationship with the applicant;

c. Is an employee, director, trustee, officer or has another fiduciary relationship with the applicant; or

d. Is a spouse of any person listed in a., b., or c. above.

3. A person who is a member of a hearing body or the Metropolitan Council and who has a conflict of interest shall declare it in writing to the HSA before it starts its review of the application or when it becomes apparent to him that he has such a conflict.

4. Any person may question the HSA orally or in writing as to whether or not a conflict of interest exists in regard to any person involved in the review of a project on behalf of an HSA. The HSA shall determine in such case whether a conflict of interest exists. Its findings shall be included in the recommendation of the HSA.

5. Any person who has a conflict of interest as determined pursuant to 7 MCAR § 1.661 D.3. and 4. shall be so identified in the recommendation of the HSA.

6. The minutes of the HSA hearing or meeting at which a project is being considered shall record a person having a conflict of interest as "absent" rather than "abstaining due to conflict of interest." Such a person shall not be counted in determining whether a quorum is present for the application being reviewed.

7. Nothing in this rule precludes any HSA from adopting bylaws or other procedures for determining conflicts of interest which are more stringent than these rules.

E. Ex parte communication.

1. "Ex parte communication" means a written or oral communication by any person as to the merits of an application which is not in a hearing record and with respect to which notice to all parties is not given. The term does not include any requests for status reports on any application, or any communication among HSAs, the SPA and the commissioner or their staffs which relates solely to information found in a hearing record, the Act, these rules or any application or request for formal action under the Act.

2. Ex parte communication to or among the HSAs, the SPA, the commissioner or their staffs and any other party, is prohibited, except when the communication relates to an allegation of material misrepresentation, inaccuracy or omission in information necessary to determine whether an action under the Act should be taken.

3. Ex parte communication received by the HSA, SPA or commissioner shall not be considered in the review of the project and shall not be part of the record.

F. Extension of review period.

1. The applicant, the HSA or the commissioner may request that the time periods for review as prescribed in the Act and these rules be extended.

2. The party requesting the extension shall notify the other two parties in writing specifying the length of the extension and the reasons therefor.

3. Within five working days of receipt of the request, the other two parties shall notify the requesting party in writing whether they agree to the extension. If all three parties agree to the extension, the new time period shall be in effect. If the parties do not agree to the extension, the time periods in effect prior to the making of the request shall remain in effect.

4. Time periods shall be deemed directory and not mandatory.

G. Time computation.

1. In computing any period of time prescribed or allowed by these rules or by any applicable statute, the day of the act or event from which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included, unless it is a Saturday, a Sunday or a legal holiday, in which event the period runs until the end of the next day which is not a Saturday, a Sunday, or a legal holiday. When the period of time prescribed or allowed is less than seven days, intermediate Saturdays, Sundays and legal holidays shall be excluded in the computation.

2. Whenever a person has the right or is required to do some act or take some proceeding within a prescribed period after the service of a document upon him, or whenever some service is required to be made in a prescribed period before a specified event, and the document is served by mail, the time period shall begin to run, under the terms described above, upon receipt of the document and not upon it being mailed. However, an act or event which must be accomplished within a specific time period, shall be considered complete upon mailing of the document.

H. Evasions.

1. A project is a single undertaking when its component parts have been jointly planned, when fiancing arrangements are made to cover the entire project or when component parts are so interdependent or interrelated that separate review would be inconsistent with the purpose of the Act.

2. The annual capital expenditure budget or long range development plan of the health care facility or health maintenance organization does not necessarily constitute a single undertaking.

I. Interpretation of rules. Interpretation of these rules shall be governed by the provisions of Minn. Stat. ch. 645 except in so far as its provisions are in conflict with the definitions or other provisions of the Act or these rules which relate to construction or interpretation of these rules.

7 MCAR § 1.662 Determination of applicability and waivers.

A. Submission of notice of intent.

1. Any person shall submit a notice of intent to the appropriate HSA when planning to embark upon a program of construction or modification* prior to engaging in any predevelopment activities with respect to the program of construction or modification.

2. The notice of intent shall be submitted in writing to the HSA at least 60 days prior to the submission of an application. No HSA shall accept or act upon an application until proper notice has been given.

3. Within ten days of receipt of a notice, the HSA shall forward a copy of such notice to the commissioner and to SPA. Upon receipt of a notice proposing construction or modification, the HSA shall notify the applicant of the schedule for submission of a certificate of need application as established pursuant to 7 MCAR § 1.663 A.

4. The notice of intent shall:

a. Identify the nature of:

(1) Architectural services;

*The reader is advised to refer to the definition of "construction or modification" pursuant to 7 MCAR § 1.661 B.7.

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(2) Professional consulting services; or

(3) Fund-raising services;

b. Identify the name, address, contact person, and planned commencement date for activities listed above;

c. Describe the proposed construction or modification;

d. Estimate the capital expenditure associated with the construction or modification;

e. Specify the intended location or neighborhood of the project; and

f. Estimate the date of commencement of the construction or modification.

5. A notice of intent submitted by an applicant shall not preclude any other person from submitting a notice of intent for a similar undertaking.

6. A notice of intent shall be valid for a one year period within which time an application or an updated notice of intent may be submitted to the HSA.

7. If the applicant provides written verification that the necessity for an application could not have been reasonably anticipated 60 days prior to submission of an application for a certificate of need, the commissioner may reduce the time requirement for advanced submission of a notice of intent to less than sixty days.

B. Determination of applicability.

1. Written determination of applicability of the Act shall be made by the commissioner when an informational request for such determination is submitted from any person directly affected by the proposed construction or modification. Such request may be submitted at any time regardless of whether a notice of intent has been submitted. The foregoing shall not prohibit the commissioner from making his own determination, regardless of whether a notice of intent has been submitted, as to whether a proposed undertaking is subject to review under the Act as part of his general authority to enforce the provisions of the Act.

2. The HSA or the commissioner, when necessary to obtain all relevant information in order to make a recommendation or to make the final determination respectively, may request additional clarifying information about the proposed undertaking. Any information requested shall relate to the provisions of Minn. Stat. § 145.833, subd. 5, and to 7 MCAR § 1.661 B.7. Failure to supply the information in a timely manner shall be sufficient grounds for determining that the proposed undertaking is subject to the Act.

3. Upon receipt of a request for determination of applicability, the HSA shall within 30 days submit a recommendation to the commissioner as to the applicability of the Act to the subject of the request. Within 30 days of receipt of the recommendation from the HSA, the commissioner shall review the matter and the HSA recommendation and shall notify the applicant in writing as to whether the Act is applicable to the subject of the request and the reasons for the decision.

C. Acquisition of equipment by physicians.

1. A requestor proposing to purchase, lease, or otherwise acquire diagnostic or therapeutic equipment which requires a total capital expenditure in excess of $150,000 for one or more related items of diagnostic or therapeutic equipment shall submit a notice to the HSA and the commissioner of the proposed equipment acquisition. Such notice shall contain the following information:

a. The legal structure or organization of the requestor;

b. A description of the equipment which is proposed to be acquired;

c. The proposed location of the equipment;

d. The estimated capital expenditure necessary to acquire the equipment as well as an estimate of those capital expenditures needed for installation and other related costs;

c. The source of funds to be used to acquire the equipment;

f. The source and estimated volume of patients utilizing the proposed equipment for the first three years of operation;

g. The party responsible for the operation of the proposed equipment;

h. The recipient of revenue generated by the proposed equipment;

i. The party responsible for any financial losses from the operation of the proposed equipment;

j. Delineation and description of the nature of any proposed existing formal or informal arrangement with a health care facility for use of equipment, including the proportions of total patients who will be either inpatients or outpatients of a health care facility during the time such equipment will be used on or for them; and

k. Whether the requestor desires a public hearing.

2. Within 20 days of receipt of the notice, the commissioner shall decide whether the information submitted pursuant to 7 MCAR § 1.662 C.1. is complete.

a. If the commissioner decides that the information is not complete, he shall immediately notify the requestor and specify in detail why the information is incomplete and what additional data must be submitted. A determination of incompleteness may occur under the following conditions:

(1) The items specified in 7 MCAR § 1.662 C.1. have not been fully answered or the answers need clarification; or

(2) The answers provided raise additional questions which must be answered in order to fully understand the situation.

b. The 60 day period in which the commissioner must decide whether the proposed acquisition is designed to circumvent the Act shall not commence to run until the commissioner determines that the notice is complete.

3. Within twenty days after the commissioner determines the notice is complete, the HSA shall forward comments to the commissioner regarding the proposed acquisition of the equipment and may request that a hearing be held.

4. If a hearing is requested by the requestor or the HSA, a public hearing shall be held pursuant to the Administrative Procedure Act. The hearing results shall be considered to be fact-finding and advisory to the commissioner.

5. The following factors shall be considered in determining whether a proposed acquisition is designed to circumvent the Act:

a. The projected proportion of patients who will use the equipment while also being inpatients or outpatients of a health care facility if such inpatient use is not on a temporary basis, such as a result of a natural disaster, major accident or equipment failure;

a. The projected proportion of patients who will use the equipment while also being inpatients or outpatients of a health care facility if such inpatient use is not on a temporary basis, such as a result of a natural disaster, major accident or equipment failure;

b. The existence of a relationship between the requestor and a health care facility for purposes of making available the proposed equipment to the health care facility;

c. The needs for a health care facility to purchase such equipment if the proposed equipment were not acquired by the requestor;

d. The accrual of material benefit from the proposed acquisition to a health care facility and that, if the acquisition were made by the health care facility, the project would be reviewable under the Act; or

e. The existence of other information which shows that the acquisition of the equipment will result in circumvention of the Act.

6. Within 60 days of determining the notice to be complete, the commissioner shall review the notice, any hearing record and hearing examiner recommendation and any information submitted by the requestor, HSA and other persons, and make a decision as to whether the proposed acquisition is designed to circumvent the Act. The applicant and the HSA shall be informed in writing of the commissioner's decisions and underlying rationale.

7. If the commissioner decides that the proposed acquisition is designed to circumvent the Act, a certificate of need must be obtained according to the process described by the Act and these rules.

D. Waivers.

1. A proposed construction or modification involving an existing health care facility may be granted a waiver based upon the information forwarded by the HSA with its recommendation and the determination of the commissioner that the factors in 7 MCAR § 1.662 D.2. are substantially fulfilled and that any one of the following situations exists:

a. The proposed construction or modification falls within the situations described in Minn. Stat. § 145.835, subd. 4 (a)

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or (b).* Additional examples or items that come with subd. 4(b) are business related equipment, telephone systems, energy conservation measures, warehouse storage, activities space, real estate acquisition and other projects of a like nature.

b. The proposed project is solely for acquisition of diagnostic or therapeutic equipment which is to replace existing equipment only when the existing and replacement equipment have approximately the same capabilities.

c. The proposed project:

(1) Is subject to Minn. Stat. § 145.833, subd. 5 (a)(2);**

(2) Is not reviewable under any other provisions of the Act or these rules; and

(3) If approved, would have no material impact on health planning consideration or on the provisions of health services within the facility's health service area.

d. The proposed project is solely to conduct reviewable predevelopment activity pursuant to 7 MCAR § 1.661 B.18.a.

e. The proposed project is solely for acquisition of an existing health care facility and the change is not reviewable under the provisions of the Act other than 7 MCAR § 1.661 B.7.a.(1).

2. The following factors shall be substantially fulfilled as a prerequisite for granting of waivers:

a. The proposed project shall not result in an increase in patient charges of more than five percent over existing charges in either the average charge for all patients or the average charge for those patients who will benefit from the project. The five percent shall be calculated after including any projected inflation increases based upon, for hospitals, the allowable increase limit established by the commissioner pursuant to 7 MCAR § 1.504 and, for other health facilities, a comparable inflation indicator established by a government agency.

b. The applicant has documented that the project:

(1) Is not unnecessarily duplicative of similar services in the facility's service area;

(2) Will not be underutilized compared with minimal utilization rates consistent with the efficient delivery of health care; and

(3) Will not otherwise result in an ineffective or inefficient operations.

c. The proposed project conforms to the facility's long range development plan and to the guidelines, criteria and goals for such services in the applicable HSP, AIP and the State Health Plan.

3. The request for a waiver shall be submitted by the applicant to the HSA at the same time as submission of a notice of intent for a proposal would have been submitted and shall include the following information:

a. Description of the project;

b. Estimated capital expenditures;

c. Annual operating budget of the current year;

d. Anticipated impact of the project on facility costs and patient charges; and

e. Information pertaining to the factors for a waiver specified in 7 MCAR § 1.662 D.2.b.

4. The HSA shall not proceed with a recommendation until complete information is received. If any additional

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*Minn. Stat. § 145.835, subd. 4. Waivers.

A proposed construction or modification may be granted a waiver from the requirements of section 145.834 by the commissioner of health if, based on the recommendation of the health systems agency, the commissioner determines that: (a) The proposed capital expenditure is less than three percent of the annual operating budget of the facility applying for a waiver, and the expenditure is required solely to meet mandatory federal or state requirements of the law; or (b) The construction or modification is not related to direct patient care services such as parking lots, sprinkler systems, heating or air conditioning equipment, fire doors, food services equipment, building maintenance, or other constructions or modifications of a like nature.

