Chapter HSS 123

CAPITAL EXPENDITURE REVIEW FOR HOSPITALS, OTHER ACUTE CARE FACILITIES AND HOME HEALTH AGENCIES

Note: Chapter HSS 123 was created as an emergency rule effective January 1, 1984.

HSS 123.01 Authority and purpose. This chapter is promulgated under the authority of s. 150.03, Stats., to implement subchs. I and III of ch. 150, Stats. Its purpose is to provide definitions, standards and procedures to be used by the department to implement the capital expenditure review program for hospitals, ambulatory surgery centers and other acute health care facilities, and for home health agencies, established by subch. III of ch. 150, Stats. That program is primarily directed at containment of health care costs, but also seeks to promote orderly and cost-effective development of efficient health facilities and services and to prevent unwarranted expansion or replacement in the health care industry. The department recognizes that the scaling down of hospital operations, development of alternatives for excess bed capacity, conversion of services from inpatient to outpatient and the enhancement of price competition both among hospitals and between hospitals and health care providers not regulated by the department are ways in which cost containment may be achieved.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.02 Applicability. (1) This chapter applies to any application declared complete by the department on or after the effective date of this chapter. Interim rules adopted under s. 2020 (11) (b) of 1983 Wisconsin Act 27 apply to projects declared complete prior to April 1, 1985.

(2) This chapter applies to any person who proposes to:

(a) Obligate for a capital expenditure, by or on behalf of a hospital, that exceeds either of the following limits, as adjusted by the department under s. 150.15, Stats., and s. HSS 123.04 (3);

1. $1,000,000; or

2. $1,500,000 in either of the following situations:

a. The project is limited to the conversion to a new use of part or all of an existing hospital building; or

b. The project is limited to the renovation of an existing hospital building. This subparagraph does not apply to new construction or building additions;

(b) Before July 1, 1986, undertake a substantial change in a health service;

(bm) On or after July 1, 1986, implement an organ transplant program, burn center, neonatal instensive care program, cardiac program or air transport services, or add psychiatric or chemical dependency beds;

(c) Obligate for an expenditure, by or on behalf of a hospital, independent practitioner, partnership, unincorporated medical group or service corporation for clinical medical equipment that exceeds $1,000,000, as adjusted by the department under s. 150.15, Stats., and s. HSS 123.04 (3);

(d) Purchase or otherwise acquire a hospital;

(e) Add to a hospital's approved bed capacity; or

(f) Construct or operate an ambulatory surgery center or a home health agency.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; correction in (1) made under s. 13.93 (2m) (b) 14, Stats., Register, March, 1986, No. 363; am. (2), Register, Janury, 1987, No. 373, eff. 2-1-87.

HSS 123.03 Definitions. In this chapter:

(1) "Acquire" means to gain ownership but does not include consolidation or merger of 2 or more corporations each of which owns a currently approved and operating hospital if the consolidation or merger is without consideration. In this subsection, "consideration" means something of value given or promised that has the effect of making an agreement a legally enforceable contract.

(2) "Affected party" means the applicant, a health systems agency or other local planning agency, a governmental agency, another person providing similar services in the applicant's service area, the public to be served by the proposed project, a 3rd-party payer or any other person who the department determines is affected by an application for approval of a project.

(3) "Annual survey of hospitals" means the survey conducted every year by the department of health and social services to collect information from all Wisconsin hospitals.

(4) "Application" means the document submitted by an applicant to the department for the purpose of obtaining approval of a project.

(5) "Approval" means a written statement from the department authorizing a person to commence implementing a project under review.

(6) "Approved bed capacity" means a hospital's bed count collected and verified by the department and by the hospital under s. HSS 123.30.

(7) "Branch office" means a location or site from which a home health agency provides services within a portion of the total geographic area served by the home health agency.

(8) "Capital expenditure" means an expenditure by or on behalf of a hospital that under generally accepted accounting principles is not properly chargeable as an expense of operations or maintenance. "Capital expenditure" does not include an expenditure relating to maintenance, housekeeping or general administration if made on behalf of one or more hospitals by a person other than a hospital.

(9) "Chemical dependency service" means an organized service for the provision of medical care and rehabilitative treatment, usually of 21 to 28 days in duration, for patients dependent on alcohol or other drugs or both alcohol and other drugs.

(10) "Clinical medical equipment" means any equipment which performs functions or tests directly on a patient, including every piece, component or appurtenance which facilitates functioning of the equipment or sharing of the equipment among users.

(11) "Clinically efficacious" means that the technology has been demonstrated to have the effect it purports to have or is represented to have under the conditions of use prescribed on the basis of well-controlled investigations, including clinical investigations, by experts qualified by training and experience to evaluate the effectiveness of the device.

(12) "Cost-effective" means the solution that achieves the intended result at the lowest cost or a cost lower than any alternative solution.

(13) "Cost overrun" means an obligation exceeding the maximum capital expenditure authorized by an approval.

(14) "Department" means the department of health and social services.

(15) "Dollar threshold" means the minimum capital expenditure amount or minimum amount of operating revenue which is subject to review under this chapter.

(16) "Emergency situation that threatens patient safety" means a situation, physical condition, practice, method or operation that presents an imminent danger of death or of severe physical or mental harm to any patient in a hospital.

(17) "Expected length of stay" means the statewide average length of stay of a patient in a hospital adjusted for diagnostic related groups as established under PL 98-21, 601 to 607.

(17m) "Financing sufficient to complete the project" means that the funds are available to the approval holder in an amount sufficient to complete the project.

(18) "Functional program" means the evaluation of services and workloads to determine the methods of meeting institutional objectives,

as defined by the committee on architecture for health of the American institute of architects.

(19) "Functional space program" means a functional program translated into facility space requirements to provide the basis for architectural design, including a tabulation of every room or area, with its designated function and the area needed to perform that function, as defined by the committee on architecture for health, American institute of architects.

(20) "General hospital" means a hospital that provides many types of medical and surgical care.

(21) "Generally accepted accounting principles" means uniform rules, procedures, methods and standards set by organizations such as the financial accounting standards board and which accountants employ in recording and reporting financial information.

(22) "Health planning area" means one of the areas of the state designated pursuant to 42 USC 300L for health planning purposes, with boundaries as specified in appendix A.

(23) "Health systems agency" or "HSA" means the agency responsible for local health planning under 42 USC 300L.

(24) "Hospital" has the meaning specified in s. 50.33 (1), Stats., but excludes facilities exempted under s. 50.39 (3), Stats., and includes all corporations and other persons who have been issued a certificate of approval under s. 50.35, Stats., to operate the hospital.

(25) "Hospital discharge survey" means the study conducted periodically by the department to collect information on patients discharged from Wisconsin hospitals.

(26) "Innovative medical technology" means equipment or procedures that are potentially useful for diagnostic or therapeutic purposes and that introduce new technology in the diagnosis and treatment of disease, illness or injury.

(27) "Inpatient psychiatric services" means services provided to patients who are admitted to institutions for the evaluation, diagnosis, and treatment of mental, emotional or behavioral disorders.

(28) "Life cycle cost" means all relevant costs associated with a project during the length of time over which alternatives are compared.

(29) "Long-term" means an average length of stay for the service of more than 30 days.

(30) "Market share population" means the ratio of the number of patients from a geographic area who are hospitalized in a particular hospital or group of hospitals to the total number of patients hospitalized from the area multiplied by the total population in the area, with the number representing the "market share population" for an area published in the state medical facilities plan (SMFP).

