Chapter H 3

CERTIFICATE OF NEED

Note: Emerg. r. and recr. as ch. HSS 123, eff. 1-1-84.

H 3.001 Administrative rules for subch. II, ch. 150, Stats. The following rules shall be used in administering the certificate of need provisions of ch. 150, Stats.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.01 Definitions. For the purpose of this section the following definitions shall apply:

(1) AFFECTED PERSONS. "Affected persons" means any or all of the following:

(a) The applicant.

(b) Those members of the public who are to be served by the proposed health service.

(c) Those persons who offer services in the same health service area which are similar to those proposed in the application or who have formally indicated an intention to provide such similar services in the future.

(d) Any agency which establishes rates for health care facilities or health maintenance organizations in the appropriate HSA.

(e) The HSA(s) in whose area the proposed health service will be offered and any HSAs serving contiguous areas.

(2) APPLICANT. An "applicant" is the person for whom a certificate of need is requested.

(3) CERTIFICATE OF NEED. A "certificate of need" is a written authorization by the department for a person to implement an approved proposal.

(4) DATE OF NOTIFICATION. The "date of notification" is the date on which the department publishes notice of the receipt of an application and the proposed period for the review in a newspaper of general circulation.

(5) DEPARTMENT. The "department" is the department of health and social services.

(6) HEALTH SYSTEMS AGENCY (HSA). A "health systems agency" is an agency designated under 42 USC 300 l. In these rules, where reference is made to a specific HSA (as in "the" HSA, or "appropriate" HSA), such reference applies to the HSA(s) within whose area the proposed health service will be offered.

(7) OBLIGATION. An "obligation" is an enforceable contract which is entered into for the construction, leasing, acquisition, or permanent financing of a capital asset.

(8) PERSON. A "person" is an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), a state or a political subdivision or instrumentality (including a municipal corporation) of a state.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.02 Non-substantive reviews. (1) Pursuant to s. 150.02(4) and (5), Stats., projects which are determined to be reviewable, and which meet any of the following criteria, shall be determined eligible for non-substantive review:

(a) A one-time capital expenditure of less than $10,000.

(b) Capital expenditure projects developed pursuant to a plan of correction for code deficiencies previously approved by the department.

(c) Capital expenditure projects which are required to remedy an emergency situation detected not more than 30 days prior to the request for a non-substantive review determination and which threatens the safety of patients or the ability of the institution to remain in operation.

(d) Replacement of clinical equipment with equipment of similar capability if the equipment is included in the facility's annual capital expenditure budget or plan.

(e) Proposals for the replacement of non-health related equipment with equipment of similar capacity.

(f) An increase in the estimated total cost of an approved proposal which is more than $100,000 but less than $500,000, or 10% of the amount for which the certificate was issued, whichever is smaller.

(g) Proposals about which both the department and the HSA agree that there is no significant financial impact on the institution, and little or no impact on the scope of the delivery of health services in the area or region.

Note: Chapter 34, Laws of 1979 created "150.02(4)(e) Predevelopment Activities" as an additional category of reviewable projects eligible for non-substantive review. Projects meeting the definition of predevelopment activity as defined in the law will, therefore, be eligible for non-substantive reviews.

(2) Applications for non-substantive reviews shall be submitted to the department and the HSA on forms printed by the department and may be supplemented by other material which the applicant wishes to include.

(3) All applications shall be reviewed for completeness upon receipt by the department and the HSA. An application shall be considered complete if all sections of the application form which have been designated as relevant are answered. If the department determines that any of the designated items required to be answered by the applicant have not been answered, the application is incomplete. Whenever the department determines that an application is incomplete, notice shall be mailed to the applicant within 5 working days of receipt of the application. If the department fails to give such notice, the application shall be deemed to be complete.

(4) Applications which include a request for a non-substantive review shall be examined by the department and the HSA and a determination of the proposal's eligibility for such review shall be made within 15 working days of the date of the receipt of a complete application or of materials making the application complete, whichever is later.

(5) If the department determines that an application for a non-substantive review is not eligible for a non-substantive review, the application shall be regarded as a notice of intent under H 3.03. The notice of intent period will have begun on the date the application was determined complete. An application for a substantive review of the proposal will be sent to the applicant. The resulting application will be reviewed under H 3.04.

(6) The department shall issue a certificate of need on all approved proposals subjected to a non-substantive review within 20 days of the determination made pursuant to sub. (3).

(7) If the department does not approve a proposal which has been subjected to a non-substantive review, the application shall, within 20 days of the determination made pursuant to sub. (3), be referred to the HSA for review in accordance with the procedures beginning at H 3.04(2).

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78; renum. (1) to (6) to be (2) to (7), cr. (1), Register, August, 1979, No. 284, eff. 9-1-79.

H 3.03 Notice of intent. (1)(a) Except as provided in H 3.02, any person proposing to engage in an activity covered in s. 150.02, Stats. shall submit a notice of intent to the department and the HSA prior to the submission of an application.

(b) The form for submitting a notice of intent shall be the form published by the department for this purpose or a letter stating the name and address of the person intending to file an application, the anticipated date for obligation or initiation of the proposal, the estimated total cost of the proposal, a brief narrative describing the resources needed to complete and operate the proposal and how these resources will be obtained, the need for the proposal, and whom it will serve.

(c) In the case of a proposal for the renovation or construction of a health care facility, the department or the HSA may schedule a meeting with the potential applicant to discuss the proposal prior to sending out an application form.

(2) A notice of intent filed pursuant to sub. (1) shall satisfy the prior consultation requirement of s. 150.04, Stats.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.04 Substantive review. (1) SUBMISSION OF AN APPLICATION. (a) Applications shall be submitted to the department and the HSA on forms printed by the department and may be supplemented by other material which the applicant wishes to include.

(b) Applications shall not be received by the department and HSA until the applicable notice of intent period has elapsed. Such period shall begin upon the HSA's receipt of a notice of intent and extend for 90 days for proposals for the construction or renovation of a health care facility, and for 30 days for other proposals, unless the department and the HSA agree to a lesser period.

(c) All applications shall be reviewed for completeness upon receipt by the department and the HSA. An application shall be considered complete if all sections of the application form which have been designated as relevant are answered and the estimated fee, if any, has been received. If the department determines that any of the designated items required to be answered by the applicant have not been answered, the application is incomplete. Whenever the department determines that an application is incomplete, notice shall be mailed to the applicant within 5 working days of the receipt of the application. If the department fails to give such notice, the application shall be deemed to be complete upon receipt.

(2) INITIATION OF THE REVIEW. (a) The review period for an application shall commence when both the department and the HSA have received a complete application, or when the department and the HSA receive additional materials making the application complete, whichever is later.

(b) The review period may be extended for up to 60 days if the department determines that it is not practicable to complete the review in the allotted time and any one of the following: the proposal has an estimated total cost in excess of $10 million, or will change the number of beds in a facility by 10% or more, or establishes or replaces a health facility; or that an extension of the review period specified in s. 150.06 (1), Stats., is necessary to comply with sub. (5).

(3) NOTIFICATION. (a) All persons affected by a proposal shall be notified of the proposed schedule for the review and of the opportunity for public meeting during the review period by the twentieth day of the month following the month in which the review period began.

(b) The applicant, HSA, and statewide health and health-related organizations shall receive the notification described in the preceding paragraph by mail.

(c) Notification to affected persons other than the general public shall be by mail and may be by newsletter.

(d) Notification of the public shall be through newspapers of general circulation.

(4) REVIEW CRITERIA. The proposal shall be reviewed on the basis of rules published by the department in accordance with s. 150.07 (1), Stats.

(5) HSA REVIEW PERIOD. The HSA shall, except as otherwise provided by these rules, submit its findings and recommendations to the department within 60 days of the date of notification to affected persons.

(6) PUBLIC MEETINGS. (a) The HSA shall be responsible for holding public meetings related to the review of a proposal. Any affected person may request a public meeting by the department if the HSA has not provided for such. These meetings shall be held according to the procedures in this section.

(b) 1. A designated representative of the agency conducting the meeting shall serve as the presiding officer and be responsible for the conduct of the public meeting including the establishment of the order and length of presentation.

2. Requests to speak shall be made to the presiding officer at the beginning of the meeting, and if the officer permits, during the meeting.

3. All directly affected persons at the meeting shall have an opportunity to present oral or written testimony on the proposal.

4. Persons wishing to present oral testimony at the public meeting may be encouraged to present a summary of the testimony on the proposal.

5. Testimony submitted to the agency or the presiding officer no later than the completion of the meeting shall be considered in the review of the proposal.

(7) DEPARTMENT REVIEW. (a) The department shall provide written notification of the status of the review and other appropriate information upon request.

(b) 1. Within 5 working days after the department receives the recommendations of the HSA, the department shall serve a preliminary determination upon the applicant and the HSA. The preliminary determination shall state whether the department will approve or disapprove a proposal for a certificate of need, and shall include a summary of the findings which serve as the basis for the preliminary determination. In addition, whenever the preliminary determination is inconsistent with the recommendations of the HSA, the preliminary determination shall include a summary of the reasons for the inconsistency.