**Minn. Stat. § 145.833, subd. 5(a)(2).

Subd. 5 "Construction or modification" means:

(a) Any erection, building, alteration, reconstruction, modernization, improvement, extension, lease or other acquisition, or other purchase, lease or other acquisition of diagnostic or therapeutic equipment, by or on behalf of a health care facility which:

(2) Changes the bed capacity of a health care facility in a manner which increases the total number of beds, or distributes beds among various categories, or relocates beds from one physical facility or site to another, by more than ten beds or more than ten percent of the licensed bed capacity, whichever is less, over a two year period.

information is requested of an applicant, it shall be relevant to the eligibility standards specified in 7 MCAR § 1.662 D.1. and the factors specified in 7 MCAR §§ 1.662 D.2.

5. Within 30 days of the receipt of a request accompanied by complete information, the HSA shall submit to the commissioner its recommendation for granting or denying the waiver. This recommendation shall be accompanied by supporting rationale based on the applicable item in 7 MCAR § 1.662 D.1. and the factors in 7 MCAR § 1.662 D.2. and all information submitted by the applicant.

6. Within 30 days of receipt of the recommendation of the HSA, the commissioner shall notify the applicant and the HSA of the decision.

7. Emergency waivers may be granted by the commissioner if the need for the project is a result of fire, tornado, flood, storm damage or other similar disasters.

a. The applicant shall submit a written request for an emergency waiver to the commissioner with a corresponding copy sent to the HSA. This request shall describe the project, estimated cost and type of disaster which occurred.

b. Within three working days, the HSA shall forward a recommendation and comments to the commissioner.

c. Within five working days of the receipt of the request from the applicant, the commissioner shall notify the applicant and HSA of the decision to grant or deny an emergency waiver.

d. An emergency waiver shall be granted if the need for the project is a result of fire, tornado, flood, storm damage or other similar disaster, and if both of the following conditions are found to exist:

(1) Adequate health care facilities are not available for the people who previously used the applicant facility; and

(2) The projected repair does not exceed the guidelines and goals for such services in the applicable health systems plan or State Health Plan.

e. A request for an emergency waiver shall be limited in nature and scope to only those repairs necessitated by fire, tornado, flood, storm damage or similar disasters.

8. For purposes of Minn. Stat. § 145.842 and for the periodic reports in 7 MCAR § 1.664 E. of these rules, granting of a waiver of certificate of need review shall be considered to have the same effect as issuance of a certificate of need.

9. The applicant shall resubmit a request for a waiver if the construction or modification for which a waiver was initially granted is not commenced, as described in 7 MCAR § 1.664 C., within 18 months of the granting of waiver or within 90 days of the granting of an emergency waiver.

10. A project may not be separated into component parts if the granting of a waiver for one part would not subject the remaining parts to certificate of need review and if taken together, the project constitutes a single undertaking which is reviewable under the Act. If, however, the remaining component parts of a project would still be subject to review, a waiver may be requested for a specific component part of a project.

7 MCAR § 1.663 Review process, procedures, and criteria.

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

1. The commissioner shall establish a schedule specifying dates when applications may be submitted to the applicable HSA. The schedule may be revised periodically by the commissioner subject to a 60 day notice which shall be printed in the *State Register* and shall be provided to each HSA by written notice. The schedule shall provide that applications may be submitted not less frequently than every 30 days.

2. Fourteen copies of an application for certificate of need shall be submitted. The HSA, immediately upon receipt of the application, shall send a copy to both the commissioner and the SPA.

3. The application shall be submitted on a form prepared by the commissioner and available through the HSA. Forms shall be printed for:

a. Hospitals;

b. Nursing homes and boarding care homes; and

c. Supervised Living Facilities certified or proposing to be certified as intermediate care facilities for the mentally

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retarded and persons with related conditions. This form shall allow substitution of acceptable alternative sets of pertinent information which have been prepared for the Department of Public Welfare to carry out its responsibility for determination of need, location and programming for the mentally retarded and for the purposes of program licensure and rate setting. In order to be acceptable substitutes, alternative sets of information shall be identifiable according to the topics specified in 7 MCAR § 1.663 A.4.; and

d. Other applicants.

4. The following information and other clarifying information shall be considered to be germane to the project and shall be in a prescribed form, as related to each type of application described in 7 MCAR § 1.663 A.3.

a. Description of the project.

(1) A description of any building or services to be constructed, modified or provided, including a comparison to existing building and services.

(2) A description of the present number and kinds of staff positions and those new staff positions to be created by the project, as well as the basis for anticipation of the successful recruitment of these new staff positions.

(3) A statement from the architect or other construction specialist describing the status of the project's conformance with applicable building codes and state licensure and federal certification requirements for physical plants.

(4) A description of the methods and projected costs of providing energy for operating the project, as well as methods of conserving energy.

(5) A statement of the anticipated dates for commencement and completion of the project.

b. Financial aspects of the project.

(1) Capital expenditures and financing.

(a) The estimated total capital expenditure for the project. There shall be a breakdown of the total capital expenditure based upon the following eight categories. The information provided with respect to each category shall include the major component expenditures within the category.

(i) Predevelopment activity;

(ii) Site acquisitions;

(iii) Land improvements;

(iv) New construction of buildings;

(v) Renovations of buildings;

(vi) Fixed equipment;

(vii) Movable equipment; and

(viii) Financing costs and any contingencies.

(b) A description of the effect of this project on the general solvency of the applicant, including the future effect on financial indicators, including ratio of debts to total assets, operating revenue to total assets, operating revenue to fixed assets, total revenue to fixed assets and interest to total expense plus interest.

(c) A description of the availability and method of financing, including the amount of all projected loans, refinancing of existing debt (if any), estimated interest rate and the projected debt service amount as a percentage of the cost per patient day, or, for hospitals, as a percentage of cost per adjusted admission, as defined in 7 MCAR § 1.472 U.

(2) Operating costs. An estimate of the total annual operating costs upon completion of the project for at least five years. The total annual operating costs shall include anticipated salary requirements of new staff. The estimated costs shall conform with the cost centers and other requirements of at least one of the following:

(i) The requirements for cost allocation under Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.*;

(ii) The requirements for cost allocation under Title XIX of the Social Security Act, 42 U.S.C. § 1396a, *et seq.*;

(iii) The requirements for cost allocation under Minn. Stat. 144.695-144.703 (Minnesota Hospital Rate Review System); or

(iv) The cost allocation requirements utilized in generally accepted reports by applicants to any other agency or program of the State of Minnesota.

(3) Revenue.

(a) An estimate of the total annual revenue of the health care facility upon completion of the project for at least five years.

(b) A description of the anticipated effect of the project for the first five years of operation on the total patient charges per outpatient visit or service if applicable, and in the case of hospital projects, the total patient charges per adjusted admission as defined in 7 MCAR § 1.472 U. Average patient charges by service which are affected by the project shall be detailed.

(c) Where a health care facility does not already exist, a projection of the anticipated patient charges for the first five years of operation.

c. Geographic area to be served.

(1) A narrative description of and graphic identification of the health care facility's service area or areas, in terms of standard political boundaries.

(2) An identification of patient origin data, local surveys and other sources utilized in determining the service area of the project.

d. Requirements of the population served.

(1) Current and projected population for the next 20 years by applicable demographic categories, such as age, sex and occupational status, which will be served by the project and identification of sources of the information.

(2) Incidence and prevalence rates of diagnoses or conditions within the population related to the services proposed.

(3) The impact of the project upon the health needs of people who have traditionally experienced difficulties in obtaining equal access to health care.

(4) A description of the applicant's performance during the past five years related to access to health services including:

(a) Extent to which the facility met its obligations, if any, under Federal regulations or State rules requiring provision of uncompensated care, community services or access to programs receiving federal financial assistance;

(b) The extent to which Medicare, Medicaid and medically indigent patients are served by the applicant; and

(c) The range of methods by which a person may have access to its services, such as, outpatient services, admission by house physicians or admission by physicians in the community.

e. Relationship to other health care facilities.

(1) Existing institutions within and contiguous to the proposed project that offer, or propose to offer, the same or similar service;

(2) The occupancy or utilization rates of the similar existing institutions during the past five years;

(3) The anticipated effect that the project will have on existing facilities and services; and

(4) The relationship of the project to health professional training programs, biomedical and behavioral research projects and medical referral facilities.

f. A description of the consumer choice plans and programs with which the applicant participates including:

(1) Current and five-year projected number of consumers involved and

(2) Methods of public information regarding cost and quality of health services.

g. Anticipated need for the facility or service to be provided by the project and identification of the factors which create the need, including at least the following:

(1) Data, information and findings collected by the applicant which establish need for each service component of the project; and

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(2) Relationship of the project to the facility's long range development plan.

h. Occupancy and utilization rates.

(1) Occupancy rates for the health care facility, based on both licensed beds and on beds which are set-up and staffed, for the following:

(a) Each of the past five years;

(b) Each of the preceding 12 months; and

(c) Each of the first five years after completion, including explanation of assumptions.

(2) Utilization rates for the health services related to the projected project for the following:

(a) Each of the past five years;

(b) Each of the preceding 12 months; and

(c) Each of the first five years after completion, including explanation of assumptions.

i. A copy of all survey reports from the Minnesota Department of Health, as well as voluntary survey groups, related to the quality of care provided by the health care facility during the past three years of operation.

j. Alternatives which were considered and found not to be acceptable as a substitute for the project and the reasons why they were determined to be unacceptable.

k. Relationship of project to the HSP, AIP and State Health Plan including established planning objectives pertaining to cost, availability, accessibility, need, quality and financial viability of health services.

B. Determination of completeness.

1. Within ten days of the receipt of an application the HSA shall review the application's contents and forward a recommendation to the commissioner and SPA as to whether it is complete. If the recommendation states that the application is incomplete, the HSA shall identify the sections which it found to be incomplete, and explain why it concluded that they were incomplete. A determination of incompleteness may occur under the following conditions:

a. The items specified in 7 MCAR § 1.663 A.4. have not been fully addressed or the information needs clarification.

b. The information provided raises additional questions which must be answered in order for the HSA and commissioner to perform their review under the Act and these rules.

2. Within ten days of receipt of the recommendation from the HSA, the commissioner, after reviewing the application in conjunction with the HSA recommendation and comments, shall notify the applicant, HSA and SPA in writing as to whether the application is complete. If the application is declared incomplete, the applicant shall be informed what additional information must be submitted.

a. If the applicant submits the required additional information to the HSA, SPA and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the application may be found to be complete without being deferred to another cycle of reviews.

b. If the required information is submitted after five working days, but within 60 days of receipt of the commissioner's determination, the complete review will be made according to the schedule specified pursuant to 7 MCAR § 1.663 A.1. The result of this clause is that the application is considered for completeness in the next cycle of the commissioner's completeness determination process.

c. If an applicant has not fully responded to a request for additional information within 60 days of the request, the incomplete application shall be returned to the applicant.

3. A determination that an application is complete shall mean only that information has been given pertaining to each component part of the application as prescribed in 7 MCAR § 1.663 A.4. Determination that the application is complete shall carry no implication with respect to the quality of the information nor shall it preclude the HSA or the commissioner from requesting additional clarifying information during the review period.

4. The 60 day review period on the HSA level shall commence on the date that the HSA receives the notice from the commissioner that the application has been determined to be complete.

C. HSA hearing process and procedures for determining recommendations on certificate of need applications. No proposal may be reviewed nor may any recommendation on an application be made by an HSA in a manner which does not comply with the Act or these rules.

1. Upon determination by the commissioner that the application is complete, the HSA shall schedule the date, time and place of a public hearing at which a determination will be made as to whether to recommend issuance of a certificate of need.

2. Notice of the hearing shall be published in a legal newspaper as required in Minn. Stat. § 145.837, subd. 2(2). The notice shall contain a brief description of the project and the date, time and place of the hearing. A separate notification shall be mailed to all other affected persons, including at least the applicant, any contiguous HSA and all health care facilities located in the applicant's proposed service area. This separate notification shall contain information similar to that in the published notice, except that contiguous HSAs shall be requested to provide written comment prior to the public hearing or to appear at the public hearing to offer an opinion as to the need for the project and the factual basis for that opinion.

3. A hearing body shall conduct the public hearing. The chairman of the hearing body, or a member designated by the chairman, shall be the presiding officer and shall conduct the hearing and rule on all motions and on the admissibility of all evidence and testimony. The presiding officer shall designate a hearing secretary who shall tape record the proceedings and provide to the commissioner a verbatim transcript or a written summary of the hearing.

4. A majority of the members of the hearing body shall constitute a quorum. No hearing may be held or recommendation made or other action be taken unless a quorum is present.

5. The hearing body, if other than the governing body of the HSA, shall forward its recommendation, findings of fact, conclusions and all evidence to the governing body, which shall vote on the project as required in 7 MCAR § 1.663 C.7. The governing body shall not hear or receive evidence other than that forwarded by the committee unless it holds an additional hearing after first publishing a notice of hearing pursuant to the Act and 7 MCAR § 1.663 C.2.

6. All interested persons shall be given the opportunity to be heard, to be represented by counsel, to present any relevant oral or written evidence and to examine and cross-examine witnesses. The applicant and any person who testifies orally or otherwise submits evidence or testimony at the hearing shall be subject to questioning by any member of the hearing body. All relevant evidence shall be heard and considered, and the inadmissibility of such evidence in a court of law shall not be grounds for its exclusion. Evidence presented in the form of governmentally issued or sponsored planning documents, studies and guidelines, such as The State Health Plan, shall be given substantial weight but shall not be considered conclusive. The hearing may be recessed to another day if the hearing body find that additional evidence or time is necessary. When the presiding officer determines that all available and relevant evidence has been heard, the hearing body shall then commence its deliberations.

