7 MCAR 1

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

12-21-81

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, 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 S 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(e)(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.

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

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. §§ 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 § 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. § 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. § 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.

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 1.662 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 § 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 HCAR S 1.663 C.

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 § 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 HCAR § 1.663 6.

(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.