(31) "Material change in project scope" means the inclusion of services which were not in the application, or a significant change in the project which has a significant financial impact on the project.

(32) "Metropolitan statistical area" or "MSA" means a county or multi-county area which is designated as a large population area for statistical reporting purposes by the U.S. office of management and budget.

(33) "Natural disaster" means a flood, ice storm, tornado, severe windstorm, mudslide or other act of destruction resulting from weather or geologic conditions beyond the control of the applicant.

(34) "Obligation" means any enforceable contract that is entered into for the construction, leasing, acquisition or permanent financing of a capital asset.

(36) "Person" means any individual, partnership, association or corporation, the state, a political subdivision or agency of the state or of a local unit of government or any other entity included under s. 990.01 (26), Stats.

(37) "Person other than a hospital" means a corporation or other person which is not wholly or substantially owned or otherwise controlled by a corporation or other person which wholly or substantially owns or otherwise controls a hospital.

(38) "Project" means the proposed service, unit, expenditure or activity subject to review under s. HSS 123.04 (1).

(39) "Rate established in the approval" means the increased cost to the hospital of operating the approved project and the effect of these costs on the overall hospital rate, overall hospital financial requirements and individual hospital charge elements, as stated in the approval.

(40) "Rate-setting authority" means the body authorized under ch. 54, Stats., which reviews and approves non-government increases in hospital rates.

(41) "Secretary" means the secretary of the department of health and social services.

(42) "Service" means any functional division of a hospital through which care to patients is provided.

(43) "Service area" means an area within the state established by the department for the collection, organization and analysis of information to determine the availability of health care resources and need for specified types of facilities and services and to serve as a basis for planning for these facilities and services.

(a) "Acute care service area" or "ACSA" means a service area designated in the state medical facilities plan (SMFP) for medical/surgical, pediatrics, obstetrics, and intensive care unit/cardiac care unit (ICU/CUU) services.

(b) "Chemical dependency service area" means a service area designated in the SMFP for patients receiving chemical dependency rehabilitation services.

(c) "Psychiatric service area" means a service area designated in the SMFP for patients receiving organized psychiatric services.

(44) "Short-term" means an average length of stay for the service of 30 days or less.

(45) "Special hospital" means a hospital that provides primarily one type of medical or surgical care.

Note: Examples of special hospitals are psychiatric hospitals, chemical dependency hospitals and rehabilitation hospitals.

(46) "Service corporation" has the meaning prescribed in s. 180.99, Stats.

(47) "State medical facilities plan" or "SMFP" means the document adopted by the department pursuant to s. 150.83, Stats.

(48) "Substantial and continuing progress" has the meaning specified in s. 150.02 (20), Stats., namely, spending more than 20% of a project's approved cost, including fees for legal services, planning studies, financing, consultants, inspections, permits, architectural services and interest during construction.

(49) "Substantial change in a health service" means the addition of a service or unit or the expansion of an existing service or unit by or on behalf of a hospital, resulting in annual operating revenues exceeding $250,000, as adjusted by the department under s. 150.15, Stats., and s. HSS 123.04 (3).

(50) "Unit" means an area within a hospital dedicated to the provision of a specific service.

(51) "Working day" has the meaning prescribed in s. 227.01 (14), Stats.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; cr. (17m), r. (35), am. (40), Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.04 Projects subject to approval by the department. (1) TYPES OF PROJECTS. Except as provided under ss. HSS 123.045 and 123.05, no person may do any of the following without first obtaining the department's approval of the action as a project:

(a) Obligate for a capital expenditure, by or on behalf of a hospital, that exceeds either of the following limits, as adjusted by the department under s. 150.15, Stats., and sub. (3):

1. $1,000,000; or

2. $1,500,000 in either of the following situations:

a. The project is limited to the conversion to a new use of part or all of an existing hospital building; or

b. The project is limited to the renovation of an existing hospital building. This subparagraph does not apply to new construction or building additions;

(b) Before July 1, 1986, undertake a substantial change in health service;

(bm) On or after July 1, 1986, implement an organ transplant program, burn center, neonatal intensive care program, cardiac program or air transport services, or add psychiatric or chemical dependency beds;

(c) Obligate for an expenditure, by or on behalf of a hospital, independent practitioner, partnership, unincorporated medical group or service

corporation, for clinical medical equipment that exceeds $1,000,000, as adjusted by the department under s. 150.15, Stats., and sub. (3);

(d) Purchase or otherwise acquire a hospital;

(e) Add to a hospital's approved bed capacity; or

(f) Construct or operate an ambulatory surgery center or a home health agency.

(2) CLARIFICATION OF PROJECTS SUBJECT TO APPROVAL. (a) An obligation is made and any other action undertaken by or on behalf of a hospital, independent practitioner, partnership, unincorporated medical group or service corporation if:

1. Any part of the cost associated with the obligation or other action is or can be chargeable to the hospital, independent practitioner, partnership, unincorporated medical group or service corporation;

2. It would transfer performance of health-related or ancillary services previously performed by the hospital to a separate corportation, if total charges to the patients of the hospital could increase; or

3. It would result in a service, program or facility represented to the public as "affiliated with" or "sponsored by" the hospital.

(b) If an expenditure under sub. (1) (a) or (c) is made by or on behalf of more than one hospital, independent practitioner, partnership, unincorporated medical group or service corporation, the amount of the expenditure may not be apportioned among the users in determining the applicability of this chapter.

(c) If a service or unit is added by or on behalf of more than one hospital, the resulting increase in annual operating revenues for all hospitals shall be aggregated in determining the applicability of this chapter pursuant to sub. (1) (b).

(d) Any person who proposes to obligate for an expenditure exceeding $600,000 for clinical medical equipment to be located part-time or full-time in this state is presumed to do so on behalf of a hospital, independent practitioner, unincorporated medical group or service corporation.

(e) Subsection (1) (f) includes establishment of a branch office in any county which is not listed on a home health agency's license under s. 141.15, Stats., and ch. HSS 133, or approval under this chapter, or expansion of services into a county not listed on a home health agency's license under s. 141.15, Stats., and ch. HSS 133 or approval under this chapter.

(f) In regard to the reviewable services under sub. (1) (bm) and s. HSS 123.02 (2) (bm):

1. "Implement" has the meaning set forth for the addition of a service or unit under sub. (4) (a) 4;

2. Cardiac program includes a cardiac catheterization service as defined in s. HSS 123.15 (2) (f) and a cardiac surgery service as defined in s. HSS 123.15 (2) (i);

3. A neonatal intensive care program includes a neonatal intensive care unit and a perinatal care center as defined in s. HSS 123.16 (2) (f) and (i);

4. An organ transplant program includes any program to transplant human, animal or artificial organs but does not include programs to transplant skin or corneas or the human heart transplant program located at St. Luke's hospital in Milwaukee on the effective date of this rule;

5. Air transport services include air ambulance services as defined in s. HSS 123.20; and

6. To implement air transport services includes putting into service one or more additional air ambulances as defined in s. HSS 123.20, by or on behalf of an entity already operating an air ambulance.

(3) ANNUAL ADJUSTMENT OF DOLLAR THRESHOLDS. (a) The department shall annually adjust the dollar thresholds under sub. (1) (a) and (c), and for review of a substantial change in health service under sub. (1) (b), to reflect change in the composite construction cost index published by the U.S. department of commerce. The adjustments shall be based upon change in the index from July 1 of the previous year through June 30 of the year in which the adjustments are made.