2. a. Except as provided below, if the preliminary determination disapproves the proposal for a certificate of need, or is inconsistent with the recommendations of the HSA, the department shall schedule a hearing, to commence not later than 15 working days after service of the preliminary determination, at which the department, the applicant, the HSA, and other interested parties may submit evidence and argument relevant to the proposal for a certificate of need. The department shall designate an official or employe of the department, or borrowed from another agency pursuant to s. 16.24 or 20.901, Stats., as a hearing officer to preside over the hearing pursuant to s. 227.09, Stats. A stenographic, electronic, or other record of oral proceedings shall be made unless waived in writing by all parties.

b. If the department's preliminary determination approves the proposal for a certificate of need, and is consistent with the recommendations of the HSA, a certificate of need shall be issued without a hearing.

c. If the department's preliminary determination approves the proposal for a certificate of need, but is inconsistent with the recommendations of the HSA, a hearing shall be conducted unless the HSA waives its appeal rights in writing to the department.

d. Whenever the department schedules a hearing, a notice of the time, place, nature, and class of the proceeding shall accompany the preliminary determination.

e. At the conclusion of the hearing, the hearing officer shall certify the record of the proceeding to the department which shall render a decision pursuant to s. 227.10, Stats.

3. For each application for a certificate of need, the department shall serve its decision upon the applicant, the HSA, and other interested parties who have filed a request in writing with the department for a copy of said decision, within 30 days from the date of receipt of the HSA's findings and recommendations. However, if the review period is extended at the applicant's request, the decision shall be served by the end of the extended period. The decision shall be served pursuant to s. 227.11, Stats. If no decision is served within said period of time, the proposal for a certificate of need shall be considered disapproved based upon the record of the hearing but if appealed, the department shall issue and serve a decision pursuant to rule H 3.06 (3).

(8) ALTERATIONS OF THE REVIEW PERIOD. (a) *Extension of review period.* The review period may be extended if the applicant submits a formal, written request to the department and the HSA, and the department, after consultation with the HSA, concurs.

(b) *Modification of a proposal.* 1. An applicant wishing to modify a proposal must request an extension of the review period in order to allow time for the development of the modification, necessary amendments to the application, and consideration by the public, the HSA, and the department. If the modification and necessary amendments to the proposal are not submitted within the period of the extension designated for that purpose and no further extension is requested, the review shall continue based upon the original application.

2. A modification to a proposal which results in a change in the estimated total cost of more than $100,000 shall require an adjustment of the application fee.

(c) *Withdrawal of a certificate of need application.* 1. An applicant may withdraw an application for a certificate of need at any time without prejudice by notifying the HSA and the department in writing of the action.

2. If an application is withdrawn before the date of notification, the application fee will be returned. If the application is withdrawn on or after the date of notification, the fee will not be returned.

(9) CERTIFICATE OF NEED. (a) If the department's decision to approve a proposal is consistent with the HSA's recommendation, the department shall issue a certificate of need on the day of the decision.

(b) If the decision of the department is to issue a certificate of need, but the terms of the same are not consistent with the recommendation of the

HSA, the department shall issue the certificate of need 30 days after the decision to approve the proposal unless an appeal is filed.

(c) If an appeal is filed, the department shall not issue a certificate of need until the hearing officer has issued a decision.

(d) A certificate of need shall be valid for one year from the date of issuance unless it is renewed.

(10) AMENDED CERTIFICATE OF NEED. If there is a change in a proposal which has previously received a certificate of need which in itself would be reviewable under a provision of ch. 150, Stats., that change shall be reviewed under the procedures described in this section. Any approval of such change shall constitute an amendment to the certificate of need issued for the previously approved proposal.

(11) RENEWED CERTIFICATE OF NEED. At the request of the applicant, a certificate of need may be renewed without any changes for any period up to one year if the department determines that substantial and continuing progress as defined in s. 150.01 (6), Stats., has been made, or if the applicant demonstrates a commitment to obligate within the extension period.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.05 Reconsideration process. (1) PERIOD FOR FILING A PETITION FOR REHEARING. A petition for rehearing shall not be a prerequisite for appeal. Any affected person may, within 20 days after entry of the decision, file a written petition for rehearing with the department which shall specify in detail the grounds for the relief sought and supporting documentation. The department may order a rehearing on its own motion within 20 days after a final decision.

(2) BASIS FOR REHEARING. A rehearing may be granted only on the basis of one or more of the following:

(a) Some material error of law.

(b) Some material error of fact.

(c) The discovery of evidence not previously considered which is sufficiently strong to reverse or modify the decision.

(d) Significant changes in factors or circumstances relied upon in reaching the decision.

(e) Some material error of administrative procedure.

(3) CONTINUED VALIDITY OF A CERTIFICATE. The filing of a petition for rehearing shall not suspend or delay the effective date of the certificate of need, and the certificate shall take effect on the date of issue and continue in effect unless the petition is granted or until the certificate is amended, or set aside as provided by law.

(4) DISTRIBUTION OF PETITIONS. Copies of the petition for rehearing shall be served on the applicant, the HSA, and other persons upon written request. These parties may file replies to the petition.

(5) PERIOD FOR ORDERING A REHEARING. The department may order a rehearing or enter an order with reference to the petition without a hear-

ing, and shall dispose of the petition within 20 days after it is filed. If the department does not enter an order disposing of the petition within the 20 day period, the petition shall be deemed to have been denied as of the expiration of the 20 day period.

(6) PERIOD FOR CONDUCTING A REHEARING. Upon granting a rehearing, the department shall set the matter for further proceedings as soon as practicable. If in the department's judgment, after such hearing, it appears that the original decision is in any respect unlawful, or unreasonable, the department may reverse, modify, or suspend the decision accordingly. Any decision made after such rehearing reversing, modifying, or suspending the original decision shall have the same force and effect as an original decision.

(7) LIMITATION ON APPEAL. If a petition for rehearing is filed under this section, the person filing the petition may not base an appeal on any ground not set forth in a petition for rehearing, unless good cause is shown to the hearing officer for failure to present the ground to the department in the petition for rehearing.

(8) FEES. No fees shall be charged by the department for a rehearing.

(9) STATEMENT OF FINDING. If a rehearing is granted, a decision pursuant to s. 227.10, Stats., shall be served on the petitioner within 45 days after the close of the rehearing.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.06 Appeal process. (1) Only the applicant or the HSA may file an appeal pursuant to s. 150.09, Stats.

(2) A petition for an appeal pursuant to s. 150.09, Stats., must be received by the department within 30 days of the date of the decision or date when a proposal is deemed disapproved pursuant to rule H 3.04 (7) (b) 3 except, when a rehearing is requested, the petition must be received within 30 days of the date of the order finally disposing of the petition for such rehearing, or within 30 days after the final disposition by operation of law of any such petition for rehearing. The petition for an appeal must be filed concurrently with the department and the office of the governor.

(3) Whenever the applicant or the HSA requests an appeal, if the decision has not previously been served or made a part of the record, the department shall issue and serve a decision upon the applicant, the HSA and the hearing officer prior to the commencement of the appeal.

(4) The hearing officer shall be appointed by the governor under s. 252.075 (3), Stats.

(5) The hearing officer shall commence proceedings within 30 days after appointment by the governor.

(6) The appeal shall be conducted according to s. 227.20, Stats., and the functions of the court shall be performed by the hearing officer appointed by the governor. In addition:

(a) The hearing officer shall make a written statement of finding pursuant to s. 227.10, Stats., regarding the hearing within 45 days of the close of the hearing.

(b) The findings, conclusions and the decision resulting from the hearing shall, to the extent the decision of the department is reversed or modified, constitute the decision of the department.

(c) Written copies of the findings of the hearing officer shall be sent to the applicant, the HSA, the department and others upon request.

(7) The burden of proof shall be as follows:

(a) In an appeal of a decision to deny a certificate of need, the department shall bear the burden of showing that the proposal fails to meet the criteria and standards published by the department pursuant to s. 150.07, Stats.

(b) Except as set forth in par. (c), in an appeal of a decision to grant a certificate of need, the appellant must show that the proposal fails to meet the criteria referred to in par. (a) above.

(c) In an appeal by the applicant of a decision to grant a certificate of need on terms not proposed or agreed to by the applicant, the burden shall be on the department to show that the applicant's proposal would not have met the criteria referred to in par. (a) above.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.07 Annual reports. The department shall make annual reports on its activities including, but not limited to, the status of projects currently under review, the number and types of reviews completed since the previous report, and a general statement of decisions and findings made since the previous report.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.08 Public access. The public shall, upon submission of a written request, have access to all application materials and all other materials pertinent to department review.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.10 General standards. The following general standards shall be used in the review of all applications for certificates of need. More detailed service-specific standards as may be adopted shall also be applied when appropriate. New methods and techniques of providing health services are encouraged. These may include approaches which are not consistent with the rules contained in this chapter. When, in the judgement of the department, the interests of the public and the intent of the certificate of need program are best served by such action, the department may grant a variance from or waive application of these rules in regard to a specific application. The department may establish time limits or conditions for variances and waivers. A violation of the conditions of a variance or waiver is a violation of these rules.