7. The hearing body, if other than the governing body of the HSA, and the governing body, after receipt of a hearing body's recommendation and necessary deliberation, shall vote on the project as follows:

a. After a motion has been made with respect to the project, each member present and qualified to vote, including the chairman or presiding officer, shall vote, or abstain from voting, on the motion. The vote of each member, or the fact of his abstention, shall be recorded in the minutes of the hearing or meeting.

b. No member may vote on behalf of a member not present.

c. A motion for approval of a project shall not pass unless a majority of the members voting, including abstentions, vote in favor of the motion. Failure to obtain a majority vote in favor of approval shall constitute the recommendation of denial.

d. An approval of the project with revisions may be recommended based upon findings of fact, conclusions and supporting evidence pursuant to 7 MCAR § 1.663 G.

(1) Within 30 days after the receipt of the HSA recommendation, the applicant shall notify the HSA and the commissioner by certified mail as to whether it accepts or rejects the revisions.

(2) If the applicant does not respond or rejects the revisions, the recommendation of the HSA to the commissioner shall remain as a recommendation for approval with revision including the findings of fact and conclusions which support revision of the application.

8. The recommendation of the HSA shall be forwarded to the commissioner and SPA in the format prescribed in 7 MCAR § 1.663 G.

9. If the applicant decides to withdraw from the review, it shall so inform the HSA and the commissioner in writing.

D. Consolidated review of Life Support Transportation Service projects. If a project subject to review under the Act is also

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subject to review under the process described in Minn. Stat. § 144.802 for the licensure of life support transportation services, a single consolidated review of the project may occur in conformance with Minn. Stat. §§ 144.802 and 145.836 and the recommended process described in attachment. In order to facilitate consolidated review of such projects, the HSA shall upon agreement of the applicant pursuant to Minn. Stat. § 145.837, subd. 3, extend its certificate of need review period from 60 to 90 days to coincide with the 90 day life support transportation service licensure review period prescribed in Minn. Stat. § 144.802, subd. 3(d). Within that 90 day period, the HSA shall make both recommendations to the commissioner. If mutual agreement pursuant to Minn. Stat. § 145.837, subd. 3, cannot be reached, the HSA shall attempt to make both the licensure and certificate of need recommendations within the 60 day period. If the HSA finds that making both recommendations within the 60 day period is not possible, it shall make the certificate of need recommendation within the 60 day period and a separate licensure recommendation within 90 days, as requested by Minn. Stat. § 144.802, subd. 3(d).

E. Review criteria. In reviewing a proposal, the HSA and the commissioner shall consider all evidence in the record and shall evaluate the evidence based upon the following factors, where applicable. In addition, these factors shall be specifically addressed in the findings of fact and conclusion required by 7 MCAR § 1.663 G.

1. Health plans and population needs.

a. The relationship of the project to and the degree to which it is consistent with the applicable HSP, AIP and State Health Plan.

b. The relationship of the project to and the degree to which it is consistent with the applicant's long range development plan.

c. The need for the project as determined by past, present and future utilization data with specific attention given to the following:

(1) Utilization rates of similar facilities within the facility's health service area for the most recent five years;

(2) Utilization rates of the existing facility or service for the most recent five years; and

(3) Five-year projected utilization rate for the proposed expanded facility or service.

d. The need for the project based upon the population requirements of the affected service area with specific attention given to the following:

(1) The population required to support the project, examined by demographic categories such as age, sex and occupational status;

(2) Incidence and prevalence rates of diagnoses or conditions within the population related to the services proposed by the project;

(3) The contribution of the project in meeting the health needs of people who have traditionally experienced difficulties in obtaining equal access to health care, in particular low income persons, racial and ethnic minorities, women, handicapped persons and other groups identified as priorities in the HSP. If the project involves a reduction, elimination or relocation of a health service, consideration shall be given to the extent which the project will affect the ability of affected members of these above priority groups to obtain needed health care.

(4) The past performance of the applicant in meeting its obligations, if any, under the applicable Federal regulations or state rules requiring provisions of uncompensated care, community service or access by minorities and handicapped persons to programs receiving Federal financial assistance, including the existence of any substantiated civil rights access complaints against the applicant.

(5) The extent to which Medicare, Medicaid, and medically indigent patients are served by the applicant.

(6) The extent to which the applicant offers a range of methods by which a person may have access to its services, such as, outpatient services, admission by house physicians or admission by personal physicians in the community.

2. Alternative approaches and system-wide effects.

a. The availability and adequacy of other less costly or more effective health care facilities and services which may serve as alternatives or substitutes for the whole or any part of the project.

b. The relationship of the project to the existing health care system in the area, including the possible economies and improvements which may be derived from operation of joint, cooperative or shared health care resources. Specific consideration shall be given the following:

(1) The effect of the project on use, capacity, and supply of existing health care facilities and services.

(2) The possibility of increasing referrals to other health care providers to achieve higher utilization of existing resources.

(3) The degree to which the project facilitates the development of an integrated system of services among health care providers.

(4) The possibility of consolidating services with other health care providers.

(5) The existence of formal arrangements established between the applicant and other health care providers to provide similar or supportig services to that being proposed.

c. Preferred alternative uses of resources included in the application, including such resources as health care providers, management personnel and funds for both capital and operational needs, for the provision of other health services by the applicant, as identified by the applicable HSP, AIP and State Health Plan.

d. The effect of the project on the clinical needs of health professional training programs in the area, including access of such programs to the project.

e. The needs for and availability of services and facilities for osteopathic physicians and patients.

3. Competition among similar services. Improvements or innovations in the financing and delivery of the proposed health services which foster price competition in a way that promotes quality assurance and cost effectiveness. Such consideration shall include:

a. The degree of participation by the applicant in consumer choice health plans and programs, such as health maintenance organizations and preferred medical provider programs and

b. The existence of methods by which public information regarding cost and quality of health services will be provided to potential consumers and payors.

4. Applicant and project attributes.

a. The availability of resources, including health manpower, management personnel, physical facilities and funds for capital and operating needs for the project.

b. The immediate and long-term financial feasibility of the project with specific analysis of the following:

(1) The comparison of the anticipated revenues with the anticipated expenses including an analysis of whether or not the estimated revenues and expenses appear accurate; and

(2) The impact of the project upon the immediate and long-term financial solvency of the facility.

c. The impact of the project on operational costs and patient charges with specific analysis of the following:

(1) The reasonableness of the proposed cost of the project compared to similar projects; and

(2) The reasonableness of proposed operating costs and impact on patient costs and charges compared with similar services in similar health care facilities.

d. The organizational and other relationship of the project to ancillary or support services including an analysis of the following:

(1) The availability of necessary ancillary or support services and arrangements made by the applicant for provision of those services;

(2) The development of multi-institutional arrangements for sharing support services.

e. The costs and methods of providing energy for the operation of the project including consideration of methods for conserving energy.

f. The quality of care as reflected in the most recent survey reports from the Minnesota Department of Health and other generally accepted survey organizations.

5. Special considerations. The review criteria specified above shall be considered in light of the special needs and circumstances of any applicant meeting at least one of the descriptions listed in this section as it relates to the project.

a. The special needs and circumstances of medical teaching, research facilities and referral facilities which provide a substantial portion of their services or resources, or both, to individuals outside of the health service area. Consideration shall be given as to whether:

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(1) The instruction, studies or consultation provided by the applicant is coordinated with other medical teaching, research facilities and referral facilities in the multi-health service area served by the applicant; and

(2) The project contributes to meeting the health service needs of the residents of the health service area.

b. The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need for which local conditions offer special advantages.

c. The special needs of hospitals to convert excess beds to long-term care or other alternative functions, but only where the termination of all acute care services is proposed and only if a need for the number of proposed long-term care beds can be shown to be consistent with the HSP.

F. Revisions.

1. A project may be revised by the applicant, the HSA or the commissioner at any time during the review process if:

a. The revision is acceptable to the HSA and the applicant; and

b. The revision is within the scope of the project as initially proposed.

2. For purposes of the Act and these rules, a revision shall be considered to be within the scope of the project as initially proposed if the revision is clearly and closely related to the proposed construction or modification and does not directly involve health services, physical plant, equipment or other services unrelated to the project as initially proposed.

G. Content of record. After making its recommendation, the HSA shall submit to the commissioner three copies of the complete record, absent the application which is part of the record and previously submitted to the commissioner. It shall include at least the items listed in this rule and when forwarded to the commissioner shall be in the following order:

1. A cover letter which includes:

a. Pertinent dates relating to the review including, but not limited to, dates of submission of application, determination of completeness, meetings of project review committee, holding of the public hearing and recommended action by the HSA;

b. Description of the project;

(1) If the project voted upon by the HSA is the same as proposed in the application, a summary only shall be provided; or

(2) If prior to the vote of the HSA, the project has been revised upon agreement of the HSA and applicant, a detailed description as revised shall be provided.

c. Estimated capital cost of the project; and

d. The recommendation of the HSA limited solely to a statement whether or not a certificate of need should be issued, denied or issued with revisions. Any revision shall be stated.

2. Proof of publication of the notice of the public hearing;

3. A summary of evidence presented at the public hearing;

4. The recommendation of the HSA which shall contain the following parts:

a. Findings of fact which shall be based upon each applicable review criterion in 7 MCAR § 1.663. E. provided however that for each project recommended for approval, written findings shall take into account the current accessibility of the facility as a whole and shall be based upon the criteria listed in 7 MCAR § 1.663 E.1.d. (1), (3), (4), (5) and (6);

b. Conclusions which shall be based on the findings of fact;

c. A recommendation which shall be based on conclusions; and

d. A record of the vote of each member of the HSA on all motions made with regard to the project.

5. Copies of all written evidence considered by the HSA as follows:

a. HSA staff reports and attachments;

b. Committee reports and attachments;

c. Any relevant coorespondence between the HSA and the applicant;

d. All additional evidence submitted by the applicant if not inserted into specific sections of the application; and

e. Any relevant evidence submitted by other affected persons including comments from contiguous HSAs.

H. Determination by commissioner.

1. The role of the commissioner in deciding whether or not a certificate of need should be issued is that of a final, independent decision maker. While the commissioner must base his review on the record presented by the HSA, his review is not merely in an appellate capacity and thus he is not required to adopt the HSA recommendation merely because it is supported by evidence in the record.

2. The commissioner shall review the application and the record presented by the HSA. The review shall include a determination as to whether the procedural requirements of the Act and these rules have been substantially met. The review by the commissioner may include other information not in the HSA record but only in order to assess the necessity of a remand to the HSA for further consideration.

3. Within 30 days of receipt of the recommendation of the HSA, the commissioner shall make one of the following decisions based upon the record as considered in light of the review factors in 7 MCAR § 1.663 E.

a. Issue a certificate of need. If the commissioner's decision is consistent with the HSA recommendation, the commissioner may adopt the findings and conclusions of the HSA by reference.

b. Issue a revised certificate of need.

(1) The commissioner may issue a decision conditionally approving a project for a certificate of need provided that the HSA and applicant agree to specified revisions. Rationale shall be set forth for each revision proposed by the commissioner. The decision shall also specify that the application shall be denied or remanded if the applicant or HSA reject the revisions.

(2) If the commissioner proposes a revision of the project, notice shall be mailed to the applicant and the HSA so informing them. Within 30 days after receipt, the applicant and the HSA shall inform the commissioner in writing as to whether or not they accept the revision.

(3) During the 30 days, the commissioner may amend his final decision by modifying the revisions as proposed with the approval of the HSA and the applicant.

(4) The 30 day period in which reconsideration can be requested pursuant ot Minn. Stat. § 145.838, subd. 2, or judicial review pursuant to Minn. Stat. §§ 15.0424 and 145.838, subd. 3, shall commence to run after receipt by the commissioner of the written notice specifying whether or not the HSA and applicant accept the revisions proposed by the commissioner, or if no notice is received, at the end of the 30 day period provided for in section b.

(5) If the HSA and applicant accept the revision, the commissioner shall issue a certificate of need and notify the HSA and SPA.

c. Deny a certificate of need. If a project is denied, the commissioner shall set forth in writing rationale for the action and notify the applicant, the HSA and the SPA. If the commissioner's decision is consistent with the HSA recommendation, the commissioner may adopt the findings and conclusions of the HSA by reference.

d. Remand the application to the HSA.

(1) A remand may occur if, during the review of the HSA record, the commissioner finds that one or more of the following conditions exist and determines that a remand will materially aid in the decision-making process.

(a) Findings of fact were not supported by the record;

(b) Findings of fact were based on inaccurate information in the record;

(c) Significant issues relating to review criteria and other provisions of rules were not addressed by the HSA;

(d) Significant evidence within the record was not addressed by the HSA;

(e) Conclusions were not supported by findings of fact;

(f) Conclusions were based on inaccurate findings of fact;

(g) Significant conclusions were not drawn from findings of fact; or

(h) The recommendation was not supported by the conclusions.

(2) The commissioner shall provide the HSA and the applicant with written rationale for the remand action and instructions for further HSA review.

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(3) Within 60 days of receipt of the remand, the HSA shall comply with the commissioner's instructions, hold another public hearing to review the project and forward a recommendation to the commissioner and the SPA.

I. Determination by the commissioner: life support transportation service projects. For projects subject to review under the Act and also subject to review under the process described in Minn. Stat. § 144.802 for the licensure of life support transportation services, the commissioner shall make a certificate of need decision as provided in 7 MCAR § 1.663 H.3. If the HSA submits a certificate of need recommendation and indicates that the life support transportation service licensure recommendation will be submitted separately, and decision of the commissioner to issue a certificate of need in such a case shall not constitute a decision by the commissioner to issue a life support transportation service license.