(b) The department shall annually report the new dollar thresholds calculated under par. (a) to the legislature's joint finance committee, beginning on December 1, 1984. Unless the department is otherwise advised by the joint finance committee, the threshold adjustments shall take effect on January 1 of the year following the year in which the report is made. The department shall publish the dollar threshold adjustments in the Wisconsin administrative register.

(4) SUBSTANTIAL CHANGE IN A HEALTH SERVICE. (a) *Addition of a service or unit.* 1. When a new service or unit is added, substantial change in service is change that is expected to result in annual operating revenues exceeding $250,000.

2. A new service or unit is one which was not offered by or on behalf of the hospital prior to July 1, 1983.

3. The determination of whether annual operating revenues will exceed $250,000 shall be made by projecting total patient revenues to include all applicable room charges and all ancillary charges for the highest number of projected days anticipated for the service for any 12-month period after the addition or expansion of a health service or unit. In this subdivision, "ancillary charges" means non-patient room charges such as operating room, laboratory, radiology, EKG, medical supplies and pharmacy.

4. The addition of a service or unit includes:

a. The establishment of a separate and distinct service or unit for patients formerly treated in other services or units;

b. Holding oneself out through acknowledgement, advertising or promotion as providing a service or having a unit;

c. Providing the service or establishing a unit to treat patients previously cared for through a formal contractual arrangement with another hospital or provider; and

d. Providing care in a service or unit in which care had not been provided over the past 12 months.

(b) *Expansion of an existing service or unit.* 1. When an existing service or unit is expanded, substantial change in service is change that is expected to result in additional annual operating revenues exceeding $250,000.

2. An existing service or unit is a service or unit that has been approved by the department or one that is exempt from approval by the department.

a. Expansion of an existing service or unit means changing the scope or adding to the capacity of the service or unit. Expansion of an existing service or unit does not include increasing charges or utilization without changing the scope or adding to the capacity.

b. A change in scope includes going from one recognized level of service to a higher level of service.

c. Adding to the capacity of a service or unit includes adding to ancillary services for the purposes of expanding an existing service or unit.

d. The determination of whether additional annual operating revenues will exceed $250,000 shall be made by projecting total patient revenues under par. (a) 3. and subtracting from that amount the total patient revenues calculated for the service or unit being expanded for the most recent fiscal year.

(c) *Revenues generated by the service.* Any revenues generated by the service or unit shall be attributed to the service or unit regardless of the cost center to which the facility assigns them.

(d) *Volume measures.* New services that experience utilization in excess of the following are presumed to result in annual operating revenues exceeding $250,000:

a. 280 cardiac catheterizations a year;

b. 720 computed tomography scans a year;

c. 1,500 dialysis procedures a year;

d. 250 intensive or cardiac care unit patient days a year;

e. 350 neonatal intensive care patient days a year;

f. 1,000 invasive diagnostic radiology procedures for each machine each year;

g. 4,200 noninvasive diagnostic radiology procedures for each machine each year;

h. 25 open heart surgery cases a year;

i. 550 radiation therapy treatments a year;

j. 10 kidney transplants a year; or

k. 3 other organ transplants a year.

(5) ACQUISITIONS THROUGH DONATION OR LEASING. No person may acquire equipment or a facility by means of donation, lease or any other arrangement without first obtaining the department's approval if the equipment or facility would have been subject to review under ch. 150,

Stats., and this chapter if purchased at fair market value. The person acquiring the facility or equipment is responsible for satisfying the requirements of ch. 150, Stats., and this chapter.

(6) SUBDIVISION OF A PROJECT. (a) *Division of a project into components.* A project otherwise subject to the provisions of ch. 150, Stats., may not be subdivided into parts which, when analyzed separately, are not subject to review under ch. 150, Stats.

(b) *Division of a project between persons.* A project undertaken by more than one person shall constitute a single consolidated project for the purpose of determining reviewability under s. 150.61, Stats., regardless of the particular form of the contractual arrangement between the persons.

(c) *Division of a project over time.* Transactions separated by 5 years or less that are components of an overall plan for meeting patient care objectives are part of one project. Components of an overall plan for meeting patient care objectives include equipment and other capital items to be used together in a single indentifiable service or unit within a facility.

(d) *Related pieces of equipment.* Two or more pieces of clinical equipment that perform their normal functions only when used together shall constitute a single piece of equipment for the purpose of determining reviewability under s. 150.61, Stats., and this section.

(7) PROJECT INITIATED WITHOUT DEPARTMENTAL APPROVAL. (a) No person may recover through charges or rates any depreciation, interest or principal payments or any operating expenses associated with a project or part of a project subject to this chapter that does not have the department's approval, including unapproved parts of a project which was subdivided as described in sub. (6).

(b) If a project with costs expected to fall below the dollar thresholds for reviewability subsequently incurs costs or generates revenues exceeding a dollar threshold, the person who operates the project shall submit an application to the department for approval of the project no later than one year after the threshold was exceeded.

(8) MONITORING. The department shall monitor activities covered by ch. 150 to ensure compliance with the statute. Existing data sources shall be utilized to the extent possible.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; am. (1) and cr. (2) (f), Register, January 1987, No. 373, eff. 2-1-87; emerg. am. (2) (f) 4., eff. 6-10-87.

HSS 123.045 Exemptions from capital expenditure review. (1) DEFINITIONS. In this section:

(a) "Computer system" means an electronic information-collecting system used for management or record-keeping purposes but does not include any system dedicated to clinical applications.

(b) "Energy conservation" means efforts undertaken by a hospital which increase efficiency of energy usage to reduce overall energy consumption by the hospital.

(c) "Hospital gross annual patient revenue" means the sum of all charges established by the rate-setting authority and levied by a hospital for all hospital inpatient and outpatient medical services.

(d) "Nonsurgical outpatient services" means all medical services, excluding operative procedures, provided on an outpatient basis.

(2) Except as provided in sub. (4), a capital expenditure by or on behalf of a hospital is exempt from review under this chapter if the expenditure is for one or more of the following purposes:

(a) A computer system;

(b) An electrical system;

(c) Energy conservation;

(d) Heating, ventilation or air conditioning;

(e) Nonsurgical outpatient services; or

(f) Telecommunications.

(3) A capital expenditure for one of the purposes listed under sub. (2) may include incidental removal and restoration of building components, such as walls, ceilings and floors, necessary for achieving the purpose.

(4) A capital expenditure is not exempt from review under sub. (2) if any of the following apply:

(a) The capital expenditure would exceed 20% of the hospital's gross annual patient revenue for its last fiscal year;

(b) The capital expenditure is for a related component of the project where the total capital expenditure for the project exceeds the applicable threshold;

(c) The capital expenditure is divided into non-reviewable parts in violation of s. HSS 123.04 (6), and the total undivided capital expenditure requires review under par. (a) or (b); or

(d) The capital expenditure is for clinical medical equipment, regardless of whether that equipment is used in whole or in part in connection with nonsurgical outpatient services.

History: Cr. Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.05 Innovative medical technology. (1) ACQUISITION. The department shall not accept an application to acquire any of the innovative medical technologies listed in sub. (3) (a), nor shall the department approve an application to acquire any technology determined under sub. (3) (c) to be an innovative medical technology.