(1) DEFINITIONS. (a) *Health service area.* The health system agency's geographic area as designated under 42 USC 300 l.

(b) *Health systems agency (HSA).* A health systems agency is an agency designated under 42 USC 300 l-4. Where, in these rules, reference is made to a specific HSA (as in "the" HSA, or "appropriate" HSA), such reference applies to the HSA (s) within whose area the proposed health service will be offered.

(c) *Planning area.* A planning area comprises the geographic unit of analysis for a determination of need.

(2) RELATIONSHIP TO HEALTH PLANS. Proposals shall not be inconsistent with federal, state, and local health plans. Consistency of the proposal with other special studies, surveys and information developed by various state and local agencies and relevant to the proposed project shall also be considered.

(3) RELATIONSHIP TO HEALTH FACILITY PLANS. Proposals from health facilities which have capital expenditure budgets or long-range plans shall not be inconsistent with the applicable sections of these budgets or plans.

Note: Long-range planning should be an ongoing function of every health care facility. The considered development of proposed projects needing certificate of need approval should be reflected in the facility's long-range capital expenditure budget or plan.

(4) NEED FOR SERVICES. The proposal must be needed.

(a) Determination of the need for a proposal shall be based upon consideration of the availability, accessibility, and acceptability of similar services in the planning area.

(b) Consideration shall be given to the special needs and circumstances of:

1. Entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service area in which the entities are located or in adjacent health service areas.

2. Health maintenance organizations (HMO) for which assistance may be provided under Title XIII Public Health Services Act. Such needs and circumstances include the needs of and costs to members and projected members of the HMO in obtaining health services and the potential for a reduction in the use of inpatient care in the community through an extension of preventive health services and the provision of more systematic and comprehensive health services.

3. Biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

(c) In the case of any new institutional health service proposed to be provided by or through a health maintenance organization, the department shall not deny a certificate of need with respect to such service (or otherwise make a finding that such service is not needed) in those cases when:

1. The department has granted a certificate of need which authorized the development of the service, or expenditures in preparation for such offering or development (or has otherwise made a finding that such development or expenditure is needed), and

2. The offering of this new institutional health service will be consistent with the basic objectives, time schedules, and plans of the previously approved application: provided, that the department shall impose a limi-

tation on the duration of the certificate of need which shall expire at the end of such time unless the health service is offered prior thereto.

Note: The information contained in (4) (b) 1. and 2. and (4) (c) is taken from 42 CFR 123.409 (9), 123.409 (10) and 123.411 respectively.

(5) ALTERNATIVE METHODS OF SERVICE PROVISION. There shall not be a less costly, more efficient or appropriate tested and relevant approach for meeting the need for a particular service. It shall be demonstrated that less costly, more efficient, or more appropriate existing alternative means of providing the services, if known, are not available, or that the establishment of such alternatives has been studied and found not practicable.

(6) ALTERNATIVE USE OF RESOURCES. There shall not be more desirable alternative uses for the financial and manpower resources contained in the proposal.

(7) FINANCIAL FEASIBILITY. (a) Proposals shall be financially feasible.

(b) Financial feasibility shall be reviewed based on the following considerations:

1. Cost indices, including but not limited to, the estimated total cost of the proposal, compared to recent similar state and regional proposals.

2. Availability of funds to service debt and depreciate the cost of the proposal.

3. Availability of funds to cover the operating costs that result from the proposal.

4. The likelihood that the proposed debt service would limit the applicant's future borrowing ability necessary for prudent operation.

5. Adequacy of financial resources available to the applicant for covering the following:

a. The proposed capital expenditure (as verified by documentation of sources of financing, including cash on hand, endowments, and letters from financial institutions).

b. Start-up costs (as estimated on a schedule of costs).

c. Initial operating deficits.

(8) COST CONTAINMENT. The proposal shall not result in unreasonable increases in patient charges.

(9) RELATIONSHIP TO EXISTING HEALTH CARE SYSTEM. The proposal shall:

(a) Promote the continuity of care in the health care system.

(b) Facilitate the care of patients in the most appropriate setting.

(c) Not be an unnecessary duplication of resources.

(10) RESOURCE AVAILABILITY. Necessary resources, including qualified personnel, shall be available to staff the proposed project, or a realistic plan for the acquisition of such resources shall be provided by the applicant.

(11) RELATIONSHIP TO ANCILLARY OR SUPPORT SERVICES. Ancillary or support services shall have capacity to accommodate the proposed project.

(12) CONSTRUCTION CONSIDERATIONS. In the case of new construction, renovation, or replacement, consideration shall be given to:

(a) The conformance of construction plans and methods with applicable federal, state, and local code.

(b) The costs and methods of the proposal's construction including, but not limited to, the costs and methods of energy provision and conservation.

(c) The probable impact of the construction project on the applicant's and other institution's costs of providing health services.

(d) The environmental impact of the construction.

(e) The effect of renovation activity on patient services.

History: Cr. Register, June. 1978, No. 270, eff. 7-1-78.

H 3.20 Acute care services. The following standards shall be used by the department in the review of applications for certificates of need for the establishment or expansion of acute care facilities and services.

(1) DEFINITION. (a) *Acute care facilities.* For purposes of this chapter, acute care facilities are those facilities defined in s. 50.33 (1), Stats., but excluding those facilities exempted by s. 50.39 (3), Stats. Facilities, or physically distinct units of facilities, which are dedicated to the diagnosis or treatment of mental illness, alcoholism or other drug abuse are excluded from the definition of acute care facilities.

(b) *Basic acute care services.* For the purposes of the acute care standards, basic acute care services include medical/surgical, pediatric, and obstetric services.

(2) ACCESSIBILITY. The location of acute care facilities shall allow reasonable access to basic acute care services. Reasonable access shall be defined as not more than 30 minutes driving time under normal conditions except in areas of low population density (less than 30 persons per square mile) which are currently in excess of 30 minutes travel time to acute care facilities, or where residents of an area have demonstrated a preference to utilize acute care facilities which are in excess of 30 minutes travel time.

(3) NEED FOR SERVICES. (a) For the purposes of the acute care standards, planning areas shall be developed to reflect changing medical trade patterns. The planning areas shall be revised in a manner consistent with the consideration enumerated below as data become available. The list of current planning areas shall be available, on request, at the health systems agencies and the department.

1. Planning areas shall be contiguous. With the exception of the southeastern Wisconsin health service area, minor civil division boundaries shall be utilized. Within the southeastern Wisconsin health service area a combination of postal zip code and minor civil division boundaries shall be utilized.

2. An analysis of existing utilization patterns, including, but not limited to, patient origin data shall substantiate that a plurality of the residents of the minor civil division or zip code areas in the planning area are treated by an acute care facility or facilities in that planning area.

3. The planning area configuration shall assure availability and reasonable accessibility to acute care facilities and basic acute care services as defined in the standards related to accessibility.

4. Except in areas of low population density (less than 30 persons per square mile) or where residents of an area travel in excess of 30 minutes to obtain acute care services, the geographic size of a planning area shall not exceed 50 miles between any 2 points in the planning area.

5. Where it can be established, based on analysis of patient origin data, that 2 or more acute care facilities serve the same geographical area, such facilities shall be included in the same planning area.

(b) Utilization. 1. The following parameters shall be established by the department with the assistance of the health systems agencies and with input from acute care providers, updated annually for each planning area, and utilized in arriving at the projected average daily census of the planning area:

a. Projected average length of stay.

b. Projected annual admissions per 1,000 population.

2. The following shall be analyzed in establishing these parameters:

a. The defined populations of the planning area, including but not limited to, the pediatric population, the female population of childbearing age, and the elderly.

b. Current and historic data describing the acute care utilization by planning area based on, but not limited to, patient origin data from the most recent State Hospital Discharge Survey, and the utilization of each acute care facility in the planning area based on, but not limited to, annual Hospital Survey Data and data presented to the Wisconsin Rate Review Program as provided for in s. 146.60 (1), Stats.

c. Migration of patients or the net effect of patients leaving the area for service as opposed to residents of other areas coming into the area for service, including inter-state migration.

d. Current trends in utilization of acute care facilities, including but not limited to, the length of stay in the state and the health service areas as defined under federal law, the size of the acute care facility, the type of service, the availability of primary care physicians, the admissions per 1,000 in the health service area, the state, and the nation, and patient days per 1,000 in the health service area, the state, and the nation.

(c) Projected average daily census. The projected average daily census shall be computed as follows:

1. Projected Patient Days/1,000 Population = Projected Average Length of Stay × Projected Admissions/1,000 Population
(these parameters are developed according to (3)(b) above)

2. Projected Patient Days = Projected Patient Days/1,000 Population × Projected Population (thousands)

3. Projected Average Daily Census = Projected Patient Days ÷ 365

(d) Projected bed need. The projected bed need for each planning area shall be computed as follows:

1. Distribute the projected average daily census among the services in the hospitals for which a need can be demonstrated. Such distribution shall be based upon an analysis of the current distribution of patient days among services in the planning area and historical trends in the distribution of these days.