7 MCAR § 1.664 Post determination actions.

A. Post determination appeals.

1. If the decision of the commissioner is consistent with the recommendation of the HSA, any person aggrieved by the decision may seek judicial review pursuant to Minn. Stat. § 145.838, subd. 3.

2. If the decision of the commissioner is contrary to the recommendation of the HSA, any person may, pursuant to Minn. Stat. § 145.838, subds. 2 and 3, either request the commissioner to reconsider his decision or seek judicial review.

a. A reconsideration request shall be submitted to the commissioner in writing within 30 days after receipt of the decision by either the HSA or the applicant. The request shall address the applicable condition specified in Minn. Stat. § 145.838, subd. 2(a) to (d). Within 30 days after receiving the reconsideration request, the commissioner shall determine whether to reconsider his decision.

b. If the commissioner determines his decision should be reconsidered, the matter shall be remanded to the HSA. The HSA shall conduct a new public hearing. The record of the second hearing shall include the record of the previous hearing(s) on the application. The HSA shall issue a new recommendation within 60 days of receipt of the remand from the commissioner.

c. If the commissioner determines that his decision should not be reconsidered, the HSA or the applicant may within 30 days request an administrative hearing pursuant to Minn. Stat. § 145.838, subd. 2.

3. Any aggrieved person may seek judicial review of the commissioner's decision rendered pursuant to Minn. Stat. § 145.838, subd. 1 or of the hearing examiner's decision rendered pursuant to Minn. Stat. § 145.838, subd. 2 by instituting an action pursuant to Minn. Stat. § 15.0424.

B. Amendment of certificate.

1. After a certificate of need has been issued and before completion of the project, an applicant may find it desirable or necessary to modify the approved project. The types of changes in or modifications to a project are described in 7 MCAR § 1.664 B.2., 3., and 4. When more than one type of change or modification is proposed, the change shall be reviewed according to the type of change which is most stringent. The effect of those changes on the issued certificate of need are as follows:

a. Changes and modification which are immaterial in nature or result (see 7 MCAR § 1.664 B.2.) shall not require any additional certificate of need review.

b. Changes and modifications which are minor in nature or result (see 7 MCAR § 1.664 B.3.) shall not be made unless the commissioner, after review and recommendation by the HSA, issues an amended certificate of need. The review conducted by the HSA and commissioner shall be limited to determining whether or not the changes or modifications are minor as defined in 7 MCAR § 1.664 B.3., that the changes or modifications fall within the scope of the project as initially approved for a certificate of need, and that the evidence supporting the certificate of need as initially issued supports the changes or modifications.

c. Changes and modifications which are significant in nature or results (see 7 MCAR § 1.664 B.4.) require the submission of a new application and require a full certificate of need review.

2. The following are immaterial changes:

a. Changes in spatial allocation or design;

b. Change in architectural plans to correct a facility's structural deficiencies or to comply with governmental rules or regulations;

c. An increase of less than 10% in the capital expenditure of the project, excluding inflation costs not projected at the time of application for a certificate of need; or

d. Other changes in project detail which will nevertheless result in the implementation of the project as approved.

3. The following are minor changes:

a. An increase of at least 10% but not more than 20% of the capital expenditure of the project, excluding inflation costs not projected at the time of application for a certificate of need;

b. Deletions of portions of the originally approved project;

c. Change in financing mechanism;

d. Change in the selection of health services equipment if not technologically different from that approved in the certificate; or

e. Change in bed capacity of a facility in a manner which increases the total number of beds, or distributes beds among various categories, by fewer than ten beds or ten percent of the licensed bed capacity, whichever is less.

4. The following are significant changes:

a. An increase equal to or in excess of 20% of the capital expenditure of the project, excluding inflation costs not projected at the time of application for a certificate of need;

b. Change in the type or scope of health service which was originally approved in the certificate;

c. Change in the selection of health services equipment if technologically different from that approved in the certificate;

d. Change in the geographical location if such change is relevant to the commissioner's reasons for approval of the certificate of need project; or

e. Change in bed capacity of a facility by more than ten beds or ten percent of the licensed bed capacity; or

f. Changes in the project which raise new material issues not previously considered by the HSA or commissioner.

5. The applicant, prior to implementing any minor change in the project, shall submit a written request for an amended certificate to the HSA.

a. The request shall contain a narrative comparison of the approved project and the proposed changes, a description of the cost implications and rationale for the proposed changes.

b. Within 30 days, the HSA shall review the request and forward all information submitted, a recommendation and rationale to the commissioner.

c. Within 30 days of receipt of the HSA recommendation, the commissioner shall review the applicant's request and the recommendation of the HSA and notify the applicant and the HSA in writing of the decision and reasons therefor.

6. The issuance of an amended certificate of need shall not result in the extension of the 18 month period which the applicant has to commence the project under the original certificate of need.

7. If a proposed amendment is not approved, the applicant shall either proceed under the certificate of need as initially issued or shall proceed through a full certificate of need review as a new applicant.

C. Expiration of certificate.

1. Notification of termination date. Each certificate of need or waiver shall specify the termination date pursuant to Minn. Stat. § 145.839.

2. Renewal of certificate or waiver.

a. If a project which had been granted a certificate of need or waiver has not commenced within 18 months, the applicant may submit information to the HSA and commissioner which updates the application and may request renewal of the certificate or waiver for a period up to 18 months.

b. Within 30 days of receipt of the request for renewal of the certificate of need or waiver, the HSA shall submit a recommendation to the commissioner as to whether the project or the reasons for approving the project have changed materially since the issuance of the certificate or waiver. If neither the project nor the reasons for approving the project have changed, renewal of the certificate of waiver shall be recommended.

c. Within 30 days of receipt of the HSA recommendation regarding renewal, the commissioner shall determine

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whether renewal shall be granted based upon the HSA recommendation regarding renewal. Renewal may be granted for a period up to 18 months.

3. In the case of a construction project, the commissioner shall use the following criteria in determining whether the project has commenced:

a. Whether final working drawings and specifications have been approved by the Minnesota Department of Health;

b. Whether construction contracts have been let;

c. Whether a timely construction schedule has been developed stipulating dates for the beginning, various stages and completion of construction;

d. Whether all zoning and building permits have been secured;

e. Whether significant physical alteration of the site has been made and is continuing in accordance with the construction schedule; and

f. Whether other factors related to the above conditions exist.

4. In the case of a project solely involving the acquisition of equipment, the commissioner shall consider the following factors in determining whether the project has commenced:

a. Whether a final purchase order or lease arrangement for all component parts of the equipment has been executed; and

b. Whether the equipment has been delivered and installed or a firm delivery date has been set and a specific schedule has been established for commencing procedures.

5. In the case of offering of a service which does not require facility construction or equipment acquisition, the commissioner shall consider the following factors in determining whether the project has commenced:

a. Whether the new service has been introduced within the facility; and

b. Whether appropriate personnel, as set forth in the application, have been identified and an employment arrangement has been executed for commencing services on a specific schedule.

D. Transfer of certificate or waiver.

1. A certificate of need or waiver shall not be transferred independently of the project with which it is associated. A certificate of need or waiver and the associated project shall not be transferred without the prior approval of the commissioner. A transfer shall be approved by the commissioner if the information submitted pursuant to this section indicates that there will be no material changes in the project as originally approved in the certificate of need or waiver that has been issued.

2. An entity proposing to purchase or otherwise acquire the project and associated certificate of need or waiver shall apply for a transfer by submitting the following information to the HSA and the commissioner:

a. A statement that it agrees to be bound by all the terms and conditions of the certificate of need or waiver originally granted for the project;

b. The financial aspects portion of a certificate of need application or waiver request; and

c. A list of any changes or modifications it proposes to make in the project.

3. Within 30 days after receipt of this information, the HSA shall review the transfer request and shall submit its recommendation to the commissioner. Within 30 days after receipt of the recommendation, the commissioner shall inform the entity requesting the transfer, the HSA and the SPA as to whether or not the transfer has been approved and the reasons for the decision.

E. Periodic report.

1. Within 60 days after completion of a project for which a certificate of need was issued or a waiver granted, the applicant shall submit actual capital expenditure information related to the project to the commissioner and the HSA. The information submitted shall compare the estimated costs as outlined in the application with actual costs. A breakdown of costs, as specified in 7 MCAR § 1.663 A.4.b. (1) (a), shall be submitted.

2. If a discrepancy of more than 5% exists between estimated and actual costs in any of the reported line items or the total project cost, the applicant shall explain why the discrepancy occurred and indicate the additional impact on operating costs and patient charges resulting from the additional capital expenditures related to the project.

3. Completion of a project shall mean the earlier of the following:

a. The last payment for construction costs and other fees related to the project is made, not including debt service related to the project; or

b. The involved service is used for its intended purpose.

4. If the involved service is used for its intended purpose before the last related payment is made, an interim report shall be submitted utilizing actual and projected expenditures. In this case, the final report shall be submitted within 60 days after the last payment is made. Additional periodic reports may be required in connection with a revision to a project according to 7 MCAR § 1.663 F.

5. The requirements of this section shall apply to certificates of need and waivers issued or granted since August 1, 1979. If the project was completed prior to the effective date of these rules, the report shall be submitted within 60 days after the effective date of these rules.

F. Investigations. For the purposes of enforcement of the Act, the commissioner shall have access to all financial and other records of any entity subject to the Act.

7 MCAR § 1.665 Applications from health maintenance organizations.

A. An HMO shall be subject to certificate of need review, unless exempt under 7 MCAR § 1.665 C., if it proposes, or undertakes on behalf of an inpatient health care facility, a project involving:

1. Any erection, building alteration, reconstruction, modernization, improvement, extension, lease, equipment purchase or other acquisition related to inpatient institutional health services which requires, or would require if purchased, a total capital expenditure in excess of $150,000, and which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance;

2. The obligation of any capital expenditure related to a change in the bed capacity of a health care facility by more than ten beds or more than ten percent of the facility's total licensed bed capacity, whichever is less, over a two year period following the most recent bed capacity change, in a way which:

a. Increases or decreases the total number of beds;

b. Redistributes beds among various categories; or

c. Relocates beds from one physical facility or site to another.

3. The obligation of any capital expenditure which is associated with:

a. The addition of an institutional health service which was not offered within the previous twelve months; or

b. The termination of an institutional health service.

4. The addition of an institutional health service which was not offered during the twelve month period before the month in which the service would be offered, and which entails annual operating costs of at least $75,000; or

5. Acquisition of an existing health care facility if the institutional health services or bed capacity, according to 7 MCAR § 1.665 A.2., will be changed as a result of the acquisition.

B. The following entities may qualify for exemption from certificate of need review if the conditions of 7 MCAR § 1.665 C. are met.

1. An HMO;

2. A combination of HMOs;

3. A health care facility which primarily serves inpatients if it is:

a. Owned or proposed to be owned, by an HMO or HMOs; or

b. Governed by a controlling body which is composed of over fifty percent principal officers or board members of the HMO or HMOs; or

4. A health care facility, or a portion of a health care facility, leased by an HMO or HMOs for a term of at least 15 years.

C. The conditions which must be met to qualify for exemption are:

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1. The applicant shall be "qualified" under Title XIII of the Public Health Services Act, 42 U.S.C. § 300e or the applicant shall satisfactorily document to the commissioner that the HMO or HMOs have substantially fulfilled the requirements of Title XIII of the Public Health Services Act, 42 U.S.C. § 300e.

2. At least 50,000 persons shall be enrolled in the pertinent HMO(s) and shall have reasonable access to the proposed project; and

3. At least 75 percent of the potential patients shall be enrolled in the pertinent HMO(s).

D. The following procedures shall be followed in applying for exemption of an HMO project from certificate of need review.

1. An application for exemption shall be submitted to the commissioner, HSA and SPA. The application shall describe the project for which an exemption is sought and shall contain information demonstrating that the HMO meets the conditions for exemption specified in 7 MCAR § 1.665 C.

2. The HSA or the commisssioner, in order to make a recommendation or to make the final determination, may request additional clarifying information about the project. Any information requested shall be pertinent to the provisions of 7 MCAR § 1.665 B. and C. Failure to supply the information in a timely manner shall constitute sufficient grounds for determining that the entity is not eligible for exemption.

3. Within 30 days after the receipt of the request, the HSA shall forward its recommendation and all evidence to the commissioner. Within 30 days of the receipt of the HSA recommendation, the commissioner shall notify the HMO and the HSA of the decision to grant or deny the exemption and the reason therefor. The commissioner shall approve an application for exemption if the applicable requirements of 7 MCAR § 1.665 B. and C. have been met or will be met on the date the proposed activity will be undertaken.

E. The project granted exempt status may not be sold or leased, a controlling interest in a project may not be acquired and a health care facility described in 7 MCAR § 1.665 B. 3. and 4. may not be used in a manner other than proposed in the project unless:

a. The commissioner issues a certificate of need approving the sale, lease, acquisition, or use; or

b. Upon request, the commissioner grants exempt status to such entity.

F. 7 MCAR § 1.661 through 1.664 shall apply to the review of a certificate of need application submitted by an entity listed in 7 MCAR § 1.665 B. for a non-exempt project. Notwithstanding the general review criteria in 7 MCAR § 1.663 E., if an entity listed in 7 MCAR § 1.665 B. applies for a certificate of need, the commissioner shall approve the project if he finds that:

1. Approval of the project is required to meet the needs of the members of the HMO and of the reasonably anticipated new members of the HMO; and

2. The HMO is unalbe to provide, through services or facilities which can reasonably be expected to be available to the HMO, its health services in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO and which makes these services available through physicians and other health professionals associated with it. In assessing the availability of these services from other providers, the HSA and commissioner shall consider only whether the services from these providers:

a. Would be available under a contract of at least five years duration;

b. Would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

c. Would cost no more to the HMO than if the services were provided by the HMO; and

d. Would be available in a manner which is administratively feasible to the HMO applicant.