(2) RECOVERY OF EXPENSES. Persons who acquire innovative medical technology, including persons who were granted exemptions for innovative technology pursuant to s. 150.63, Stats., may recover capital expenses only upon approval of an application under s. HSS 123.08, and may recover operating expenses only after the innovative medical technology has been approved by the U.S. food and drug administration for safety and efficacy and a 3rd-party payer agrees to pay for these expenses.

(3) INNOVATIVE TECHNOLOGIES. (a) The department finds that the following are innovative medical technologies:

1. Transplantation of artificial organs other than those approved by the U.S. food and drug administration for safety and efficacy;

2. Transplantation of animal organs; and

3. Transplantation of human organs other than skin, cornea and kidney, and the organs specified in s. HSS 123.26.

(b) For consideration of an addition to or deletion from the list of innovative medical technologies in par. (a), interested persons may petition the department under s. 227.12, Stats., to make the change through rulemaking.

(c) The department may also declare equipment or a procedure to be an innovative medical technology following receipt of a request for determination of reviewability under s. HSS 123.06 or after having received a notice of intent under s. HSS 123.08 (3), if the proposed equipment or procedure:

1. Has not been proven safe;

2. Has not been proven clinically efficacious;

3. Has not been proven cost-effective;

4. Has not been proven appropriate for a clinical setting;

5. Is being assessed by the federal office of technology assessment; or

6. Is the first generation of a technology that is likely to undergo rapid change and improvement.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; r. (6) (a) 1. and 2. and (d), Register, March, 1986, No. 363, eff. 4-1-86; renum. (6) (a) 3. and 4. to 1. and 2. under s. 13.93 (2m) (b) 1, Stats., Register, March, 1986, No. 363; r. and recr. Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.06 Determination of reviewability. (1) REQUEST FOR DETERMINATION. (a) Any potential applicant or an affected HSA may request that the department make a determination concerning the reviewability of a project. The purpose of the request is to ascertain whether the project is reviewable under ch. 150, Stats.

Note: The request should be submitted to the Bureau of Planning and Development, P.O. Box 1808, Madison, Wisconsin 53701.

(b) The request shall be in writing and shall include a brief description of the project, the estimated capital expenditure, the estimated annual operating revenue to be generated by the proposed project, and the name of an authorized representative of the applicant.

(c) The department may ask for additional information of the person submitting the request before issuing a determination. A request is not complete until the additional information is received by the department.

(2) ISSUANCE OF DETERMINATION. (a) The department shall issue a written determination of reviewability which states whether the project is reviewable under ch. 150, Stats., within 30 days following receipt of a request for a determination unless the department has requested information within 30 days of receipt of the request for a determination or has asked the potential applicant or affected HSA for a 30-day extension. When additional information or an extension has been requested, the determination shall be issued within 30 days following the department's

receipt of additional information or 30 days following the date on which the extension was granted. If the department fails to issue a written determination within 30 days, the project shall be considered nonreviewable.

(b) The department's determination of reviewability is neither a declaratory ruling within the meaning of s. 227.41, Stats., nor a final decision within the meaning of s. 227.47, Stats. The determination of reviewability is binding upon the department and the person submitting the request unless:

1. Section HSS 123.08 (8) is applicable; or

2. The affected HSA or potential applicant requests a declaratory ruling under sub. (3).

(3) APPEAL. The exclusive means of review of a determination under this section is by petition for declaratory ruling under s. 227.41, Stats. Notwithstanding s. 227.41 (1) and (4), Stats., the department shall issue a declaratory ruling in response to each petition under this section.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.08 Review process. (1) PROCEDURES AND CRITERIA. Projects shall be reviewed in accordance with the process established under ss. 150.65 to 150.71, Stats., and this section, the review criteria in s. 150.69, Stats., and s. HSS 123.13, the applicable service-specific criteria in ss. HSS 123.14 to 123.22 and the state medical facilities plan.

(2) NONACCEPTABILITY OF APPLICATIONS. The department may not accept any application under this chapter:

(a) For the addition of hospital beds that would exceed the total number of beds authorized by the state medical facilities plan for the service area where the project would be located;

(b) For a capital expenditure, by or on behalf of a hospital, to establish a new hospital or to totally relocate a hospital. This paragraph does not prohibit accepting an application to totally relocate a hospital as a result of either of the following:

1. The consolidation or merger of 2 or more corporations, each of which owns a currently approved and operating hospital; or

2. The consolidation of hospital services between 2 or more currently approved and operating hospitals, at least one of which is owned by a governmental unit; or

(c) To obligate for a capital expenditure to acquire specific equipment or procedures described in s. 150.63, Stats., and s. HSS 123.05 (3).

(3) NOTIFICATION OF INTENT. (a) Any person intending to submit an application for approval of a project shall submit a notice of intent to the department and the HSA on a form prescribed by the department prior to the submission of the application.

(b) The form shall include the name and address of the applicant, the anticipated date for the obligation or initiation of the project, the estimated cost of the project and a brief narrative describing the scope and purpose of the project.

(c) Prior to sending out an application form, the department or the HSA may schedule a meeting with the potential applicant to discuss the project.

(d) There shall be a 30-day waiting period between the submission of the notice of intent and the submission of an application.

(e) A notice of intent is valid for one year after receipt by the department. If after one year a complete application has not been received, the applicant shall submit a new notice of intent before submitting an application.

Note: Notice of intent forms may be obtained from the local health systems agency or, if no HSA exists in the area, from the Bureau of Planning and Development, P.O. Box 1808, Madison, Wisconsin 53701. Completed applications should be sent to the same address.

(4) SUBMISSION OF AN APPLICATION. (a) *Forms and reviewers.* Applications shall be submitted to the department and HSA on forms provided by the department. Additional questions may be included as the department and HSA determine necessary for the review of an application. The forms shall be sent to the applicant by the HSA, or by the department if no HSA exists, within 10 working days after receipt of the notice of intent. Forms may also be sent to other health care providers for the purpose of concurrent review as specified in sub. (10). Applications from projects proposing to serve persons in more than one health planning area may be reviewed by all involved HSAs. The HSA in which a project will be serving most of the persons shall act as the lead agency with the other HSAs submitting comments to the lead agency. The applicant shall send materials to all involved HSAs.

Note: Application forms may be obtained from the local health systems agency or, if no HSA exists in the area, from the Bureau of Planning and Development, P.O. Box 1808, Madison, Wisconsin 53701. Completed applications should be sent to the same address.

Upon written request, the department will provide technical assistance to any small business, as defined in s. 227.16 (1) (a), Stats., or other small organization with fewer than 25 full-time employes or annual revenues of less than $2,500,000 regarding application materials and procedures. Requests should be sent to the same address.

(b) *Waiting period.* The department and the HSA shall not accept an application until the notice of intent waiting period under sub. (3) (d) has elapsed.

(c) *Review for completeness.* On receipt of an application, the department and all HSAs involved shall review the application for completeness. An application may not be considered complete unless:

1. The application form and any additional questions are completed to the satisfaction of the department. Additional questions may be asked or additional information sought of the applicant prior to a determination of completeness;

2. The application fee has been received. The fee shall be equal to .37% of the estimated project cost, but not less than $1,850 and not more than $37,000;

3. When the applicant is a hospital, the department has on file a current capital budget report which meets the reporting requirements of s. HSS 123.29; and

4. When the applicant is a hospital, the applicant has furnished the department with an affidavit of mailing as proof that it has submitted the application to the rate-setting authority.