2. For each service, apply the bed need formula:bed need = ADC + $(1.65 \sqrt{ADC})$ where ADC = the projected average daily census for that service.

3. Sum the projected bed needs for the services in the planning area. The result shall be the projected bed need for the planning area.

(4) RELATIONSHIP TO EXISTING HEALTH CARE SYSTEM. Acute care facilities proposing replacement or renovation shall provide written evidence of plans to achieve optimal efficiency through cooperative arrangements with other acute care facilities. These may include arrangements for shared services, for obtaining specialized services or consultation, and for transfer of patients, when necessary, to facilities providing specialized services.

(5) MAXIMUM SPACE LIMITS. (a) The following maximum clear floor space limits for general medical/surgical, obstetric, and pediatric inpatient rooms shall be used in reviewing allocation of square footage in projects.

Number of Beds	Maximum Square Footage
1	150
2	225
3	300
4	375

(b) The above maximums may be exceeded in situations, such as special care CCU patient rooms, where additional space may be justified within a patient room or in a proposal to renovate a facility when such renovation will result in a reduction of bed capacity.

(6) MINIMUM SIZE/PATIENT VOLUME. (a) The following standards shall apply in determining the minimum size for acute care facilities:

1. The minimum size of an acute care facility in an SMSA shall be 200 beds.

2. The minimum size of an acute care facility in a non-SMSA area shall be 75 beds or the 5 year projected bed need for the planning area, whichever is less.

3. These standards shall not be applied to facilities where it can be demonstrated that reasonable access to an acute care facility (as defined in the standard relating to access) cannot be achieved in the absence of such a facility.

(b) The following standards shall apply in determining the minimum patient volume in obstetric services.

1. The minimum patient volume for obstetric services in a facility shall be the projected annual number of deliveries in the planning area or 750, whichever is less.

2. These standards shall not be applied to facilities where it can be demonstrated that reasonable access to obstetric services defined in the standard relating to access can not be achieved in the absence of such a facility.

(c) The following standards shall apply in determining the minimum patient volume in pediatric services.

1. The minimum patient volume for pediatric services in a facility shall be the projected annual number of pediatric admissions in a planning area or 1,500, whichever is less.

2. These standards shall not be applied to facilities where it can be demonstrated that reasonable access to pediatric services defined in the standard relating to access can not be achieved in the absence of such a facility.

(d) Consolidation of acute care facilities resulting from the application of minimum size/patient volume standards shall be undertaken in a manner that assures continued availability of the full range of all needed health care services existing prior to consolidation.

(7) SHELLED IN SPACE. Shelled in space shall not be allowed.

(8) COST CONTAINMENT. (a) Acute care facilities shall justify space allocations for each proposed service.

Note: The following departmental gross square feet spatial allocations may be used for selected services of acute care facilities.

Services	Range of Annual Ratios	Units
Clinical Laboratories	46.88-56.88	Procedures per sq. ft.
Diagnostic Radiology	4.10- 4.60	Procedures per sq. ft.
Surgery	0.56- 0.82	Procedures per sq. ft.
Emergency and Triage	6.25- 6.95	Visits per sq. ft.
Food Preparation	54.00-69.00	Meals prepared per sq. ft.
Cafeteria	32.50-39.00	Meals served per sq. ft.

(b) In determining whether a proposed project fosters cost containment, an analysis of the facility's existing and projected per diem rate shall be conducted to determine:

1. How the per diem rate compares with other acute care facilities in the same rate review group established pursuant to s. 146.60, Stats.

2. How the capitalization cost, the per diem cost of depreciation and interest, the cost per square foot, and the cost per bed compares with other recently approved or constructed projects of similar size and scope.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.23 Long-term care facilities. The following standards shall be used by the department in the review of applications for certificates of need for long-term care facilities in Wisconsin. For purposes of the review of

applications for long-term care, standards defined in this section apply to all facilities subject to licensure under ch. H 32, [HSS 132].

(1) DEFINITIONS. (a) Long-Term Care Facility. For purposes of this chapter, long-term care facilities are those which are licensed under the provisions of ch. H 32, [HSS 132].

(b) Specialized Long-Term Care Facilities. For purposes of this chapter, specialized long-term care facilities include:

1. Facilities serving primarily a state or nationwide population and in which less than 50% of the residents have originated from any one non-specialized long-term care planning area.

2. Facilities in which:

a. More than 50% of the residents are under age 65 and have a primary diagnosis of mental retardation or mental illness, and

b. A program oriented to the care and treatment of the mentally retarded or mentally ill is offered.

3. Facilities in which:

a. More than 50% of the residents have a primary diagnosis of drug abuse or alcoholism, blindness, or severe physical handicap, and

b. A corresponding program of care and treatment is offered.

Note: The designation of specialized facilities for purposes of determination of need in no way implies that the populations served by those facilities cannot or should not be treated in long-term care facilities having adequate personnel or programs nor does it imply the appropriateness of any particular treatment modality in what has been described as either specialized or non-specialized long-term care facilities.

(2) ACCESSIBILITY. The location of long-term care facilities should allow reasonable access to facilities by physicians, staff, relatives, and friends of the patient. Reasonable access shall be defined as not more than 30 minutes driving time under normal conditions.

(3) NEED FOR SERVICES. (a) For the purpose of the long-term care facilities standards, planning areas shall be counties except that the following areas within the southeastern Wisconsin health service area designated in the 1974-75 Hill-Burton State Plan shall constitute planning areas: Milwaukee northwest; Milwaukee south; Racine south central; Kenosha southeast; Washington/Ozaukee north; Walworth/Racine/Kenosha southwest; Waukesha west.

(b) For the purposes of the specialized long-term care facilities standards, planning areas shall be coterminous with the health service areas except that for those facilities identified as serving a statewide population, the state shall constitute a single planning area.

(c) Long-term care facilities. 1. For purposes of estimating need for non-specialized long-term care beds in Wisconsin, the adjusted use rate employed in estimating need shall not be less than the most currently available average use rate for DHEW, Region V, or more than the most currently available average use rate for Wisconsin. Specificially, in estimating need for long-term care beds for areas having adjusted use rates lower than the Region V average, the Region V average shall be the use rate. For areas with an adjusted use rate between the Region V average

and the state average, the adjusted use rate shall be the use rate for that area and, for areas with an adjusted use rate in excess of the state average, the state average shall be the use rate. The statewide average long-term care use rate will be determined by subtracting the patient days of all specialized facilities in the state from the total number of patient days for facilities licensed under H 32, [HSS 132] and dividing the net patient days by the current estimated statewide population age 65 and over. Calculations for individual service area bed need determination will similarly eliminate from service area consideration the beds located in specialized facilities.

2. Adjustment for patients under age 65. The use rate and bed need determinations for long-term care facilities in a planning area shall be adjusted to account for use of the facilities by patients under age 65.

3. Information submitted by religious organizations. Information submitted by a religious organization in support of its application, demonstrating a desire on the part of persons in the area being served by the facility to be cared for in an institution supported by that particular religious organization, shall be a significant consideration in determining need for that facility. This information may consist of waiting lists, substantiated by verified applications for admission to the institution, surveys, and any other forms of information required by the department.

Note: Adjustment for Migration. The use rate employed in calculating long-term care bed need may be adjusted for areas having substantial in or out migration. In such cases, the migration pattern may be examined and a determination made whether the migration is appropriate, or whether it results from a lack of long-term care beds in adjoining planning areas in which construction of new beds might be justified.

Note: Adjustment for Age/Sex Variation. The use rate employed in calculating long-term care bed need may be adjusted if the age/sex distribution of the age 65 and over population deviates significantly from the statewide average.

(d) Specialized long-term care facilities. In determining the need for additional specialized long-term care beds, the department shall take into consideration the following:

1. The actual utilization of beds within existing specialized facilities including:

a. Types of patients currently being served by the facility.

b. The place of origin of current and proposed patients.

2. The percentage of potential residents of the facility in the state and planning area who can be expected to require institutional services.

3. The availability of alternative non-institutional services in the planning area.

4. The comments and recommendations received by the department from, but not limited to, the following agencies:

a. Division of Community Services

b. 51.42/.437 Board

c. County social service department

d. Health Systems Agency

e. Mental health planning agency or body

f. Bureau of Protective Services

g. Other relevant agencies and organizations

5. The ability of long-term care facilities in the planning area to serve the specialized population.

(4) RELATIONSHIP TO EXISTING HEALTH CARE SYSTEM. Applicants proposing to establish or expand long-term care facilities shall provide evidence of the accessibility of physicians and other health care personnel to residents of the facility.