G. Any party aggrieved by a decision of the commissioner pursuant to 7 MCAR § 1.665 D. may seek judicial review of the commissioner's decision by instituting action pursuant to Minn. Stat. § 15.0424.

[Repealer clause. State Planning Agency rules 10 MCAR §§ 1.202 to 1.210 (formerly SPA 201 to 210) are hereby repeal.]

ATTACHMENT
RECOMMENDED PROCEDURE FOR HSA CONSOLIDATED REVIEW
OF
LIFE SUPPORT TRANSPORTATION SERVICE PROJECTS

Relevant Provisions of Certificate of Need Act and Rules

Minn. Stat. § 145.836 APPLICATION FOR CERTIFICATE OF NEED. Subdivision 1. Application procedure. Applications for certificate of need shall be submitted to the health systems agency serving the area in which the proposed construction or modification is to take place. Prior to acting on the application and within ten days of receipt, the health systems agency shall send a copy to the commissioner of health and to the state planning agency with a recommendation that the application be considered either complete or incomplete. The commissioner of health shall determine that the application is initially complete or incomplete within ten days of receipt of a recommendation from a health systems agency. If the application is incomplete, it is not to be considered to be submitted to the health systems agency or the commissioner and it shall be returned stating the specific needs to be met in order for the application to be considered complete.

7 MCAR § 1.663 B. Determination of completeness.

1. Within ten days of the receipt of an application the HSA shall review the application's contents and forward a recommendation to the commissioner and SPA as to whether it is complete. If the recommendation states that the application is incomplete, the HSA shall identify the sections which it found to be incomplete, and explain why it concluded that they were incomplete. A determination of incompleteness may occur under the following conditions:

a. The items specified in 7 MCAR § 1.663 A.4 have not been fully addressed or the information needs clarification.

Relevant Provisions of Life Support Transportation Service Law (Minn. Stat. §§ 144.801 - 144.8091)

Minn. Stat. § 144.802 LICENSING Subd. 3.(a) Each prospective licensee and each present licensee wishing to offer a new type or types of life support transportation service, to establish a new base of operation, or to expand a primary service area, shall make written application for a license to the commissioner on a form provided by the commissioner. The commissioner shall promptly send notice of the completed application to the health systems agency or agencies, the community health service agency or agencies, and each municipality and county in the area in which life support transportation service would be provided by the applicant. The commissioner shall publish the notice, at the applicant's expense, in the state register and in a newspaper in the municipality in which the service would be provided, or if no newspaper is published in the municipality or if the service would be provided in more than one municipality, in a newspaper published at the county-seat of the county or counties in which the service would be provided.

Recommended Procedure for Consolidated HSA Review (Includes All the Requirements of Both Statutes and Assumes Certificate of Need Review Period Has Been Extended to 90 Days Pursuant to 7 MCAR § 1.663 D.

A. Submission of applications and determinations of completeness

The applicant shall submit a completed licensure application to the commissioner and should also submit a copy to the appropriate HSA. Simultaneously, the applicant should submit a completed certificate of need application to the appropriate HSA.

1. Within ten days of the receipt of the certificate of need application, the HSA shall review the application's contents and forward a recommendation to the commissioner and SPA as to whether it is complete. If the recommendation states that the application is incomplete, the HSA shall identify the sections which it found to be incomplete, and explain why it concluded that they were incomplete. A determination of incompleteness may occur under the following conditions:

a. The items specified in 7 MCAR § 1.663 A.4 have not been fully addressed or the information needs clarification.

b. The information provided raises additional questions which must be answered in order for the HSA and commissioner to perform their review under the Act and these rules.

2. Within ten days of receipt of the recommendation from the HSA, the commissioner, after reviewing the certificate of need application in conjunction with the HSA recommendation and comments, shall notify the applicant, HSA, and SPA in writing as to whether

b. The information provided raises additional questions which must be answered in order for the HSA and commissioner to perform their review under the Act and these rules.

2. Within ten days of receipt of the recommendation from the HSA, the commissioner, after reviewing the application in conjunction with the HSA recommendation and comments, shall notify the applicant, HSA and SPA in writing as to whether the application is complete. If the application is declared incomplete, the applicant shall be informed what additional information must be submitted.

a. If the applicant submits the required additional information to the HSA, SPA and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the application may be found to be complete without being deferred to another cycle of reviews.

b. If the required information is submitted after five working days, but within 60 days of receipt of the commissioner's determination, the complete review will be made according to the schedule specified pursuant to 7 MCAR § 1.663 A.1. The result of this clause is that the application is considered for completeness in the next cycle of the commissioner's completeness determination process.

c. If an applicant has not fully responded to a request for additional information within 60 days of the request, the incomplete application shall be returned to the applicant.

3. A determination that an application is complete shall mean only that information has been given pertaining to each component part of the application as prescribed in 7 MCAR § 1.663 A.4. Determination that the application is complete shall carry no implication with respect to the quality of the information nor shall it preclude both the licensure and the certificate of need applications are complete. If either application is declared incomplete, the applicant shall be informed what additional information must be submitted.

a. If the applicant submits the required additional certificate of need information to the HSA, SPA and commissioner within five working days of receipt of the commissioner's determination, the commissioner shall review the new information and notify the applicant, HSA and SPA within five working days of receipt of the new information as to whether the application is complete. The result of this clause is that the certificate of need application may be found to be complete without being deferred to another cycle of reviews.

b. If the required certificate of need information is submitted after five working days, but within 60 days of receipt of the commissioner's determination, the complete review will be made according to the schedule specified pursuant to 7 MCAR § 1.663 A.1. The result of this clause is that the certificate of need application is considered for completeness in the next cycle of the commissioner's completeness determination process.

c. If an applicant has not fully responded to a request for additional certificate of need information within 60 days of the request, the incomplete certificate of need application shall be returned to the applicant.

d. The applicant should submit any additional information requested to complete the licensure application within the time frames specified in 2 a.-c. so as to assume a consolidated HSA hearing and consolidated determination by the commissioner.

3. If both applications are determined to be complete, the commissioner shall promptly send notice of the completed applications to the HSA(s), community health service agency or agencies, and each municipality and county in the area in which the life support transportation

clude the HSA or the commissioner from requesting additional clarifying information during the review period.

4. The 60 day review period on the HSA level shall commence on the date that the HSA receives the notice from the commissioner that the application has been determined to be complete.

Minn. Stat. § 145.837, Subd. 2. Review procedures. In reviewing complete applications, the health systems agency shall:

(1) Hold a public hearing;

(2) Provide notice of the public hearing by publication in a legal newspaper of general circulation in the area for two successive weeks at least ten days before the date of such hearing and notify affected persons which shall include at least the applicant and other persons subject to review, contiguous health systems

Minn. Stat. § 144.802, subd. 3

(b) Each municipality, county, community health service, and other person wishing to make recommendations concerning the disposition of the application shall make written recommendations to the health systems agency in its area within 30 days of the publication of notice of the application.

Minn. Stat. § 144.802, subd. 3

(c) The health systems agency or agencies shall:

(1) hold a public hearing in the municipality in which the services base of operation is or will be located;

(2) provide notice of the public hearing in the newspaper or newspapers in which notice service would be provided by the applicant. The commissioner shall publish this notice, at the applicant's expense, in the *State Register*, and in a legal newspaper of general circulation in the municipality in which the service would be provided. If no legal newspaper of general circulation is published in the municipality, or if the service would be provided in more than one municipality, the notice shall be published in a legal newspaper of general circulation published at the county seat of the county or counties in which the service would be provided.

4. A determination that a certificate of need application is complete shall mean only that information has been given pertaining to each component part of the application as prescribed in 7 MCAR § 1.663 A.4. Determination that the application is complete shall carry no implication with respect to the quality of the information nor shall it preclude the HSA or the commissioner from requesting additional clarifying information during the review period.

5. The 90 day review period on the HSA level shall commence on the date that the HSA receives the notice from the commissioner that the applications have been determined to be complete.

B. Any municipality, county, community health service agency, or other person wishing to make recommendations concerning the dispositions of the applications shall make recommendations to the HSA within 30 days of the publication of notice of the applications pursuant to A.3.

C. HSA hearing process and procedures for determining recommendations on consolidated review of certificate of need and life support transportation service licensure applications.

1. Upon determination by the commissioner that the applications are complete, the HSA shall schedule the date and time of a public hearing at which a determination will be made as to whether to recommend issuance of a certificate of need and licensure of a life support

agencies, the health care facilities located in the health service area and which provide institutional health services, and the rate review agency;

(3) Allow any interested person the opportunity to be heard, to be represented by counsel, to present oral and written evidence, and to confront and cross-examine opposing witnesses at the public hearing;

(4) Provide a transcript of the hearing at the expense of any individual requesting it, if the transcript is requested at least three days prior to the hearing;

(5) Make written findings of fact and recommendations concerning the application. The commissioner of health shall promulgate by rule the required findings of fact which shall address the criteria specified in subdivision 1, and the provisions of the National Health Planning and Resources Development Act, 42 U.S.C., Section 300k, et seq. The findings of fact and recommendations shall be available to any individual requesting them; and

(6) Follow any further procedure not inconsistent with sections 145.832 to 145.845 or sections 15.0411 to 15.052, which it deems appropriate.

Within 60 days after the commissioner has determined the application to be complete, the health systems agency shall make its recommendation to the commissioner of health. The health systems agency shall either recommend that the commissioner of health issue, deny or issue with revisions a certificate of need for the proposed construction or modification. The reasons for the recommendation shall be set forth in detail.

7 MCAR § 1.663 C. HSA hearing process and procedures for determining recommendations on certificate of need applications.

No proposal may be reviewed nor may any recommendation on an application be made by an HSA in a manner which does not comply with the Act or these rules.

was published under part (a) for two successive weeks at least ten days before the date of the hearing;

(3) allow any interested person the opportunity to be heard, to be represented by counsel, and to present oral and written evidence at the public hearing;

(4) provide a transcript of the hearing at the expense of any individual requesting it; and

(5) follow any further procedure not inconsistent with chapter 15, which it deems appropriate.

(d) The health systems agency or agencies shall review and comment upon the application and shall make written recommendations as to its disposition to the commissioner within 90 days of receiving notice of the application. In making the recommendations, the health systems agency or agencies shall consider and make written comments as to whether the proposed service, change in base of operations, or expansion in primary service area is needed, based on consideration of the following factors:

(1) the relationship of the proposed service, change in base of operations or expansion in primary service area to current health systems and annual implementation plans;

(2) the recommendations or comments of the governing bodies of the counties and municipalities in which the service would be provided;

(3) the duplication, if any, of life support transportation services that would result from granting the license;

(4) the estimated effect of the proposed service, change in base of operation of expansion in primary service area on the public health;

(5) whether any benefit accruing to the public health would outweigh the costs associated with the proposed service, change in base of operations, or expansion in primary service area.

The health systems agency or agencies shall re-

transportation service. The hearing shall be scheduled to be held in the municipality in which the service's base of operations is or will be located.

2. Notice of the hearing shall be published in the legal newspaper(s) in which notice of the applications was published pursuant to A.3. The notice shall contain a brief description of the project and the date, time and place of the hearing. A separate notification shall be mailed to all other affected persons, including at least the applicant, any contiguous HSA, and all health care facilities located in the applicant's proposed service area. This separate notification shall contain information similar to that in the published notice, except that contiguous HSAs shall be requested to provide written comment prior to the public hearing or to appear at the public hearing to offer an opinion as to the need for the project and the factual basis for that opinion.

3. A hearing body shall conduct the public hearing. The chairman of the hearing body, or a member designated by the chairman, shall be the presiding officer and shall conduct the hearing and rule on all motions and on the admissibility of all evidence and testimony. The presiding officer shall designate a hearing secretary who shall tape record the proceedings and provide to the commissioner a verbatim transcript or a written summary of the hearing. A majority of the members of the hearing body shall constitute a quorum. No hearing may be held or recommendation made or other action taken unless a quorum is present:

The hearing body, if other than the governing body of the HSA, shall forward its recommendation, findings of fact, conclusions and all evidence to the governing body, which shall vote on the project as required in 7 MCAR § 1.663 C.7. The governing body shall not hear or receive evidence other than that forwarded by the committee unless it holds an additional hearing after first publishing a notice of hearing pursuant to the Act and 7 MCAR § 1.663 C.2.

1. Upon determination by the commissioner that the application is complete, the HSA shall schedule the date, time and place of a public hearing at which a determination will be made as to whether to recommend issuance of a certificate of need.

2. Notice of the hearing shall be published in a legal newspaper as required in Minn. Stat. § 145.837, subd. 2 (2). The notice shall contain a brief description of the project and the date, time, and place of the hearing. A separate notification shall be mailed to all other affected persons, including at least the applicant, any contiguous HSA and all health care facilities located in the applicant's proposed service area. This separate notification shall contain information similar to that in the published notice, except that contiguous HSAs shall be requested to provide written comment prior to the public hearing or to appear at the public hearing to offer an opinion as to the need for the project and the factual basis for that opinion.

3. A hearing body shall conduct the public hearing. The chairman of the hearing body, or a member designated by the chairman, shall be the presiding officer and shall conduct the hearing and rule on all motions and on the admissibility of all evidence and testimony. The presiding officer shall designate a hearing secretary who shall tape record the proceedings and provide to the commissioner a verbatim transcript or a written summary of the hearing.