(d) *Fee refund.* The department shall refund the application fee if requested within 10 working days after receipt of the application is declared complete unless a determination of nonreviewability has been made under sub. (8). Fees may only be refunded as provided in this paragraph.

(e) *Notice of incompleteness.* If the department, upon conferring with the HSA and rate-setting authority, determines that any applicable item on the application form or additional question has not been adequately answered, the application is incomplete. Within 10 working days of receipt of all application materials, the department shall mail to the applicant a notice of incomplete application. The notice shall state which items were determined incomplete and the basis for that determination. If the department fails to give this notice, the application shall be deemed complete as of the date the department received the last application materials.

(5) COMPLETE APPLICATION NOTIFICATION. On or before the 10th day of the month following the receipt of a complete application, the department shall send a notice of receipt of a complete application to the applicant and publish the notice in a daily newspaper of general circulation that serves the area where the proposed project would be located.

(6) PUBLIC MEETING AND HSA RECOMMENDATION. (a) At the request of any affected party, the appropriate HSA, or the department if no HSA exists in the area, shall hold a public meeting at which all affected parties may present testimony regarding the review of projects seeking approval. A public meeting request shall be made to the local HSA or, in an area where no HSA exists, to the department no later than 10 days from the date of notification under sub. (5). An HSA, as an affected party, may hold a public meeting on a project seeking approval without the request of another affected party. If a request for a public meeting is made by an affected party in an area where no HSA exists, the department shall conduct the public meeting.

(b) Any affected party presenting testimony regarding the review of a project seeking approval shall state any organizational affiliation and shall register in support of the project, in opposition to the project, in support of the project with modifications, or as presenting information which is neither in support of or in opposition to the project.

(c) The record of the public meeting shall include:

1. A list of persons, their organizational affiliations, and how they registered under par. (b); and

2. An electronic transcription of the meeting.

(d) Within 60 days after the date of notification under sub. (5), the HSA shall recommend to the department approval or a denial of the project based upon the review criteria set forth in this chapter. An applicant and HSA may agree to an amendment to an application in order for an applicant to obtain a favorable HSA recommendation only if the amendment does not change the substance of a project. The amendment shall be submitted by the applicant to the department in writing. A

change in the substance of a project requires resubmission of a new application.

(7) DEPARTMENT REVIEW. (a) 75-day period for department review of an application shall begin on the date of notification of a complete application under sub. (5).

(b) The department shall issue an initial finding to the applicant and the HSA within the review period specified in par. (a). Unless the HSA or the applicant requests a hearing under s. HSS 123.09 within 10 days following the department's issuance of the initial finding, the department's initial finding is its final action. Upon request of an applicant for good cause shown, the department and HSA may agree to issue their recommendation and initial finding within a stated period of time less than the deadlines specified in par. (a) and sub. (6) (d).

(8) DETERMINATION OF NON-REVIEWABILITY. If, during the review process, the department finds that a project previously thought to be or determined to be reviewable is not in fact reviewable, the department shall return the application and the application fee to the applicant.

(9) CONDITION OF APPROVAL. The department and applicant may agree to any modification of the project as a condition of approval.

(10) CONCURRENT REVIEW. (a) Pursuant to s. 150.67 (2), Stats., the department may group for concurrent review applications for similar types of facilities or services that are proposed within the same health planning area or service area. Applications from an acute care service area which overlaps HSA boundaries or applications which will serve several health planning areas may be reviewed by both HSAs. The review procedures set forth under subs. (1) to (9) and sub. (11) shall apply in reviewing all applications except as modified by this subsection in the review of applications for concurrent review. The department may initiate concurrent review as follows:

1. The department may initiate concurrent review upon receipt of any notice of intent under sub. (3), by sending to the person who submitted the notice of intent a notice of concurrent review and publishing and distributing that notice as the department deems fit. The notice of concurrent review shall include the name of the person who submitted the notice of intent, the type of facility or service being concurrently reviewed and the area of concurrent review. Upon receipt of the first completed application for the concurrent review, the department shall notify all other applicants and persons who have submitted notices of intent relevant to the concurrent review that complete applications must be received by the end of the current calendar month may be reviewed separately or concurrently with other applications for similar types of facilities or services or within the same planning area or service area which are completed during the same calendar month.

2. The department may concurrently review applications which are declared complete within the same calendar month, regardless of when the notices of intent were received. Concurrent review under this paragraph shall be initiated by including a notice to that effect in the notice under sub. (5).

3. The department may initiate concurrent review by publishing at the end of any calendar month a notice that all completed applications for a particular type of facility or service or within particular health planning

areas or service areas which are received during the second calendar month following publication of the notice will be grouped for concurrent review. The notice shall state that notices of intent for the concurrent review will be accepted during the calendar month following publication of the notice. Completed applications received after the second calendar month following publication of the notice may be reviewed separately or reviewed concurrently with other completed applications for similar types of facilities or services or within the same health planning area or service area which are received during the same calendar month.

(b) The department shall base concurrent review on a comparative analysis of the applications under all applicable review criteria set forth in this chapter. If, after removing from consideration all applications which fail to meet one or more applicable review criteria, there remain more applications than can be approved under applicable need criteria, the department shall rank the remaining applications according to how each meets each applicable review criterion, assigning the lowest number to the application which best meets each criterion. Applications shall be approved in order beginning with the lowest total score, until all need is met. If there is a tie between applications for the last available approval, the department shall rank the applications according to their scores on review criteria under s. 150.69 (5), Stats.

(c) The department shall issue one initial finding for all projects reviewed concurrently under this subsection. A request for hearing under s. HSS 123.09 (2) precludes issuance of any approval under this subsection until a final decision is issued by the secretary or the secretary's designee.

(d) If another hospital has reported a proposal similar to the applicant's project in the hospital's current capital budget report, the department may advise that other hospital to submit a competing application for concurrent review.

(e) The department may extend the review period by up to 60 days for applications undergoing concurrent review if warranted by the volume of applications received. A determination of whether an extension is necessary and the length of the extension shall be made by the department no later than 31 days after the date of notification under sub. (5).

(f) The initial finding pursuant to concurrent review may take any of the following forms:

1. The approval of a single project;

2. The approval of more than one project;

3. The approval of parts of any project, if agreed to by the applicant;

4. The approval of any combination of projects or parts of projects if agreed upon by the applicants; or

5. The approval of no projects.

(g) A request for hearing pursuant to s. HSS 123.09 (2) shall preclude issuance of any approval until a final decision is issued by the secretary or the secretary's designee.

(11) EXPEDITED REVIEW PROCESS. The department shall expedite the review of projects involving a substantial change in a health service re-

sulting in revenues of between $250,000 and $500,000. The review procedures set forth under this section shall apply except for the following:

(a) Projects undergoing an expedited review shall not be grouped for concurrent review; and

(b) The department shall issue its initial finding no later than 5 working days after receipt of the HSA recommendation or the rate-setting authority's analysis, whichever is received later.

(12) HOSPITAL MERGER PROJECTS. (a) This subsection governs review of certain projects resulting from merger or consolidation of 2 or more corporations each of which owns a currently approved and operating hospital. Projects subject to review under this subsection are limited to service consolidation at one or more sites, service closure at one or more sites and expansion at others, and service relocation from one or more sites to others. Service retention at one site and introduction of the service at the other site as part of merger or consolidation is also governed by this subsection if the merged hospitals agree as a condition of approval to consolidate the service at one site within 3 years following introduction of the service at the second site. In order to be reviewed under this subsection, reviewable projects resulting from a merger or consolidation must be submitted for review under this chapter and ch. 150, Stats., within 3 years following merger or consolidation.