(5) MINIMUM FACILITY SIZE. The minimum acceptable size for the establishment or replacement of a long-term care facility shall be 60 beds, except in those cases where proposed facilities are in areas where the 30-minute accessibility standard is not met.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.40 Burn centers. The following standards shall be used by the department in the review of applications for certificates of need for designated burn centers. The general criteria and standards shall be used in the review of all applications to establish other levels of burn services such as a burn program.

(1) DEFINITIONS. (a) *Burn center.* A discrete, self-contained service that is equipped, staffed, and devoted exclusively to the provision of burn care. A burn center has its own nursing station; intensive care beds, rooms, and equipment are distinct from other units; and it is spatially separate from any other inpatient service. It has the capacity to provide: emergency care and stabilization of burn patients; evaluation of burn severity; acute, convalescent, and rehabilitative burn care; basic and clinical research; and education and training. All persons diagnosed as sustaining severe burn should be considered candidates for a burn center even though it may be geographically distant.

(b) *Burn program.* A burn program is not a discrete, dedicated unit. A burn program may exist in any acute care facility which offers a consistent burn treatment plan and associated protocols directed by a qualified physician. It has the capability to provide: emergency care and stabilization of burn patients; evaluation of burn severity; referral of severe burns to burn centers for more intensive care; definitive care for low risk burn patients; and convalescent and rehabilitation burn care (optional).

(c) *Severe burn.* Severe burns include all life-threatening burns, all burns to persons under 2 years of age or over 60 years of age that require hospitalization, and all second and third degree burns involving a significant area of the body. Significant area of the body is defined as 20% of the body surface for adults, 10% of the body surface for children and persons aged 65 and over; and 2% of the body surface for all electrical burns. These percentages may be reduced for burns involving multiple sites.

(d) *Dedicated burn bed.* A dedicated burn bed is one which is used solely for the care of the severely burned patient and for which specially trained staff are provided.

(2) NEED FOR SERVICES. (a) For purposes of reviewing proposals to establish or expand burn centers, the state of Wisconsin shall constitute a single planning area.

(b) The need for additional burn center beds shall be clearly demonstrated and documented. The demonstration of need shall include at least the following considerations:

1. A projection based on the current utilization in days of care/1,000 population which includes estimates of changes due to alterations in physician referral practices, patient migration, and the availability of alternate treatment resources.

2. The anticipated relationship with other burn centers and burn programs.

3. A description of the methodology used to calculate the projections and the underlying assumptions made to arrive at the forecast.

(c) No additional burn center shall be approved unless each existing burn center is developed to the size of 20 dedicated beds (of which at least 6 are intensive care beds) and maintains an occupancy rate of at least 75%. A determination of full utilization shall consider at least the following:

1. Technological capability and capacity of existing burn centers.

2. The volume of patients who can appropriately be served in intensive care unit beds, or other appropriate beds, in burn centers.

3. Patient mix (acute, intensive care, outpatient, pediatric).

4. Patient referral resulting from unit overload.

(d) A facility proposing to develop a burn center shall provide evidence that it can reasonably expect to provide hospitalization for at least 50 severely burned patients the first year of operation and 75 severely burned patients the second year.

(3) RELATIONSHIP TO EXISTING HEALTH CARE SYSTEM. (a) Facilities proposing to expand the number of burn center beds shall provide documentation that they have established:

1. Transfer agreements with hospitals not having burn center beds to assure the transfer of an adequate volume of severe burn patients.

2. Transfer agreements with other acute care facilities having burn center beds to assure accommodation of peak patient loads, and optimal use of existing burn centers.

(b) Facilities proposing to establish or expand burn center services shall provide evidence of the capability of the existing emergency medical system adequately to provide transportation for the severe burn patient from those areas of the state to be served by the new or expanded burn center.

(c) Facilities proposing to establish or expand burn centers shall show evidence of their interest and ability to participate in programs of education and training in the diagnosis of severe burns, and provision of care to

the non-severe burn patient for the medical and nursing staff of facilities not housing a burn center.

(4) RELATIONSHIP TO ANCILLARY OR SUPPORT SERVICES. Facilities proposing to establish or expand the number of burn center beds shall provide documentation of the 24-hour availability of the services rated essential for hospital burn centers and units by the American Burn Association in criteria A.1. and A.3. of *Specific Optimal Criteria for Hospital Resources for Care of Patients with Burn Injury,* (April, 1976) which may be obtained from:

American Burn Association
Charles Hartford, Secretary
Crozer-Chester Medical Center
15th Street and Upland Avenue
Upland, Chester, PA 19013

(5) MINIMUM SIZE. The minimum size of any new burn center shall be 4 acute and 2 intensive care beds. Where the need for additional burn center services is indicated, proposals to expand existing burn centers shall be given priority over proposals to establish new burn centers.

(6) RESOURCE AVAILABILITY. Facilities proposing to develop or expand a burn center shall provide documentation that the resources necessary for the projected number of severe burn patients are available. Such resources shall include those rated essential in criteria A.2., A.4., B., C., D., E., F., and G. of *Specific Optimal Criteria for Hospital Resources for Care of Patients with Burn Injury,* (April, 1976).

(7) LOCATION OF STANDARDS. The above mentioned standards are available on file in the department of health and social services, division of health, in the office of the secretary of state, and the revisor of statutes bureau.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.42 Perinatal services. The following standards shall be used in the review of proposals to establish or expand perinatal care centers, neonatal intensive care units including special care nurseries or high-risk obstetrics services.

(1) DEFINITIONS. (a) *Delivery base.* The annual number of deliveries within a planning area from which the center expects to draw its high-risk patients.

(b) *High-risk obstetric service.* An organized health care service combining specialized facilities and staff for the intensive care and management of high-risk maternal and fetal patients before and during birth, and to maternal patients following birth. A high-risk obstetrics service provides the most specialized level of care to maternal and fetal patients.

(c) *Low birth-weight.* Under 5 pounds, 8 ounces (under 2,500 grams).

(d) *Neonatal.* Pertaining to the first 28 days of life.

(e) *Neonatal intensive care unit.* An organized health care service combining specialized facilities and staff for the intensive care and management of high-risk neonatal patients.

(f) *Neonatal intensive care bed.* A bed in a neonatal intensive care unit or special care nursery capable of providing temperature support, oxygenation, ventilation, hydration, and monitoring heart rate, respiration, and direct and indirect blood pressure.

(g) *Neonatal intermediate care bed.* A bed in a neonatal intensive care unit or special care nursery capable of providing temperature support, continuous cardiac monitoring, and indirect blood pressure determination.

(h) *Perinatal.* Pertaining to the mother, the fetus, or the neonatal infant.

(i) *Perinatal care center.* An organized health care service which includes a high-risk obstetrics service and a neonatal intensive care unit.

(j) *Special care nursery.* An organized health care service which provides care for a large number of newborns at some degree of risk.

(2) NEED FOR PERINATAL SERVICES. (a) For purposes of planning for perinatal care centers in Wisconsin, planning areas shall be coterminous with health service areas. Patterns of patient migration between planning areas will be considered in applying this standard.

(b) The location of a perinatal care center shall allow reasonable access to the perinatal services by patients in the region served. Reasonable access shall be interpreted as a maximum of 2 hours of normal driving time one way.

(c) Determination of need for neonatal intensive and intermediate care beds shall be calculated in the following manner:

1. In a planning area, the projected need for neonatal intensive and intermediate care beds shall be computed as follows:

a. Divide the annual number of low birth-weight deliveries in the planning area by the annual number of births.

b. Divide the result by 80.

c. Multiply the result times 4, times the projected annual number of births in the planning area 5 years from the date of the application.

2. The neonatal ICU bed need shall be adjusted to reflect the volume of patients who may appropriately be served in facilities located out of state or in adjacent planning areas and the volume of patients from adjacent areas who may appropriately be served in facilities within the planning area.

3. The number of additional neonatal ICU beds needed in a planning area shall be determined by subtracting existing and approved beds from the projected bed need.

(d) The minimum projected delivery base of each perinatal care center 5 years from the date of application shall be the projected annual number of deliveries in the planning area or 15,000, whichever is less.

(e) A facility proposing to establish or expand a perinatal care center shall currently perform, or document that upon initiation of service it shall perform, at least 1,500 deliveries annually.

(f) In a planning area where a need for additional high-risk perinatal services, or the neonatal ICU or high-risk obstetrics components of these services, is indicated, a proposal to expand these services at an existing perinatal care center shall be given priority over proposals to establish new high-risk perinatal services at other institutions in the planning area.

(3) RELATIONSHIP TO EXISTING HEALTH CARE SYSTEM. (a) The neonatal ICU and high risk obstetrics components of a perinatal care center shall be located in close physical proximity. Applicants proposing to establish or expand a neonatal ICU or high-risk obstetrics components of a perinatal care center where these components are located in separate institutions, shall provide evidence of an agreement between the institutions. The agreement shall include:

1. Provisions for a perinatal care center coordinating board involving medical and administrative staff from participating institutions.

2. A description of the perinatal care center system which clearly distinguishes the respective roles, functions, and responsibilities of the institutions in the system.