4. A majority of the members of the hearing body shall constitute a quorum. No hearing may be held or recommendation made or other action taken unless a quorum is present.

5. The hearing body, if other than the governing body of the HSA, shall forward its recommendation, findings of fact, conclusions and all evidence to the governing body, which shall vote on the project as required in 7 MCAR § 1.663 C.7. the governing body shall not hear or receive evidence other than that forwarded by the committee unless it holds an additional hearing to receive evidence concerning the recommendation. The governing body shall vote to recommend that the commissioner either grant or deny a license or recommend that a modified license be granted. The reasons for the recommendation shall be set forth in detail. The health systems agency or agencies shall make the recommendations and reasons available to any individual requesting them.

6. All interested persons shall be given the opportunity to be heard, to be represented by counsel, to present any relevant oral or written evidence, and to examine and cross-examine witnesses. The applicant and any person who testifies orally or otherwise submits evidence or testimony at the hearing shall be subject to questioning by any member of the hearing body. All relevant evidence shall be heard and considered, and the inadmissibility of such evidence in a court of law shall not be grounds for its exclusion. The hearing may be recessed to another day if the hearing body finds that additional evidence or time is necessary. When the presiding officer determines that all available and relevant evidence has been heard, the hearing body shall then commence its deliberations.

7. The hearing body, if other than the governing body of the HSA, and the governing body, after receipt of a hearing body's recommendation and necessary deliberation, shall vote on the project as follows:

a. After a motion has been made with respect to the project, each member present and qualified to vote, including the chairman or presiding officer, shall vote, or abstain from voting, on the motion. The vote of each member, or the fact of his abstention, shall be recorded in the minutes of the hearing or meeting.

b. No member may vote on behalf of a member not present.

c. A motion for approval of a project shall not pass unless a majority of the members voting, including abstentions, vote in favor of the motion. Failure to obtain a majority vote in favor of approval shall constitute the recommendation of denial.

d. An approval of the certificate of need project with revisions may be recommended based upon findings of fact, conclusions and supporting evidence pursuant to 7 MCAR § 1.663 G.

(1) Within 30 days after receipt of the HSA recommendation, the applicant shall notify

the HSA and the commissioner by certified mail as to whether it accepts or rejects the revisions.

(2) If the applicant does not respond or rejects the revisions, the recommendation of the HSA to the commissioner and shall remain as a recommendation for approval with revision including the findings of fact and conclusions which support revision of the application.

8. The certificate of need recommendation of the HSA shall be forwarded to the commissioner and SPA in the format prescribed in 7 MCAR § 1.663 G.

9. The licensure recommendation of the HSA shall be to issue, deny or issue with modifications a life support transportation service license. The licensure recommendation shall contain the HSA's written and detailed comments as to whether the proposed service, change in base of operations, or expansion in primary service area is needed, based on consideration of the factors specified in Minn. Stat. § 144.804, subd. 3(d).

10. If the applicant decides to withdraw from the review, it shall so inform the HSA and the commissioner in writing.

ing after first publishing a notice of hearing pursuant to the Act and 7 MCAR § 1.663 C.2.

6. All interested persons shall be given the opportunity to be heard, to be represented by counsel, to present any relevant oral or written evidence, and to examine and cross-examine witnesses. The applicant and any person who testifies orally or otherwise submits evidence or testimony at the hearing shall be subject to questioning by any member of the hearing body. All relevant evidence shall be heard and considered, and the inadmissibility of such evidence in a court of law shall not be grounds for its exclusion. The hearing may be recessed to another day if the hearing body finds that additional evidence or time is necessary. When the presiding officer determines that all available and relevant evidence has been heard, the hearing body shall then commence its deliberations.

7. The hearing body, if other than the governing body of the HSA, and the governing body, after receipt of a hearing body's recommendation and necessary deliberation, shall vote on the project as follows:

a. After a motion has been made with respect to the project, each member present and qualified to vote, including the chairman or presiding officer, shall vote, or abstain

(1) Within 30 days after receipt of the HSA recommendation, the applicant shall notify the HSA and the commissioner by certified mail as to whether it accepts or rejects the revisions.

(2) If the applicant does not respond or rejects the revisions, the recommendation of the HSA to the commissioner shall remain as a recommendation for approval with revision including the findings of fact and conclusions which support revision of the application.

8. The recommendation of the HSA shall be forwarded to the commissioner and SPA in the format prescribed in 7 MCAR § 1.663 G.

9. If the applicant decides to withdraw from the review, it shall so inform the HSA and the commissioner in writing.

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

AFFIDAVIT OF JOHN R. DILLEY

STATE OF MINNESOTA)
) ss.
COUNTY OF RAMSEY)

John R. Dilley, being first sworn upon oath, deposes and says:

My name is John R. Dilley. I am the Director of the State Health Planning and Development Agency of the Minnesota State Planning Agency and have held this position since approximately 1973. Responsibilities of the Agency include administering the federal health planning and resources development legislation for the State and coordinating State health planning matters, including certificate of need, arising under the Minnesota Certificate of Need Act between Health Systems Agencies and the Minnesota Department of Health (hereinafter "Department"). In this capacity, my staff and I have represented the State Planning Agency for the purpose of consulting with the Department regarding proposed rules on certificate of need waivers, certificate of need determinations, and membership in Health Systems Agencies as authorized in Minn. Stat. §§ 145.835, subd. 4, 145.837, subd. 1, and 145.845. The Department, however, has consulted with us not only with respect to these three areas but also with respect to the entire set of proposed rules. My staff and I have received from the Department copies of all drafts of the proposed rules, have been invited to submit written or oral comment at any time, have met with Department staff on at least

20 occasions between July of 1979 and February of 1981, and have had frequent telephone communications with Department staff regarding the proposed rules. The Department, therefore, has consulted with the State Planning Agency concerning development of the above-captioned rules with specific attention given to the three areas cited above.

Dated: May 21, 1981

STATE OF MINNESOTA

STATE PLANNING AGENCY

JOHN R. DILLEY
Director
Division of Health Planning
and Development

Subscribed and sworn to before
me this 21 day of May, 1981.

LEONARD O. HISLOP
NOTARY PUBLIC-MINNESOTA
RAMSEY COUNTY
My Comm. Expires March 18, 1983

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

AFFIDAVIT OF MALCOLM MITCHELL

STATE OF MINNESOTA)
) ss.
COUNTY OF RAMSEY)

Malcolm Mitchell, being first sworn upon oath, deposes and says:

My name is Malcolm Mitchell. I am the ~~Executive~~ Director of the Metropolitan Health Board (hereinafter "HSA"), 300 Metro Square Building, Seventh and Robert Streets, St. Paul, Minnesota 55101, and have held that position since November, 1974. One of my responsibilities is to coordinate with staff of the Minnesota Department of Health (hereinafter "Department") regarding administration, implementation, and enforcement of the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845. For this reason, my staff and I have represented the HSA for the purpose of consulting with the Department regarding proposed rules on certificate of need waivers and certificate of need determinations as authorized in Minn. Stat. §§ 145.835, subd. 4, and 145.837, subd. 1. The Department, however, has consulted with us not only with respect to these two areas but also with respect to the entire set of proposed rules. My staff and I have received from the Department copies of drafts of the proposed rules, have been invited to submit written and oral comments at any time, have met with Department staff on at least five occasions between November of 1979 and January of 1981, and have had telephone

communications with Department staff regarding the proposed rules. The Department, therefore, has consulted with the HSA concerning the development of the above-captioned rules with specific attention given to the two areas cited above.

Dated: ~~May~~ JUNE 5, 1981

METROPOLITAN HEALTH BOARD

Malcolm Mitchell

MALCOLM MITCHELL
Executive Director

Subscribed and sworn to before
me this 5th day of ~~May~~ June, 1981.

Beverly Conerton

BEVERLY CONERTON
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
My Comm. Expires Jan. 2, 1986

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

AFFIDAVIT OF BJORN LARSEN

STATE OF MINNESOTA)
) ss.
COUNTY OF REDWOOD)

Bjorn Larsen, being first sworn upon oath, deposes and says:

My name is Bjorn Larsen. I am the Executive Director of Minnesota Health Systems Agency Six (hereinafter "HSA"), PO Box 156, Redwood Falls, Minnesota 56283, and have held that position since 08/15/76. One of my responsibilities is to coordinate with staff of the Minnesota Department of Health (hereinafter "Department") regarding administration, implementation, and enforcement of the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845. For this reason, my staff and I have represented the HSA for the purpose of consulting with the Department regarding proposed rules on certificate of need waivers and certificate of need determinations as authorized in Minn. Stat. §§ 145.835, subd. 4, and 145.837, subd. 1. The Department, however, has consulted with us not only with respect to these two areas but also with respect to the entire set of proposed rules. My staff and I have received from the Department copies of drafts of the proposed rules, have been invited to submit written and oral comments at any time, have met with Department staff on at least five occasions between November of 1979 and January of 1981, and have had telephone communications with Department staff regarding the proposed rules. The

Department, therefore, has consulted with the HSA concerning the development of the above-captioned rules with specific attention given to the two areas cited above.

Dated: May 29, 1981

MINNESOTA HEALTH SYSTEMS
AGENCY SIX

BJORN LARSEN
Executive Director

Subscribed and sworn to before
me this 29 day of May, 1981.

L. PHILLIP OMAN
NOTARY PUBLIC - MINNESOTA
REDWOOD COUNTY
My Commission Expires Feb. 9, 1985

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

AFFIDAVIT OF GWEN CRAWLEY

STATE OF MINNESOTA)
) ss.
COUNTY OF OLMSTED)

Gwen Crawley, being first sworn upon oath, deposes and says:

My name is Gwen Crawley. I am the Executive Director of Southeastern Minnesota Health Systems Agency (hereinafter "HSA"), 2200 Southwest Second Street, Rochester, Minnesota 55901, and have held that position since 8-18-81. One of my responsibilities is to coordinate with staff of the Minnesota Department of Health (hereinafter "Department") regarding administration, implementation, and enforcement of the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845. For this reason, my staff and I, and my predecessor prior to my assumption of the Executive Director position, have represented the HSA for the purpose of consulting with the Department regarding proposed rules on certificate of need waivers and certificate of need determinations as authorized in Minn. Stat. §§ 145.835, subd. 4, and 145.837, subd. 1. The Department, however, has consulted with us not only with respect to these two areas but also with respect to the entire set of proposed rules. The HSA has received from the Department copies of drafts of the proposed rules, have been

invited to submit written and oral comments at any time, have met with Department staff on at least five occasions between November of 1979 and January of 1981, and have had telephone communications with Department staff regarding the proposed rules. The Department, therefore, has consulted with the HSA concerning the development of the above-captioned rules with specific attention given to the two areas cited above.

Dated: May _____, 1981

SOUTHEASTERN MINNESOTA
HEALTH SYSTEMS AGENCY

Gwen Crawley

GWEN CRAWLEY
Executive Director

Subscribed and sworn to before
me this 28th day of May, 1981.

Susan K. Richardt



STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

AFFIDAVIT OF BARB CASPERS

STATE OF NORTH DAKOTA)
) ss.
COUNTY OF CASS)

Barb Caspers, being first sworn upon oath, deposes and says:

My name is Barb Caspers. I am the Executive Director of Min-Dak Health Systems Agency (hereinafter "HSA"), 1721 South University Drive, Fargo, North Dakota 58103, and have held that position since March 13, 1981. One of the responsibilities of the Executive Director is to coordinate with staff of the Minnesota Department of Health (hereinafter "Department") regarding administration, implementation, and enforcement of the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845. Because I have only recently assumed the duties of Executive Director, I have not personally been involved in consultation between the HSA and the Department regarding the Department's proposed certificate of need rules. However, my staff has informed me that it and my predecessor have represented the HSA for the purpose of consulting with the Department regarding proposed rules on certificate of need waivers and certificate of need determinations as authorized in Minn. Stat. §§ 145.835, subd. 4, and 145.837, subd. 1. In addition, the Department has consulted with the HSA with respect to the entire set of proposed rules. My predecessor and/or my staff have received from the Department copies of drafts of the proposed rules, have been invited to

submit written and oral comments at any time, have met with Department staff on at least five occasions between November of 1979 and January of 1981, and have had telephone communications with Department staff regarding the proposed rules. The Department, therefore, has consulted with the HSA concerning the development of the above-captioned rules with specific attention given to the two areas cited above.

Dated: May 21, 1981

MIN-DAK HEALTH
SYSTEMS AGENCY

Barb Caspers
BARB CASPERS
Executive Director

Subscribed and sworn to before
me this 21 day of May, 1981.

Carol Stoudt

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

AFFIDAVIT OF GERALD WANTULOK

STATE OF MINNESOTA)
) ss.
COUNTY OF BENTON)

Gerald Wantulok, being first sworn upon oath, deposes and says:

My name is Gerald Wantulok. I am the Executive Director of the Central Minnesota Health Systems Agency (hereinafter "HSA"), 113 Division Street, Sauk Rapids, Minnesota 56379, and have held that position since 12-9-76. One of my responsibilities is to coordinate with staff of the Minnesota Department of Health (hereinafter "Department") regarding administration, implementation, and enforcement of the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845. For this reason, my staff and I have represented the HSA for the purpose of consulting with the Department regarding proposed rules on certificate of need waivers and certificate of need determinations as authorized in Minn. Stat. §§ 145.835, subd. 4, and 145.837, subd. 1. The Department, however, has consulted with us not only with respect to these two areas but also with respect to the entire set of proposed rules. My staff and I have received from the Department copies of drafts of the proposed rules, have been invited to submit written and oral comments at any time, have met with Department staff on at least five occasions between November of 1979 and January of 1981, and have had telephone communications with Department staff regarding the proposed rules. The

Department, therefore, has consulted with the HSA concerning the development of the above-captioned rules with specific attention given to the two areas cited above.