(b) The department shall issue its initial finding under s. 150.71 (2), Stats., to approve or disapprove any project reviewed under this subsection within 5 working days after the department receives the recommendation of the HSA under s. 150.71 (1), Stats., or, if there is no HSA, within 60 days after the department publishes its notice under s. 150.67 (1), Stats.

(c) The department and the merging or consolidating hospitals, prior or subsequent to merger or consolidation, may enter into a memorandum of understanding which generally describes the project to be reviewed under this subsection, identifies which of the review criteria set forth in this chapter and ch. 150, Stats., are applicable to those projects, and specifies the approved bed capacity of the merged or consolidated hospital which may not be altered by either the department or applicant during review.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; renum. (10) (b) 1. to be (10) (b) and am., r. (10) (b) 2., Register, March, 1986, No. 363, eff. 4-1-86.

HSS 123.09 Hearing process. (1) RIGHT TO A HEARING. An applicant whose project is rejected or any adversely affected HSA may request a public hearing to review the department's initial finding or may ask for a contested case hearing.

(2) REQUEST FOR A HEARING. (a) An applicant or HSA desiring either a public hearing or a contested case hearing shall submit a written request, no later than 10 days after the issuance of the initial finding, to both the department's division of health and the department's office of administrative hearings. The request shall identify whether the hearing requested is a public hearing or a contested case hearing, and the writer as an applicant or an affected HSA.

Note: The request for a hearing should be submitted to the Director, Bureau of Planning and Development, P.O. Box 1808, Madison, Wisconsin 53701 and Office of Adminstrative Hearings, P.O. Box 7875, Madison, Wisconsin 53707.

(b) The applicant or HSA requesting the hearing shall identify the criteria at issue no later than 20 days after the issuance of the finding.

(c) An applicant or HSA may select only one type of hearing for the duration of the hearing process. Multiple hearing requests based on an initial finding resulting from a concurrent review shall be adjudicated within one hearing. If more than one party which has undergone concurrent review requests a hearing and the requests are not in agreement on the type of hearing, a contested case hearing shall be held.

(3) PUBLIC HEARING. (a) Within 30 days after the filing of the request or the last request in the event of a concurrent review, a public hearing shall be held in the health planning area where the project is to be located. The department shall publish a notice of the public hearing in a daily newspaper of general circulation in the area of the project at least 5 days before the hearing.

(b) An examiner appointed by the department shall conduct the hearing. The examiner need not be an attorney.

(c) The following shall be the order of business at the hearing except as modified by the examiner:

1. The hearing shall commence with the examiner introducing the following items into the record:

a. The application, supporting documents which were submitted with the application, and additional information submitted in response to the department's request;

b. The staff analysis, initial finding and supporting documents relied upon in making the initial finding;

c. The record of the public meeting, if any, under s. 150.71 (1), Stats., and s. HSS 123.08 (6), the HSA's recommendation and supporting documents relied upon in making the recommendation;

2. The hearing examiner shall enumerate the issues upon which the hearing shall focus;

3. The applicant may make an opening statement;

4. The HSA may make an oral presentation of its recommendations and comments;

5. Members of the public may comment orally or in writing. The examiner shall furnish cards at the beginning of the hearing to persons wishing to speak. Persons who have completed cards shall be called to speak, but failure to submit a card shall not preclude a person from speaking. Irrelevant or unduly repetitious evidence shall be excluded;

6. The department shall state its position;

7. The examiner may ask questions of persons who make oral presentations; and

8. At the conclusion of the taking of evidence, any party shall be given, upon request, a reasonable period of time for oral argument. Questions may be submitted to the examiner by the parties to the proceeding to be asked at the discretion of the examiner of individuals making oral presentations.

(d) The hearing examiner shall make a tape recording of the hearing, including the testimony of all witnesses and oral argument. Copies of the tape recording shall be made available to any party at cost upon reasonable notice.

(e) If any testimony was presented in writing at the hearing, the examiner shall leave the record open for 10 days for the submission of responses to the written testimony. After the record is closed, the hearing examiner may allow up to 20 days for the submission by the parties of written briefs. Each party filing a brief shall serve the brief upon the other parties and the examiner.

(f) Within 20 working days after the deadline for submission of briefs, the examiner shall prepare and serve findings of fact, conclusions of law and a proposed decision on each of the parties. The service of the decision shall constitute the conclusion of the hearing.

(g) The final decision shall be made in accordance with sub. (5).

(4) CONTESTED CASE HEARING. (a) *Start of hearing process.* The department shall commence the hearing process for a contested case hearing within 30 days after receiving a request or the last request in the event of a concurrent review under sub. (2) unless all parties to the hearing consent to an extension of this period. The hearing process shall begin upon appearance of the parties before the hearing examiner as part of a prehearing conference.

(b) *Applications undergoing concurrent review.* All applications undergoing concurrent review shall be considered at one hearing.

(c) *Location.* All contested case hearings and prehearing conferences shall be held in the city of Madison unless any party demonstrates that this would impose an undue hardship on that party.

(d) *Legal issues.* A contested case hearing under this subsection shall consist of a review of the department's initial finding to approve or reject the project. The only issues in the hearing are whether the department's initial finding was:

1. Contrary to the weight of the evidence on the record when considered as a whole;

2. Arbitrary and capricious; or

3. Contrary to law.

(e) *Prehearing conference.* 1. At least 14 days prior to the contested case hearing, a prehearing conference shall be held. The purpose of the prehearing conference shall be to consider:

a. The possibility of obtaining admissions of fact and documents which will avoid unnecessary proof; and

b. The scheduling of the submission of names of witnesses to be called and the subject matter of testimony to be presented at the hearing.

2. The hearing examiner may issue prehearing orders:

a. Directing the order of presentation;

b. Limiting evidence and number of witnesses;

c. Requiring that evidence be presented in written form and exchanged among parties prior to the hearing; and

d. Determining whether a party as defined under s. 227.01 (8), Stats., has standing to participate in the hearing.

3. The hearing examiner shall prepare a memorandum summarizing the action taken at the conference.

(f) *Procedures for conducting the hearing.* 1. Issues raised at the hearing shall be limited to the review criteria cited as grounds for disapproval in the initial finding. Criteria not identified in the initial finding are deemed met or not applicable. Evidence may be received which relates to non-contested criteria only to the extent the evidence is relevant to contested criteria. In appeals by the HSA, the issues shall be limited to those review criteria upon which the HSA's recommendation and the initial finding differ and to the reasons for differences as cited in the initial finding.

2. Except as provided in subd. 3, evidence admitted at the hearing shall be limited to:

a. The application, supporting documents which were submitted with the application, and additional information submitted in reponse to the department's requests;

b. The staff analysis, initial finding and supporting documents relied upon in making the initial finding;

c. The record of the public meeting, if any, under s. 150.71 (1), Stats., and s. HSS 123.08 (6), the HSA's recommendation and supporting documents relied upon in making the recommendation; and

d. Cross-examination of persons preparing or making statements contained in the documents under subpars. a to c.

3. Parties may be allowed to present additional evidence only to the extent that the additional evidence is directly responsive to and made necessary by the evidence presented by any other party to the proceedings.