3. Provisions for the effective coordination between the institutions of the perinatal care team designed to assure continuity of care to perinatal care center patients and to prevent the unnecessary duplication of staff in the perinatal care center.

4. Provision for the effective coordination of perinatal facilities and equipment between the institutions designed to minimize the duplication of these facilities and equipment in the perinatal care center.

(b) Applicants proposing to establish or expand perinatal care center components shall provide evidence that they are able to conduct programs of inservice, outreach, and consumer education.

(c) Applicants proposing to establish or expand a perinatal care center component shall provide documentation that they have established or have plans to establish a 24-hour telephone consultation service to physicians and other professionals and hospitals in the service area of the perinatal care center.

(4) AVAILABILITY OF RESOURCES. Applicants proposing to establish or expand components of a perinatal care center shall document that they shall be able to meet the following minimum staffing requirements:

(a) *Perinatal care centers.* 1. Nursing care aspects of both the obstetric and neonatal components of the perinatal care center shall be coordinated by a registered professional nurse. This nurse shall have obtained specialized nursing knowledge and skills by successfully completing an organized educational program in maternal or neonatal intensive care, and shall have at least one year of experience in an obstetrics unit associated with a neonatal intensive care unit, or in a recognized perinatal care center.

2. A physician trained in anesthesiology shall be on call 24 hours per day.

(b) *High-risk obstetrics component.* 1. The high-risk maternal/fetal and intrapartum intensive care segment of a perinatal care center shall be

under the direction of a physician trained in high-risk obstetrics. This obstetrician shall have at least one year of experience in high-risk intensive care in an organized high-risk program beyond the standard residency in obstetrics. Consultation from a physician trained in high-risk obstetrics shall be available for all high-risk patients.

2. A registered professional nurse shall be available to assist the antepartum, intrapartum, and postpartum care of each high-risk mother. These RNs shall have obtained specialized nursing knowledge and skills by successfully completing an organized educational program in maternal intensive care.

(c) *Neonatal intensive care component.* 1. The high-risk fetal/neonatal intensive care segment of the perinatal care center shall be under the direction of a physician who is board-eligible or board-certified in neonatology. Consultation from a physician trained in high-risk neonatology shall be available for all high-risk patients.

2. Registered professional nurses shall be on the nursing staff of the neonatal intensive care unit of each shift. At least one RN on each shift shall have obtained specialized nursing knowledge and skills by successfully completing an organized educational program in neonatal intensive care.

3. The neonatal intensive care unit shall maintain a minimum ratio of one RN for every 2 intensive care infants. The intermediate care unit shall be staffed with one RN for every 4 patients or one RN and additional nursing personnel at a minimum ratio of one RN or LPN for every 4 patients.

(5) RELATIONSHIP TO SUPPORT SERVICES. Applicants proposing to develop or expand a perinatal care center shall document that they shall be able to provide the following minimum facilities and services:

(a) Family planning services as part of the perinatal services. Medical services do not need to include abortions, but perinatal center staff shall be knowledgeable of, and shall provide information regarding the availability of, abortion services and problem pregnancy counseling.

(b) Laboratory services.

(c) A follow-up clinic for the continued evaluation and care of the patient following discharge.

(d) A 24-hour emergency transport capability for high-risk infants, either through agreements with ambulance services outside of the perinatal care center or through a transport capability operated by the perinatal care center.

1. A perinatal care center shall demonstrate an ability to maintain portable equipment with a self-contained power source necessary for the intensive treatment and life support of newborn infants while in transit.

2. Equipment for high-risk infant transport shall include, but is not limited to: infant transport incubator, infant resuscitator, air/oxygen supply, intravenous fluid therapy, emergency medications, and monitoring equipment for infant's temperature, heart rate, and environmental oxygen.

3. The transport team for high-risk neonatal patients shall be composed of medical and health care professionals who are active in newborn intensive care at the perinatal care center and who have undergone a program of inservice training in the preparation and transport of high-risk infants.

4. The transport team shall include a physician, a nurse, or other paramedical personnel appropriate to the needs of the individual case. A physician need not accompany the infant in all cases, but at least one trained individual whose only responsibility is the care of the infant should staff the transport team.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.44 End-stage renal disease services. The following standards shall be used by the department in the review of applications for certificates of need for the establishment or expansion of end-stage renal disease services.

(1) DEFINITIONS. (a) *Chronic maintenance dialysis.* A process by which waste products and excess fluid are removed from a patient's body by osmosis from one fluid compartment to another. The 2 types of dialysis which are currently in common clinical practice are hemodialysis and peritoneal dialysis.

(b) *Chronic maintenance dialysis station.* The plumbing, electrical system, dialysis machine, and space which will accommodate a bed, chair, and other equipment used to perform chronic maintenance dialysis.

(c) *Dialysis machine.* The device used to perform dialysis. Distinguished from the term "station" in that "machines" are not restricted for chronic maintenance dialysis and do not require approval; rather, they may be used for backup support for the stations, acute care of patients, or with patients who require isolation.

(d) *End-stage renal disease (ESRD).* That stage of renal impairment which is almost always irreversible and requires dialysis or kidney transplantation to maintain life.

(e) *Free-standing renal dialysis facility.* A non-hospital-based unit which is approved by the department and federal government to furnish chronic maintenance dialysis.

(f) *Renal dialysis center.* A hospital-based unit which is approved by the department and federal government to furnish the full spectrum of diagnostic, therapeutic (including inpatient dialysis furnished directly or under arrangement or agreement), and rehabilitative services, except renal transplantation, required for the care of ESRD dialysis patients.

(g) *Renal dialysis facility.* A hospital-based unit which is approved by the department and federal government to furnish chronic maintenance dialysis.

(h) *Renal transplantation center.* A hospital unit which is approved by the department and federal government to furnish transplantation and other medical and surgical specialty services required for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement or agreement.

(i) *Self-care dialysis.* Chronic maintenance dialysis performed by a trained ESRD patient and patient helper at home or in an approved self-care dialysis unit.

(j) *Self-care dialysis training program.* A program which formally trains ESRD patients and patient helpers to perform self-care dialysis.

(k) *Self-care training station.* The plumbing, electrical system, and space which will accommodate a dialysis machine, bed, chair, and other equipment used to train ESRD patients and patient helpers to perform self-care dialysis.

(2) NEED FOR RENAL TRANSPLANTATION SERVICES. (a) For purposes of reviewing proposals for the establishment of renal transplantation services, the state shall constitute a single planning area. The population base required to support a single transplant center shall be at least 2 million persons.

(b) Determination of need for renal transplantation centers shall be based upon consideration of the following:

1. The capacity of existing transplantation centers in the state and also in adjoining states;

2. The volume of transplants provided to patients from Wisconsin and adjoining areas.

(c) Applicants proposing to establish transplantation centers shall demonstrate that they will perform at least 15 transplants the first year of operation, and at least 25 transplants the second year of operation.

(3) NEED FOR CHRONIC MAINTENANCE DIALYSIS SERVICES. (a) For purposes of reviewing proposals for chronic maintenance dialysis facilities or centers, planning areas shall be coterminous with health service areas.

(b) The determination of need for the establishment or expansion of renal dialysis centers, hospital-based renal dialysis facilities, and free-standing renal dialysis facilities shall be based upon the following considerations:

1. Utilization of Hemodialysis Stations. a. Centers or facilities having fewer than 6 stations and proposing to add stations up to a unit total of 6 shall be approved only after the facility or center is operating at 80% of capacity as determined by dividing the total number of chronic maintenance dialysis treatments per week in the facility or center (based upon the annual Facility Survey Report or equivalent data that may be available) by the maximum number of chronic maintenance dialysis treatments per week in the facility or center (one treatment per station per day times 6 days of operation per week times the number of chronic maintenance hemodialysis stations).

b. Expansion beyond the number of 6 hemodialysis stations in a facility or center shall be approved only after the facility or center is operating at 80% of capacity as determined by dividing the total number of chronic maintenance dialysis treatments per week in the facility or center (based upon the annual Facility Survey Report or equivalent data that may be available) by the maximum number of chronic maintenance hemodialysis treatments per week in the facility or center (2 treatments per station per day times 6 days of operation per week times the number

of chronic maintenance hemodialysis stations). Self-care training stations are excluded from these calculations at the rate of one exclusion for each 6 self-care patients trained per station within the preceding 12 months.

c. New hemodialysis units shall not be established until all existing or approved facilities and centers within 90 minutes travel time, including those in adjacent planning areas, are operating at 80% capacity. Where the need for additional hemodialysis services is indicated, proposals to expand existing facilities or centers shall be given priority over proposals to establish new units.

2. Utilization of Peritoneal Dialysis Stations. a. A facility or center proposing to establish a peritoneal dialysis station must demonstrate that at least one patient is in need of this type of treatment.

b. No additional peritoneal dialysis stations shall be established until each peritoneal dialysis station is actively treating at least 2 patients simultaneously.

c. Peritoneal dialysis stations used for the purpose of self-care training shall be excluded from consideration as active treatment stations at the rate of one exclusion for each 6 self-care patients trained per station within the preceding 12 months.