Dated: May 20, 1981

CENTRAL MINNESOTA
HEALTH SYSTEMS AGENCY

Gerald J. Wantulok

GERALD WANTULOK
Executive Director

Subscribed and sworn to before
me this 20th day of May, 1981.

Elaine Poepping

Elaine M. Poepping
NOTARY PUBLIC - MINNESOTA
BENTON COUNTY
MY COMMISSION EXPIRES MAR. 6, 1985

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

AFFIDAVIT OF FELIX SEREICIKAS

STATE OF MINNESOTA)
) ss.
COUNTY OF ST. LOUIS)

Felix Sereicikas, being first sworn upon oath, deposes and says:

My name is Felix Sereicikas. I am the Executive Director of Health Systems Agency of Western Lake Superior ("HSA"), 202 Ordean Building, 424 West Superior Street, Duluth, Minnesota 55802, and have held that position since 10/1/78. One of my responsibilities is to coordinate with staff of the Minnesota Department of Health (hereinafter "Department") regarding administration, implementation, and enforcement of the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845. For this reason, my staff and I have represented the HSA for the purpose of consulting with the Department regarding proposed rules on certificate of need waivers and certificate of need determinations as authorized in Minn. Stat. §§ 145.835, subd. 4, and 145.837, subd. 1. The Department, however, has consulted with us not only with respect to these two areas but also with respect to the entire set of proposed rules. My staff and I have received from the Department copies of drafts of the proposed rules, have been invited to submit written and oral comments at any time, have met with Department staff on at least five occasions between November of 1979 and January of 1981, and have had telephone communications with Department staff regarding the proposed rules. The

Department, therefore, has consulted with the HSA concerning the development of the above-captioned rules with specific attention given to the two areas cited above.

Dated: May 27, 1981

HEALTH SYSTEMS AGENCY OF
WESTERN LAKE SUPERIOR

FELIX SEREICIKAS
Executive Director

Subscribed and sworn to before
me this 27 day of May, 1981.

Margaret A. Fanaselle

MARGARET A. FANASELLE
NOTARY PUBLIC - MINNESOTA
ST. LOUIS COUNTY
My Commission Expires Oct. 10, 1984

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

AFFIDAVIT OF TIMOTHY LANGELIERS

STATE OF NORTH DAKOTA)
) ss.
COUNTY OF GRAND FORKS)

Timothy Langeliers, being first sworn upon oath, deposes and says:

My name is Timothy Langeliers. I am the Acting Director of Agassiz Health Systems Agency (hereinafter "HSA"), 31 South Third Street, Box 129, Grand Forks, North Dakota 58201, and have held that position since 1-25-81. One of the responsibilities of the Acting Director is to coordinate with staff of the Minnesota Department of Health (hereinafter "Department") regarding administration, implementation, and enforcement of the Minnesota Certificate of Need Act, Minn. Stat. §§ 145.832 to 145.845. Because I have only recently assumed the duties of Acting Director, I have not personally been involved in consultation between the HSA and the Department regarding the Department's proposed certificate of need rules. However, my staff has informed me that it and my predecessor have represented the HSA for the purpose of consulting with the Department regarding proposed rules on certificate of need waivers and certificate of need determinations as authorized in Minn. Stat. §§ 145.835, subd. 4, and 145.837, subd. 1. In addition, the Department has consulted with the HSA with respect to the entire set of proposed rules. My predecessor and/or my staff have received from the Department copies of drafts of the proposed rules, have been invited to

submit written and oral comments at any time, have met with Department staff on at least five occasions between November of 1979 and January of 1981, and have had telephone communications with Department staff regarding the proposed rules. The Department, therefore, has consulted with the HSA concerning the development of the above-captioned rules with specific attention given to the two areas cited above.

Dated: ~~May~~ June 4, 1981

AGASSIZ HEALTH
SYSTEMS AGENCY

Timothy R Langeliers

TIMOTHY LANGELIERS
Acting Director

Subscribed and sworn to before
me this 4th day of ~~May~~ June, 1981.

Laurel Dow

HLTH-81-020-JL

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA DEPARTMENT OF HEALTH

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.

ORDER OF THE CHIEF HEARING EXAMINER

WHEREAS, on May 26, 1981, the Minnesota Department of Health, by Richard A. Wexler, Assistant Attorney General, submitted a request to the Chief Hearing Examiner for approval of the incorporation by reference of certain documents in rules to be proposed; and

WHEREAS, pursuant to Minnesota Statutes § 15.0412, subd. 4e, agencies may incorporate by reference provisions of federal law or rule or other materials from sources which the Chief Hearing Examiner determines are conveniently available for viewing, copying and acquisition by interested persons; and

WHEREAS, the Chief Hearing Examiner has reviewed the following documents and has found them to be in excess of 3,000 words, has determined that they would exceed five pages of publication in the State Register and has determined that they are conveniently available for viewing, copying and acquisition:

1. Provisions of Title XVIII and Title XIX of the Social Security Act found at 42 U.S.C.;

2. Rules adopted pursuant to the Social Security Act found at 42 C.F.R. §§ 405.401-.406 and 405.453; and

3. Title XIII of the Public Health Services Act found at 42 U.S.C. § 300e.

NOW, THEREFORE, IT IS ORDERED that the Department of Health shall have the approval of the Chief Hearing Examiner to incorporate by reference in their proposed rules the above-referenced documents.

Dated: May 27, 1981.

DUANE R. HARVES
Chief Hearing Examiner

HLTH-81-020-JL

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HEALTH

IN THE MATTER OF THE ADOPTION OF PROPOSED RULES IMPLEMENTING, ENFORCING, AND ADMINISTRERING 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.

ORDER OF THE CHIEF HEARING EXAMINER

WHEREAS, a hearing was held on June 9, 1981, before Jon L. Lunde, a Hearing Examiner of the State Office of Administrative Hearings, on the above-entitled matter in compliance with Minn. Stat. § 15.0412, subd. 4; and

WHEREAS, the Report of Hearing Examiner made pursuant to Minn. Stat. § 15.052, subd. 3, was issued to the Department of Health and;

WHEREAS, the Department of Health has now determined to adopt rules pursuant to Minn. Stat. § 15.0412, subd. 4-4f; and

WHEREAS, the Department of Health has submitted said rules to the Chief Hearing Examiner for review pursuant to Minn. Stat. §§ 15.0412, subd. 4e and 15.052, subd. 4, and 9 MCAR § 2.111; and

WHEREAS, the Chief Hearing Examiner finds that the final proposed rules are not substantially different from those proposed at the public hearing and that the Department of Health has cured the defects in the rules as required.

NOW, THEREFORE, upon receipt of this Order, the Department of Health has the responsibility of submitting the complete hearing record and the rules as adopted by the Department of Health to the Attorney General and to publish in the State Register, all pursuant to Minn. Stat. § 15.0412, subd. 4e and 4f.

Dated: November 18, 1981.

DUANE R. HARVES
Chief Hearing Examiner

By: George A. Beck

GEORGE A. BECK
Hearing Examiner

EXHIBIT A

DEPT. #30000
SEQ #1V AID 611012
SEQ # AID
SEQ # AID
SPA # 1005

An Agreement Between
The Minnesota State Planning Agency
and
The Minnesota Department of Health

Relative to Implementation of the Minnesota Certificate of Need Act

This agreement is entered into by and between the Minnesota State Planning Agency (SPA) and the Minnesota Department of Health (MDH) for the purpose of implementing Minnesota Statutes § 145.832 - 145.845 (1979 Supp.), The Minnesota Certificate of Need Act (hereinafter "Act").

WHEREAS, SPA is authorized to carry out certain health planning responsibilities by Minnesota Statutes § 145.834 (1979 Supp.), 42 U.S.C. §300k, et. seq. and Executive Order 79-26;

WHEREAS, SPA is authorized by Minnesota Statute §4.12, Subd. 6 (1) (1978) to use other agencies of the State to carry out such responsibilities;

WHEREAS, MDH is required to administer the Act;

WHEREAS, SPA is required by Minnesota Statute § 145.834 (1979 Supp.) to enter into an agreement with MDH regarding the promulgation of rules pursuant to the Act;

WHEREAS, both MDH and SPA desire that MDH assist SPA in the fulfillment of SPA's responsibilities under 42 U.S.C. §§300k, et. seq.

NOW, THEREFORE IT IS AGREED:

A. Functions to be Performed

Exh. No.
File No.
Date

MDH will perform the following functions:

1. Promulgate rules pursuant to the Act.

2. Implement, execute, and administer all aspects of the Act.

B. Encumbrances, Allocation of Monies, Records and Documentation

1. The SPA agrees to transfer in advance to the MDH the sum of $35,800 for the performance of functions noted in A above during the period of July 1, 1980 through June 30, 1981. These funds will be used to reimburse MDH for one staff position and related costs associated with performance of certificate of need reviews and implementation of the Act in a sum not to exceed $35,800.

2. MDH will establish a special account for such monies and will keep such records as will fully disclose the amounts and their disposition. The procedures developed will provide for the accurate and timely recording of the receipt, expenditures and return of such monies. MDH will be subject to federal audit in relation to the receipt of such monies.

3. MDH will provide the Health Planning Director of the SPA with copies of any contract for consulting services pertaining to the above monies prior to contract's execution.

4. MDH will provide the Health Planning Director of the SPA with quarterly reports on the performance of functions under this agreement.

5. MDH will provide the Health Planning Director of the SPA with quarterly reports describing all expenditures pursuant to this agreement on or before the 15th day of the month following each reporting quarter.

6. At the termination of this agreement any unexpended funds shall be transferred from the MDH to the SPA.

D. Period of the Agreement

1. This agreement shall be effective on July 1, 1980 and shall be renewable on June 30, 1981, subject to amendment of the funding in Section B.1. of page 1.

2. This agreement may be terminated by either party involved upon 60 days written notice.

IN WITNESS WHEREOF, the parties have caused this contract to be duly executed intending to be bound thereby.

APPROVED:

DEPARTMENT OF ADMINISTRATION

BY D J Erickson

DATE JUL 7 1980

STATE PLANNING AGENCY

BY Arthur E. Sidner

DATE 7-2-80

ATTORNEY GENERAL

BY Catharine T. Hawbecker

DATE 7-3-80

MINNESOTA DEPARTMENT OF HEALTH

BY Duane K Johnson

DATE 7/1/80

APPROVED
DEPARTMENT OF FINANCE
By
Date 7/8

of the residues. Not actually equipped to handle waste disposal, the St. Louis firm contracted with the Bliss Waste Oil Company to remove the material. The Company is owned and operated by Russel Bliss, who deals in waste oil, lubricants, organic solvents, and transformer oils generated by automobile service stations and industrial sources. For many years, Mr. Bliss had been spraying the nonrefinable grades of waste oils on horse arenas as a means of dust control.

From February to October, 1971, the Bliss Waste Oil Company transferred six truckloads (approximately 18,000 gallons) of industrial residues containing about 300 ppm dioxin from the original storage tank to its own storage tanks in eastern Missouri. Three horse arenas and a farm road on Mr. Bliss's own property are known to have received the dioxin-contaminated oil. The dioxin concentration of the soil in the most serious affected horse arena was analyzed at about 30 ppm. The overall toll in the four disposal areas can be summarized as follows: Ten persons developed toxic symptons (two children became seriously ill), and at least 63 horses died along with 6 dogs, 12 cats, 70 chickens, hundreds of birds, numerous rodents and insects. In addition, there were 26 known abortions and six birth abnormalities among the horses.

Two lawsuits, for a total of $954,000 in compensatory and punitive damages, had been filed by the former owners of one of the horse arenas against Bliss Waste Oil Company, et al. Also, a lawsuit for $60,000 has been filed by several horse owners against one of the other two horse arenas. The estimated total financial loss, based on filed lawsuits (excluding punitive damages), is close to $500,000.

8. Having determined that there is a need for rules to regulate hazardous waste, this Report will address the issue of whether the proposed rules are reasonable.

9. In determining the reasonableness of the within considered hazardous waste rules, the Examiner applied the following meaning to the word "reasonableness": "Reasonableness" is the opposite of arbitrariness and caprice. An arbitrary and capri

cious standard can be defined as follows:

> That standard [arbitrary and capricious] is a narrow one, to be applied only where administrative action "is not supportable on any rational basis" or where it is "willfull and unreasoning action, without consideration and in disregard of the facts or circumstances of the case."

Greenhill v. Bailey, 519 F.2d 5, 10 (8th Cir. 1975). Reasonableness, then, means to have a rational basis for the action.

In setting forth the findings that establish the rational basis for adoption of these hazardous waste rules, the Agency is not limited to only those facts that are supported by substantial evidence in the record. Rulemaking is a legislative function; it is not an adjudicatory function like a contested case is. There is a difference between the kind of facts relied on in a rulemaking hearing and the kind of facts relied on in an adjudication. Professor Kenneth Culp Davis identifies this difference:

> Two main elements in rulemaking are (1) facts, and (2) ideas about policies. The two are generally interwoven in such a degree that in some parts of the whole problem of what to do, they are inseparable. Even so, a main element in rulemaking is necessarily the policy choice that the administrator must make. Adoption of a rule may require some understanding of facts, but it always requires legislating. Courts must leave administrators free to legislate, within the limits of rationality. And legislating inevitably involves the addition of something to the facts in the rulemaking record.