4. Persons preparing or making statements contained in the application, staff analysis, initial finding, recommendation or supporting documents shall be available for cross-examination, unless cross-examination is waived by opposing parties, and may give rebuttal testimony. Witnesses giving direct oral testimony shall be subject to cross-examination in the same manner as other witnesses.

5. Any party to the proceeding may be represented by counsel and present evidence and conduct cross-examination subject to the provisions of subd. 2.

6. The examiner conducting the hearing may question all witnesses and take administrative notice of all judicially cognizable facts.

7. Evidence shall be duly offered and made part of the case record.

8. Any party adversely affected by a ruling may make an offer of proof which shall be made part of the record.

9. An applicant whose project is rejected or any adversely affected HSA has the burden of going forward.

(g) *Hearing examiner duties.* The hearing examiner shall:

1. Make all rulings as to evidence, testimony and official notice;

2. Set the order for examination and cross-examination of witnesses;

3. Administer oaths and affirmations;

4. Prepare written and oral summaries of cases heard;

5. Prepare a recommendation for the secretary, consisting of findings of fact, conclusions of law and a recommended course of action; and

6. Adjourn the hearing to a specific time, date and place.

(h) *Hearing record.* A stenographic record shall be made in all contested case hearings. If any party wants a transcript or a portion of the transcript, that party shall make arrangements with the court reporter and shall pay whatever costs are agreed upon for making the transcript.

(i) *Posthearing oral arguments and briefs.* 1. Following presentation of the testimony, posthearing briefs may be filed by the applicant, the department and any interested party. Parties submitting briefs shall file copies within a reasonable time specified by the hearing officer.

2. The examiner may permit oral arguments in lieu of posthearing briefs. Any party that wishes to file a written brief shall be permitted to do so.

(j) *Close of hearing.* A hearing is closed when the evidentiary record is closed and any period established by the hearing officer for filing of briefs has expired. If the briefing period has expired and no brief of any party has been filed, the department may proceed to its final decision.

(k) *Ex parte communication.* The ex parte communication restrictions set forth in s. 227.50, Stats., including s. 227.50 (1) (d), Stats., shall apply to projects for which a contested case hearing has been requested.

(l) *Proposed decision.* Unless designated by the secretary as the final decision-maker, the examiner shall issue a proposed decision containing findings of fact, conclusions of law, and a recommendation for action to be taken. A copy of the proposed decision shall be served on each party.

(5) FINAL DECISION. (a) In any hearing under this section, the examiner shall establish a comment period during which the parties may submit comments pertaining to the proposed decision. At the close of the comment period, the parties' submissions shall be forwarded to the secretary or a designee of the secretary along with the proposed decision. The final decision shall then be made by the secretary or the secretary's designee. In the event a designee is chosen, all parties shall be notified.

(b) A final decision may be issued to either approve or deny the application or to approve the application with conditions pursuant to s. HSS 123.08 (9). If the record is deemed incomplete on any issue identified in the initial finding, the case may be remanded back to the examiner for the taking of further testimony.

(c) The secretary or designee of the secretary may ask all parties to the proceedings to present oral arguments before he or she makes a final decision.

(6) BURDEN OF PROOF. Each applicant or adversely affected HSA at any hearing under this section has the burden of proving, by clear and convincing evidence, that the department's initial finding was contrary to the weight of evidence on the record when considered as a whole, arbitrary and capricious, or contrary to law.

(7) REHEARING. (a) A petition for rehearing of a public hearing or a contested case hearing shall meet the requirements set forth under s. 227.49, Stats. The department shall review a petition for rehearing as provided in s. 227.49, Stats.

(b) A petition for rehearing under this subsection shall set forth the particular grounds for the relief sought. Copies of the petition shall be served on all parties of record.

(8) REQUIREMENTS FOR JUDICIAL REVIEW. Pursuant to s. 227.53 (1) (a), Stats., petitions for judicial review shall be filed in the circuit court within 30 days after the department issues its final decision under this section, and shall be served on the department and other parties to the proceeding.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; corrections made under s. 13.93 (2m,) (6) 7, Stats., Register, October, 1991, No. 430.

HSS 123.10 Progress reports and cost overruns. (1) CONTENT OF PROGRESS REPORTS. Each approval holder shall submit, on forms provided by the department, regular progress reports giving the status of the project as of the date of the report.

(a) For projects involving construction, the reports shall include:

1. An up-to-date copy of the proposed building plans;

2. An up-to-date copy of the estimate or bids, or both, for constuction costs;

3. An up-to-date report on total project costs, including the source of funds and a declaration indicating the extent to which the rates established in the approval will increase; and

4. A narrative description of the project's status, specifying any changes in project scope, cost, or design anticipated by the approval holder.

(b) For projects not involving constuction, the reports shall include:

1. A schedule for implementing the project;

2. An update-to-date report on total project costs, including the source of funds and a declaration indicating the extent to which rates established in the approval will increase; and

3. A narrative description of the project's current status, specifying any changes in project scope or cost anticipated by the approval holder.

(2) SCHEDULE FOR SUBMITTING PROGRESS REPORTS. The applicant shall send progress reports to the department according to the following schedule:

(a) For projects involving construction:

1. At the completion of design development drawings;

2. On the receipt of bids prior to the start of construction;

3. At 6-month intervals throughout the construction period; and

4. At project completion.

(b) For projects that do not involve construction:

1. Within 60 days of approval;

2. At 6-month intervals throughout project implementation; and

3. At project completion.

(3) REVIEW OF PROGRESS REPORTS. The department shall review each status report within 5 working days of receipt. Unless the status report indicates a projected cost overrun or material change in project scope, the department shall advise the approval holder to proceed. The department shall inform the approval holder if submission of an additional application is required. If the project can be accomplished for an amount less than that approved, the department shall adjust the approval accordingly when the project is completed.

(4) MONITORING OF INTEREST RATES. The interest rate determined as part of an application shall be monitored by the department between application approval and obligation of the note to verify the appliant's compliance with conditions for obtaining market rate financing under s. HSS 123.13 (6).

(5) COST OVERRUNS. (a) All cost overruns are subject to approval of the department.

(b) An approval holder shall report a projected cost overrun to the department before an obligation for the overrun is made.

(c) The department shall not approve a cost overrun in excess of 5% of the approved project cost if the approval holder incurs an obligation for the overrun prior to reporting it. The department may disapprove a cost overrun if an approval holder fails to submit the required information according to the schedule in sub. (2).

(7) REVIEW OF COST OVERRUN APPLICATION. (a) An application to incur a cost overrun shall be submitted to the department and reviewed in the following manner:

1. The approval holder shall submit another application for review pursuant to s. HSS 123.08 (3) to (8);

2. Review of the application shall be limited to questions regarding changes in the approved project; and

3. In determining maximum allowable inflation rates, the department shall make use of standard indices. To determine inflation rates for construction, the department shall use the *Enginering News Record's* building cost index. To determine inflation rates for other project costs, the department shall use indices provided by data resources, incorporated.

(b) The original approval is not affected by the submission of an application for a cost overrun. If the department approves the overrrun, the

original approval shall be amended accordingly. If the department does not approve the overrun, the original approval shall be unchanged.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.11 Civil forfeitures. (1) COST OVERRUNS. Each approved cost overrun shall be subject to a single forfeiture. The department shall use the following schedule for determining a forfeiture resulting from an approved cost overrun:

(a) 1. If a cost overrun occurs that is 10% or less of the approved project cost, the department shall assess a forfeiture equal to 10% of the overrun.