3. The availability of self-care dialysis training in the planning area.

4. The incidence and prevalence rates for ESRD within the planning area.

5. The availability of appropriate treatment for pediatric patients with end-stage renal disease.

6. Alternate methods of providing care and treatment for ESRD patients.

7. The existence of a documented medical emergency situation, or seasonal influx of patients, for which a temporary station may be approved for up to 6 months of operation. After that period, full approval must be sought by the facility or center.

(c) When the need for additional dialysis service capacity is demonstrated, existing facilities or centers shall increase the number of shifts operating daily, rather than institute additional stations.

(d) An additional self-care training station is justified only for those facilities or centers which have trained at least 6 persons per station within the previous year.

(4) RELATIONSHIP TO EXISTING HEALTH CARE SYSTEM. Renal dialysis centers and facilities shall have referral agreements with renal transplantation centers.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.50 Open heart surgery. The following standards shall be used by the department in review of proposals to establish or expand open heart surgery or pediatric heart surgery services.

(1) DEFINITIONS. (a) *Closed heart surgery.* Surgery for congenital or acquired cardiac disease, pericardial disease, or disease of the great vessels near the heart which does not require cardiopulmonary bypass.

(b) *Dedicated pediatric heart surgery service.* A service which provides heart surgery to only infants and children.

(c) *Open heart surgery.* A class of highly technical operations on the heart and intrathoracic great vessels which requires temporary use of cardiopulmonary bypass equipment to perform the functions of circulation during surgery.

(d) *Pediatric heart surgery.* Surgery related to the congenital or acquired diseases of the heart, pericardium or intrathoracic great vessels, and cardiovascular system in infants and children.

(2) NEED FOR SERVICES. (a) For the purposes of open heart surgery services planning areas shall be coterminous with the health service areas designated pursuant to 42 USC 300 l. There shall be permitted at least one open heart surgery service in each planning area. For the purposes of dedicated pediatric heart surgery services, the planning area shall be the entire state.

(b) The determination of the need for the establishment or expansion of open heart or dedicated pediatric heart surgery services shall be based upon an evaluation of factors including, but not limited to, the applicant's demonstration of the following:

1. Projection of the annual number of open heart or pediatric heart surgery candidates identified by referring physicians, facilities, and other sources. Projections shall be based upon relevant historical data and shall include the geographical origins of such candidates by zip code or minor civil division.

2. Annual patient volume projections based upon the incidence of heart conditions for which open heart or pediatric heart surgery has been scientifically accepted to be an effective and appropriate modality.

3. The underlying assumptions made to arrive at the projections and the data and methodology used to calculate the projected number of adult open heart and pediatric heart surgery candidates. The assumptions, data, and methodology used to arrive at the projections shall be provided in the application.

4. Where the population to be served has received open heart or pediatric heart surgery in the past 3 years.

5. A documented plan that the proposed open heart or pediatric heart surgery service can be adequately staffed when completed and operational.

(c) The location of a facility proposing to establish open heart or pediatric heart surgery services relative to other facilities in the planning area shall be considered. If there are approved heart surgery services in the planning area, the impact of the proposal on the utilization and staffing of these existing programs shall be addressed. Patterns of patient migration, and referrals between planning areas and other geographical areas shall also be considered.

(d) A facility proposing to establish open heart surgery shall demonstrate that it will have a volume of open heart surgery candidates equal to, and the resource capability to perform a minimum of, 200 adult cases per year and it shall be demonstrated that this rate will be attained within the first 3 years of operation. Such demonstration shall conform to par. (b) of these standards.

(e) No additional open heart surgery programs shall be approved until each open heart surgery program in the planning area is consistently operating at a minimum of 350 open heart surgery cases per year.

(f) A facility proposing to establish a dedicated pediatric heart surgery program shall demonstrate that it will have a volume of pediatric heart operations equal to, and the resource capability to perform a minimum of, 130 cases per year and that this rate will be attained within the first 3 years of operation. At least 50% of these cases shall be open heart surgery.

(g) No additional dedicated pediatric heart surgery program shall be approved until each dedicated pediatric heart surgery program is consistently operating at a minimum rate of 250 pediatric heart surgery cases annually.

Note: In the review of the resource capability and other features of open heart surgery not covered in this rule, the department may consider up-to-date planning guidelines adopted by national professional and scientific organizations, Wisconsin health systems agencies, and the department of health, education and welfare in the review of applications to establish or expand open heart surgery services. Such guidelines may include those of the inter-society commission for heart disease resources, the American heart association, the Wisconsin chapter of the american college of cardiology, and the American academy of pediatrics.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.52 Cardiac catheterization services. The following standards shall be used by the department in review of proposals to establish or expand cardiac catheterization services and for the acquisition of cardiac catheterization equipment and facilities.

(1) DEFINITIONS. (a) *Cardiac catheterization laboratory.* A diagnostic facility for disorders of the heart, lung, and the great vessels with the resource capability to skillfully insert catheters into the heart and adjacent great vessels, to reliably measure multiple parameters of cardiac physiological activity, and to obtain visualization of the appropriate heart chambers and adjacent vessels.

(b) *Cardiac catheterization service.* The provision of intracardiac or coronary artery catheterizations.

(c) *Coronary artery catheterization.* A distinct procedure involving the introduction of a catheter through a peripheral artery into the coronary arteries. The catheter tip is positioned into the coronary arteries and a diagnostic agent is injected for the purpose of visualizing these vessels for evidence of cardiac disease. Left ventriculography may be a part of the study to determine myocardial status.

(d) *Dedicated pediatric cardiac catheterization laboratory.* A laboratory which provides cardiac catheterization to only infants and children.

(e) *Intracardiac catheterization.* A procedure carried out in a cardiac catheterization laboratory in which a catheter is passed through the

blood vessels into the heart to measure multiple parameters of cardiac physiological activities and to obtain visualization of the cardiac chambers and great vessels.

(f) *Pediatric cardiac catheterization.* A procedure carried out in a cardiac catheterization laboratory in which a catheter is introduced into the heart of infants and children to reliably measure multiple parameters of cardiac physiological activity and to obtain visualization of the cardiac chambers and great vessels.

(2) NEED FOR SERVICES. (a) For the purposes of the cardiac catheterization standards, planning areas shall be coterminous with the health service areas designated pursuant to 42 USC 300 l. There shall be permitted at least one cardiac catheterization laboratory in each health service area. For the purposes of standards for dedicated pediatric cardiac catheterization services, the planning area shall be the entire state.

(b) The determination of the need for the establishment or expansion of cardiac catheterization services and the acquisition of cardiac catheterization equipment and facilities shall be based upon an evaluation of factors including, but not limited to, the applicant's demonstration of the following:

1. Projection of the annual number of cardiac catheterization candidates identified by referring physicians, facilities, and other sources. Projections shall be based upon relevant historical data and shall include the geographical origins of cardiac catheterization candidates by zip code or minor civil division.

2. Annual patient volume projections based upon the incidence of heart conditions for which cardiac catheterization has been scientifically accepted to be an effective and appropriate modality.

3. The assumptions made to arrive at the projection and the methodology used to calculate the projected number of adult and pediatric cardiac catheterization candidates. The assumptions, data and methodology used to arrive at the projection shall be provided in the application.

4. Documentation of where the population to be served has received cardiac catheterization services in the past 3 years.

5. A documented plan that the proposed cardiac catheterization service can be staffed and operated when completed.

(c) The location of a facility proposing to establish or expand cardiac catheterization services or acquire equipment relative to other facilities in the planning area shall be considered. If there are cardiac catheterization laboratories in the planning area, the impact of the proposal on the utilization and staffing of these programs shall be addressed. Patterns of patient migration, referrals between planning areas and other geographical areas, and birth rates shall also be considered.

(d) An applicant proposing to establish or expand cardiac catheterization services or to acquire cardiac catheterization equipment shall demonstrate that it will have a volume of cardiac catheterization candidates equal to, and the resource capability to perform a minimum of, 300 cases per year and that this rate will be attained within the first 3 years of operation. For dedicated pediatric cardiac catheterization units, there

shall be a minimum of 150 cases per year and it shall be demonstrated that this rate will be attained within the first 3 years of operation. Such demonstration shall conform to par. (b) of these standards.

(e) No cardiac catheterization laboratories shall be approved in any facility not performing open heart surgery unless there are cogent reasons for exemption from this standard.

(f) No new or additional cardiac catheterization laboratories shall be approved until each cardiac catheterization laboratory in the planning area is consistently performing a minimum of 500 intracardiac or coronary artery catheterizations annually.

Note: In the review of the resource capability and other features of cardiac catheterization services not covered in this rule, the department may consider up-to-date planning guidelines adopted by national professional and scientific organizations, Wisconsin health systems agencies, and the department of health, education and welfare in the review of applications to establish or expand cardiac catheterization services or to acquire cardiac catheterization equipment. Such guidelines may include those of the inter-society commission for heart disease resources, the American heart association, the Wisconsin chapter of the american college of cardiology, and the American academy of pediatrics.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.