K. Davis, Administrative Law of the Seventies, (Cumulative Supp. 1977) (emphasis in original).

The Minnesota Supreme Court has recognized the difference between legislative facts and adjudicatory facts and has identified the support needed to uphold the two kinds of facts. In St. Paul Area Chamber of Commerce v. Minnesota Public Service Comm'n., 251 N.W.2d 350 (Minn. 1977), the Court said:

> [T]he substantial evidence test of § 15.0425 [is] applicable to commission decisions only when it is acting in a quasi-judicial manner, in a role similar to that of a trial judge sitting without a jury. In cases where the commission acts primarily in a judicial capacity, that is, hearing the views of opposing sides presented in the form of written and oral testimony, examining the record, and making findings of fact, the administrative process is best served by allowing the district court to apply the substantial evidence standard on review. . . .

> . . .[H]owever, rate allocation is not a judicial or quasi-judicial function. Once revenue requirements have been determined it remains to decide how, and from whom, the additional revenue is to be obtained. It is at this point that many countervailing considerations come into play. The commission may then balance factors such as cost of service, ability to pay, tax consequences, and ability to pass on increases in order to achieve a fair and reasonable allocation of the increase among consumer classes. . . .It is clear that when the commission acts in this area it is operating in a legislative capacity, as the above cases have stated. The careful balancing of public policies and private needs is not a matter for the courts, unless statutory authority has been exceeded or discretion abused. . . .In ascertaining whether or not the statute has been contravened, the district court must give wide latitude to the commission in allowing it to consider many factors which might not ordinarily be considered by a court, as we have explained above. This is so because, while the court is qualified to review agency findings when an agency acts in a quasi-judicial manner in factual matters, it is not so qualififed to review legislative judgments when social policies must be weighed in the balance.

Id. at 356-357.

In the within considered rulemaking proceeding, many of the facts are legislative facts --policy decisions and judgments. A dermal toxicity value that distinguishes a hazardous waste from a nonhazardous waste is a legislative fact. There is no one right answer--there are only reasonable answers.

In another Public Service Commission ratemaking case, Northwestern Bell Telephone Co. v. State, 253 N.W.2d 815 (Minn. 1977), the Minnesota Supreme Court distinguished the two kinds of facts involved in exercising a legislative function. There the Court said:

> In determining the extent of the allowable adjustment, it appears that the PSC was acting in both a judicial and a legislative capacity. In finding as a fact the amount of the 1974 impact of the contract, the PSC's decision was amply supported by the evidence. In deciding to limit the adjustment to a one-year period, the PSC determined as a matter of public policy that changes occurring more than one year beyond the test year would best be considered in proceedings taking into account all of the facts necessary to accurately set Bell's rates. This determination cannot be said to be arbitrary or unjust. . . .

Id. at 822. See also, Northwestern Bell Telephone Co. v. State, 299 Minn. 1, 216 N.W.2d 841 (1974) and Reserve Mining Co. v. Herbst, 256 N.W.2d 808 (Minn. 1977).

Although the federal rulemaking process differs from that of Minnesota, it would be helpful to examine the federal system.

An example of a federal agency acting on legislative facts is Mourning v. Family Publications Service, Inc., 411 U.S. 356 (1973), where the U.S. Supreme Court upheld regulations of the Federal Reserve Board governing credit transactions of more than four installments. Professor Davis' discussion of the Mourning case is helpful:

> [T]he Supreme Court had no power to change "four" to three or five, because Congress had delegated that power to the Board and the Board had made its determination. On the question of what the number should be, the Court could do no more than determine whether "four" was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

K. Davis, Administrative Law of the Seventies, 206 (Cumulative Supp. 1977).

Dry Color Manufacturers' Ass'n v. Department of Labor, 486 F.2d 98 (3rd Cir. 1973), involved temporary emergency standards of the Department of Labor intended to prevent exposure to 14 chemicals found to be carcinogens. In striking down the regulations, the Court essentially said the Department did not have sufficient reasons for the regulations. Davis, however, is critical of the Court's decision:

> If carcinogenicity of the chemicals in humans can be neither proved nor disproved by scientific evidence, the problem for rulemakers is not one of fact; it is one of making a legislative choice of policy in light of the absence of evidence. When an agency is assigned the task of making rules that are in the public interest, it seldom can prove with evidence what is in the public interest; it has to use its policy preferences when proof is lacking.

K. Davis, Administrative Law of the Seventies, 674 (1976).

Some of the recent cases involving rulemaking by federal agencies in the environmental and health areas indicate the kind of latitude agencies have in making these legislative policy decisions. A leading example is Ethyl Corp. v. EPA, 541 F.2d 1, 8 E.R.C. 1785 (D.C. Cir. 1976), where the Court upheld regulations of the EPA requiring a reduction of lead in gasoline.

> Man's ability to alter his environment has developed far more rapidly than his ability to foresee with certainty the effects of his alterations. It is only recently that we have begun to appreciate the danger posed by unregulated modification of the world around us, and have created watchdog agencies whose task it is to warn us, and protect

> us, when technological "advances" present dangers unappreciated--or unrevealed--by their supporters. Such agencies, unequipped with crystal balls and unable to read the future, are nonetheless charged with evaluating the effects of unprecedented environmental modifications, often made on a massive scale. Necessarily, they must deal with predictions and uncertainty, with developing evidence, with conflicting evidence, and, sometimes, with little or no evidence at all. Today we address the scope of the power delegated one such watchdog, the Environmental Protection Agency (EPA). We must determine the certainty required by the Clean Air Act before EPA may act to protect the health of our populace from the lead particulate emissions of automobiles.
>
> * * *
>
> . . .We find that deletion of the findings requirement for action under Section 211(c)(1)(a) [of the Clean Air Act] was a recognition by Congress that a determination of endangerment to public health is necessarily a question of policy that is to be based on an assessment of risks and that should not be bound by either the procedural or the substantive rigor proper for questions of fact.
>
> * * *
>
> . . .The Administrator may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as "fact", and the like. We believe that a conclusion so drawn--a risk assessment--may, if rational, form the basis for health-related regulations. . . .
>
> All of this is not to say that Congress left the Administrator free to set policy on his own terms. To the contrary, the policy guidelines are largely set, both in the statutory term "will endanger" and in the relationship of that term to other sections of the Clean Air Act. These prescriptions direct the Administrator's actions. Operating within the prescribed guidelines, he must consider all the information available to him. Some of the information will be factual, but much of it will be more speculative--scientific estimates and "guesstimates" of probable harm, hypotheses based on still-developing data, etc. Ultimately he must act, in part on "factual isues", but largely "on choices of policy, on an assessment of risks, [and] on predictions dealing with matters on the frontiers of scientific knowledge . . . ." Amoco Oil Co. v. EPA, supra 163 U.S. App. D. C. at 181, 501 F.2d at 741. A standard of danger--fear of uncertain or unknown harm--contemplates no more.

Id. at 6, 24, and 28, 8 E.R.C. at 1786, 1801, and 1804-1805. The Amococase cited in Ethyl was another case by D. C. Circuit in which the court upheld for the most part regulations of EPA prohibiting use of leaded gasoline in automobiles fitted with

catalytic converters. Amoco Oil Co. v. EPA, 501 F.2d 722, 6 E.R.C. 1481 (D.C. Cir. 1974).

Another leading case in this area, and one relied on by the Ethyl court, is Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974), involving a review of asbestos regulations promulgated by the Secretary of Labor. There the court said:

> From extensive and often conflicting evidence, the Secretary in this case made numerous factual determinations. With respect to some of those questions, the evidence was such that the task consisted primarily of evaluating the data and drawing conclusions from it. The court can review that data in the record and determine whether it reflects substantial support for the Secretary's findings. But some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis.

Id. at 474 (footnote omitted).

10. Note must be taken that during the hearing process and before the close of the record, the Pollution Control Agency made various amendments to the proposed rules as originally published for hearing.

One of the principal benefits of a public hearing process is that it gives the administrator the benefit of criticisms and suggestions from representatives of the industries that will be regulated. It was just such a give-and-take process that prompted the Pollution Control Agency to amend the rules as finally proposed for adoption.

Because of such amendments, it will be necessary during certain portions of this Report, to specify whether an examination of the "reasonableness" of the proposed rules is being examined in light of the original proposal or the rules as finally proposed for adoption.

11. In determining the issue of "reasonableness", this Report will first examine the reasonableness of the wastes regulated by reason of being designated as "hazardous" pursuant to the proposed rules.

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

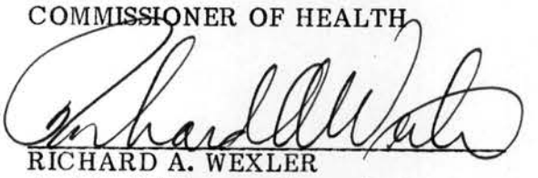
STATEMENT OF COMPLIANCE WITH RULEMAKING PROCEDURES

I, Assistant Attorney General Richard A. Wexler, do hereby declare that I have examined the above-captioned rules and all related documents and that, based on my examination and my personal familiarity with the applicable procedures, the Administrative Procedure Act, the rules of the Office of Administrative Hearings, and the rules of the Attorney General have been followed without any exceptions.

Dated: November 20, 1981

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH



RICHARD A. WEXLER
Assistant Attorney General

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

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

AFFIDAVIT OF MAILING NOTICE OF SUBMISSION TO THE ATTORNEY GENERAL

Linda Karwoski, being first duly sworn, deposes and says:

That on the 20th day of November, 1981, in the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached Notice of Submission to the Attorney General by depositing in the United States mail at said City of Minneapolis, a copy thereof, properly enveloped, with postage prepaid, on all persons and associations who requested notice that the rules in the above-entitled matter have been submitted to the Attorney General

Linda M. Karwoski

Subscribed and sworn to before me
this 20th day of November, 1981

Marie B. Tromiczak

MARIE B. TROMICZAK
NOTARY PUBLIC - MINNESOTA
HENNEPIN COUNTY
My Commission Expires Oct. 23, 1987

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

NOTICE OF SUBMISSION TO THE ATTORNEY GENERAL

Pursuant to your request and in accordance with the Minnesota Statutes, section 15.0412, subd. 4e:

PLEASE TAKE NOTICE that the above-captioned rules have been submitted to the Office of the Attorney General on November 20, 1981, for review as to form and legality. Pursuant to 1 MCAR § 1.206 C., the Attorney General will not approve the rules for at least ten calendar days after receipt to allow any person or association time to comment on the legality of the rules, after which that Office will complete its review. If you desire to comment on the legality of the above-captioned rules, you should direct your comments to the Office of the Attorney General, 530 State Office Building, 435 Park Street, St. Paul, Minnesota 55155, telephone (612) 296-7030. Please note that the above-cited rule of the Attorney General also provides that a copy of any written comments submitted to the Attorney General must be submitted simultaneously to this agency.

If you are interested in determining what changes, if any, were made in the proposed rules after the hearing and before submission to the Attorney General, you may contact Kent Peterson, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55414 (telephone: (612) 296-5365).

Dated: November 20, 1981

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

Deane H. Johnson Deputy

for GEORGE R. PETTERSEN, M.D.
Commissioner of Health

SF-00006-01

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL - Health

Office Memorandum

RECEIVED
NOV 20 1981
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

TO : Jerry Anderson
Administration Division

DATE: November 20, 1981

FROM : Richard A. Wexler
Assistant Attorney General

PHONE: 341-7272

SUBJECT: Rules of the Commissioner of Health 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

Attached are the above subject rules plus all of the supporting documents required by the Administrative Procedure Act, the Rules of the Office of Administrative Hearings, and the Rules of the Attorney General Relating to Rulemaking. The rules are submitted to you for approval as to form and legality pursuant to Minn. Stat. § 15.0412, subd. 4e. The specific documents attached are listed below. In each case one copy is enclosed unless a different number is indicated.

1. Rules as Adopted (four copies, all of which indicate by strike-out and underline the changes in the rules from what was proposed as published in the State Register).

2. Findings, Conclusions, and Order Adopting Rules (two copies).

3. Notice of Intent to Solicit Outside Opinion (see Agency Exhibit 1 of hearing record).

4. Material submitted in response to Notice of Intent (see Agency Exhibit 2 of hearing record).

5. Order for Hearing (see Agency Exhibit 3 of hearing record).

6. Notice of Hearing (see Agency Exhibit 4 of hearing record).

7. Affidavit of Mailing with Mailing List Certificate attached (see Agency Exhibit 6 of hearing record).

8. Rules as Proposed (copy from the State Register - see Agency Exhibit 5 of hearing record).

9. Report of Hearing Examiner.

10. Chief Hearing Examiner Reports (as required by Minn. Stat. § 15.0412, subds. 4d and 4e).

11. Order of the Chief Hearing Examiner (relating to incorporation by reference - see Agency Exhibit 10 of hearing record).

12. Statement of Need and Reasonableness (see Agency Exhibit 8 of hearing record).

13. Record.

14. Statement of Compliance with Rulemaking Procedures.

15. Affidavit of Mailing Notice of Submission to the Attorney General and accompanying Notice.

A transcript of the hearing was not prepared. However, the hearing was tape recorded. The seven tapes of the hearing are also included in the attached material.

Notice of submission of these rules to your office was sent by the Department of Health to those who had requested it on the day this memorandum and the attached documents were sent to you. In addition, a copy of the rules as adopted were delivered to the Revisor of Statutes office for the purpose of obtaining the revisor's certificate of approval of the form of the rules.

If you have any questions, please feel free to call me.

RAW:sd

Attachments

cc: George R. Pettersen, M.D.
Kent Peterson