H 3.70 Computed tomography services. The following standards shall be used by the department in the review of applications for the acquisition of computed tomography equipment.

(1) DEFINITIONS. (a) *Computed tomography equipment.* Diagnostic equipment which uses radiographic and computer techniques to produce cross-sectional images of the head and body. In this document all computed tomography equipment will be referred to as CT. When specifically a head or body scanner is under consideration, it will be so stated.

(b) *Enhancement.* Alteration of coefficients of absorption by administration of contrast media.

(c) *Scan.* The series of images (slices) necessary for CT diagnosis of one anatomical area. Tabulation of scans for CT utilization data:

1. An unenhanced scan shall count as one scan.

2. An enhanced scan shall count as one scan.

3. An unenhanced scan, followed by an enhanced scan, shall count as 2 scans.

(2) NEED FOR SERVICES. (a) For purposes of reviewing proposed applications for the acquisition of computed tomography equipment, planning areas shall be coterminous with health service areas.

(b) Utilization. 1. The quantitative demonstration of projected utilization shall include, but not be limited to, the following:

a. A description of the assumptions and methodology used to calculate the utilization projections.

b. Annual utilization projections based upon relevant historical data, physician referral and practice patterns (including the geographical origin of CT candidates by county or zip code), and the incidence of pathologic conditions or disease in the population for which CT is medically indicated.

c. The application shall contain a list of the active medical staff of the facility indicating medical specialty of each physician and other hospitals where the physician has staff privileges.

d. Documentation of where the CT patient population to be served received CT diagnostic services in the past or the modalities used to provide diagnostic services in lieu of CT.

e. A description of the proposed services' impact on the utilization of similar or alternate services in the planning area or adjacent planning areas.

2. Projected utilization volumes of the proposed CT scanner shall be evaluated by the department. Such evaluation shall include, but not be limited to, the following considerations:

a. Utilization rates of existing operational scanners in the state based upon the number of admissions and inpatient CT procedures, the number of outpatient visits and outpatient CT procedures, the number of emergency room visits and the number of emergency CT procedures.

b. The total resource capability and activity volumes of other facilities with CT.

c. The diagnostic radiology resource capability and activity volume (i.e., radioisotope brain studies, cerebral angiograms, abdominal angiograms, etc.) of other facilities in the state with CT.

d. The number, specialty, and inpatient activity of the active medical staff especially in the neurosciences and oncology related specialties. The number of patients diagnosed as stroke, dementia, intracranial trauma, tumors or other neurologic abnormalities, plus the number of intracranial surgeries will be compared plus the number of new cancer patients seen yearly and the cancer patients in follow-up.

3. Acquisition of additional computed tomography equipment shall not be approved unless each existing approved CT scanner in the planning area has been in operation for one year and is performing a minimum of 2,500 procedures (scans) per year. A determination of full utilization may be adjusted upon consideration of additional factors such as, but not limited to:

a. Technological capabilities of existing CT units including scan time, type of equipment, possible updates and age of equipment.

b. Patient mix (inpatient, outpatient, pediatric, aged, etc.)

c. Mix of procedures performed (percent head scans vs. body scans).

d. Hours of operation per day.

e. Number of emergency cases for immediate treatment.

f. Existing patient backlogs.

g. Availability for fully staffed, 24-hour emergency services with anesthesiology and surgery back-up appropriate for immediate treatment of CT diagnosis when necessary.

h. Procedures performed by non-approved CT facilities.

i. The research use of CT units at medical school facilities shall be recognized as reducing the clinical capacity of these installations when evaluating their utilization.

4. A facility proposing to acquire a CT scanner shall provide evidence that it will perform 1,600 scans the first year of operation, 2,000 the second year and 2,500 every year thereafter.

(c) Additional technological enhancement, if reviewable, shall be approved only after demonstrating cost effectiveness or increased quality of care.

(3) RELATIONSHIP TO EXISTING HEALTH CARE SYSTEM. To ensure a maximum potential for sharing of a CT scanner with other facilities within a health service area, a facility proposing to acquire a CT scanner shall provide evidence of cooperative agreements for utilization of the proposed equipment including, but not limited to:

(a) Multiple facility application.

(b) Letters of support from referring physicians, clinics, and other acute care facilities indicating a commitment to make referrals to the proposed CT scanner site.

(c) A detailed plan of the proposed methods by which these referrals are to be accommodated including at least:

1. Administrative procedures to ensure equitable access to non-facility patients.

2. Methods to be used in transportation of patients.

3. The prompt reporting of CT results to referring physicians according to standard medical practice.

4. A willingness and ability, when necessary, to operate beyond a regularly scheduled day.

(4) RESOURCE AVAILABILITY. (a) *Staffing resources.* A facility proposing to acquire a CT unit shall:

1. Provide full-time (24 hours/day, 7 days/week) coverage of the unit by physicians trained in the interpretation of CT images.

2. Have at least 2 physicians trained and certified in radiology, who are proficient in CT interpretation.

3. Provide adequate numbers of registered or licensed radiological technologists trained in CT operation who will be assigned full-time to the CT unit.

(b) *Technical resources.* 1. An applicant proposing to acquire a CT scanner shall provide evidence that it is now providing in its facility or in a contiguous facility a broad spectrum of imaging modalities and special procedures which complement CT scanning, including but not limited to, angiography, lymphangiography, ultra-sound and nuclear medicine imaging, and 40,000 inpatient and outpatient (report separately) radiographic procedures (including fluoroscopy).

2. A facility proposing to acquire a CT scanner shall have an active neurological and neurosurgical service providing a wide range of diagnostic and surgical capabilities.

3. A facility proposing to acquire a CT body scanner shall demonstrate an active comprehensive diagnostic and treatment service for cancer.

4. Additional and appropriate consideration shall be given to facilities which offer other services which have implications for CT utilization including, but not limited to, internal medicine, urology, gastroenterology, thoracic surgery, oncology, and ophthalmology.

5. In the case of 2 facilities proposing to acquire CT which have equal resources, additional consideration shall be given to the facility which has:

a. The capability of treating most of the conditions diagnosed by CT procedures or the ready accessibility to such therapeutic capabilities.

b. The availability of a fully staffed, 24-hour emergency service with anesthesiology and surgery back-up appropriate for immediate treatment of CT diagnoses when necessary.

c. Demonstrated greater geographic accessibility.

(5) QUALITY ASSURANCE. The applicant shall submit a plan to establish a formal ongoing utilization review program.

(6) FINANCIAL FEASIBILITY. (a) An applicant proposing to obtain a CT scanner shall demonstrate the financial feasibility of the project, including a description of the following:

1. The total capital expenditure required for the acquisition of the CT scanner, including planning, space acquisition, lease, renovation, and installation costs.

2. The method and source of financing including interest and other costs related to the total projected utilization period.

3. Direct costs including:

Depreciation
Interest
Paraprofessionals
Clerical
Professionals (M.D., Ph.D.)
Supplies
Maintenance (repair)
Installation Amortization
Maintenance Agreement after Warranty
Lease

4. Indirect costs including those relating to space (physical plant), management support, and other relevant overhead costs.

5. Provision for the establishment of separate accounting of costs of the proposed CT scanning operation.

6. The projected non-professional and professional charges for:

a. An unenhanced scan.

b. An enhanced scan without an unenhanced scan.

c. An unehanced scan followed by an enhanced scan.

7. The projected number of scans to be performed annually.

(b) The proposed patient charges shall be based on the projected annual utilization of the CT service. Direct costs, indirect costs, rates, etc., are to be annualized and provided in the application over a 3-year projected utilization period. The amortization period for CT shall not be less than 5 years using a straight line method.

(c) The department's analysis of the financial feasibility of a proposal to acquire CT shall include consideration of at least the following:

1. Charges due to the direct costs associated with providing the service.

2. Charges due to the indirect costs associated with providing the service.

3. Debt capacity of the facility.

4. Economies of scale.

5. Current rate structure.

(7) COST CONTAINMENT. The applicant shall demonstrate that the proposed project fosters cost containment and improves the quality of care. The CT scanner shall be treated as a cost center in the facilities accounting system. The applicant shall provide a plan for amendment of the accounting system so that the CT services can be financially partialed out of the entire accounting system. The demonstration of cost containment shall address the following:

(a) Savings or losses for distance traveled, work time, convenience and other non-medical factors affecting patients.

(b) Projected savings due to the elimination of other tests by the use of CT.

(c) The cost impact of utilization, geographic locations, and relationship of the proposed CT scanners on existing approved scanners in the service area and state.

(8) DATA REPORTING REQUIREMENTS. Applicants proposing to obtain computed tomography equipment shall agree to provide the department and health systems agencies with data relating to numbers, types, operating costs, patient origin, and other pertinent demographic and diagnostic information upon request (but not more often than semi-annually) or at such time that current data are required for the review of a proposal to establish additional CT capabilities within the health planning area.

History: Cr. Register, June, 1978, No. 270, eff. 7-1-78.