2. If a cost overrun occurs that is greater than 10% of the project costs, the department shall assess a forfeiture equal to 15% of the overrun.

(b) If after review of a first cost overrun on a project, a second cost overrun occurs, the department shall assess a forfeiture equal to 30% of the cost overrun.

(c) If after review of the second cost overrun on a project, a third or subsequent cost overrun occurs, the department shall assess a forfeiture equal to 50% of the cost overrun.

(2) PROJECTS SUBSEQUENTLY APPROVED AFTER BEING INITIATED WITHOUT DEPARTMENTAL APPROVAL. Where a project is subsequently approved after being initiated without departmental approval, the person operating the project shall be subject to a single forfeiture using the following schedule:

(a) If a capital expenditure or the operating revenue for a project implemented before July 1, 1986, is greater than the applicable dollar threshold but less than 110% of that threshold, the forfeiture assessed shall equal 10% of the amount exceeding the applicable dollar threshold.

(b) If a capital expenditure or the operating revenue for a project implemented before July 1, 1986, is equal to or greater than 110% of the applicable dollar threshold, the forfeiture assessed shall equal 15% of the amount exceeding the applicable dollar threshold.

(c) If a project subsequently approved after being initiated without departmental approval incurs approved cost overruns, the department shall assess the forfeitures under sub. (1).

(d) Operators of projects not mentioned in pars. (a) and (b) which are subject to review pursuant s. 150.61, Stats., and this chapter, shall pay a forfeiture equal to 15% of either the total capital expenditure or total annual operating revenues, whichever is greater.

(3) MULTIPLE VIOLATIONS. If a person is subject to a forfeiture under sub. (1) or (2) on more than one project within a 5-year period, the department shall assess a forfeiture of 30% on the second project and a forfeiture on 50% on the third and subsequent projects.

(4) RECOVERY OF FORFEITURES. No person may recover through charges or rates any forfeitures paid. This does not prohibit the use of endowments, savings or contingency funds nor the use of any voluntary contribution expressly for the purpose of defraying the cost of a forfeiture.

(5) PAYMENT OF FORFEITURES. The department shall not approve a project subject to a forfeiture until the forfeiture has been paid.

(6) CONSEQUENCE OF INCURRING PENALTIES. The department may reject an application for approval of a project from any person who has incurred a penalty under this section or s. 150.11, Stats., on 2 or more occasions within a 5-year period. This paragraph does not apply to penalties assessed for cost overruns caused by the actual inflation rate exceeding the inflation rate stated in the original application or caused by code corrections mandated by the department as part of an approved plan of correction issued after the original approval.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; r. and recr. (2) (a) and (b), Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.12 Validity of an approval. (1) PERIOD OF VALIDITY. (a) Pursuant to s. 150.75, Stats., an approval granted under this chapter is valid for one year from the date of issuance unless extended under par. (b).

(b) At the request of the approval holder, the department may grant one 6-month extension of the period during which a project is valid due to circumstances beyond the approval holder's control which has prohibited undertaking the project within the first 12 months or which has resulted in project costs temporarily exceeding approved costs. These circumstances include strikes, natural disasters or higher than contemplated interest rates.

(2) INVALIDITY. (a) The department may declare an approval invalid if:

1. At the end of the period of validity under sub. (1), the capital expenditure specified in the approval has not been obligated, financing sufficient to complete the project has not been obtained, or substantial and continuing progress has not been made; or

2. The person granted the approval under this chapter substantially fails to comply with any term or condition set forth in the approval.

(b) The applicant has a right to a hearing under s. 227.42, Stats., to review an invalidation under this subsection.

(3) TRANSFERABILITY OF APPROVAL. No person may transfer to another person an approval granted under this chapter. Any attempted transfer of an approval granted under this chapter voids the approval. The transfer of a controlling interest in a corporation which has been granted an approval under this chapter is considered a transfer of an approval under this section if:

(a) The corporation holding the approval is without significant assets;

(b) The corporation holding the approval has been substantially inactive since receiving the approval;

(c) The capital expenditure specified in the approval has not been obligated; or

(d) Approval of the department was sought and obtained to make the transfer.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; am. (2) (a), Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.13 Review criteria. The department shall use the following criteria in its review of all applications for project approval:

(1) CONSISTENCY WITH STATE PLANS. (a) Projects shall be consistent with the state health plan created under s. 14.25 (1) (c), Stats., if adopted by the department. Projects shall be consistent with the state medical facilities plan adopted under s. 150.83, Stats., and s. HSS 123.27, which is in effect on the date a completed application has been received. Criteria and standards in the state medical facilities plan not related to needed and surplus hospital beds or needed and surplus health services shall be adopted as administrative rules under ch. 227, Stats.

(b) For a hospital identified in the SMFP as having a low medical/surgical or pediatric occupancy rate, a low volume of obstetric deliveries or as operating less efficiently than other hospitals pursuant to s. HSS 123.27 (6) and (7), the department shall not approve an application unless an improvement plan is submitted with the application and the occupancy improvement plan is found acceptable by the department. This paragraph does not apply to applications by or on behalf of a hospital proposing to operate a home health agency or applications submitted by or on behalf of 2 or more hospitals participating in a joint venture.

1. An acceptable improvement plan to correct low medical/surgical and pediatric occupancy rates shall:

a. State the basis for and means by which occupancy increases are expected to occur within one year, or how at least part of the service will be phased out or merged and how beds will be reduced or converted within a 2-year period. Bed deactivation completed under s. HSS 123.30 (4) to comply with occupancy standards in the SMFP and in appendix C shall constitute an acceptable plan; and

b. Use a methodology, estimate of probable financial consequences, and service area need estimate which are reasonable and are consistent with the findings in the SMFP.

2. An acceptable improvement plan to correct low obstetrics volume shall:

a. Document that the low volume of deliveries does not result in a greater per unit cost in comparison to higher volume obstetrics services with volumes exceeding 730 deliveries a year and that personnel working in the obstetrics service are managing a minimum number of obstetrical patients to enable personnel to have a minimum level of continuing experience; or

b. Identify how deliveries will increase or how the service will be phased out or merged within a 2-year period.

3. An acceptable efficiency improvement plan shall indicate the steps that will be taken to improve the facility's operation for those areas cited by the department in the SMFP and the timetable by which this improvement shall occur.

(c) The department shall not approve an application submitted 3 years or more after an improvement plan has been submitted under par. (b)1., unless the hospital has made a good faith effort to implement that plan. This requirement does not apply to applications from a hospital

proposing to remedy an emergency situation that threatens patient safety.

(2) NEED FOR THE PROJECT. The department shall not approve a project unless there is need for the project.

(a) *Sufficient market share.* The department shall not approve an application unless the project is in a service area containing sufficiently large current and future market share population to justify the project. This does not apply to applications for the construction or operation of an ambulatory surgery center or home health agency.

(b) *Excess capacity for emergency room and laboratory.* Until service-specific CER standards are promulgated, the department shall not approve an emergency room or laboratory project if the proposed capacity exceeds need projected under par. (c).

(c) *Utilization.* 1. The department shall not approve a project where an applicant's estimated utilization rate for a new service will exceed the actual utilization rate for similar facilities or in the state as a whole, where baseline data are available.

2. Need estimates for an existing service shall be based on utilization over the past 5 years and a 5-year future utilization projection. The estimates shall be based on a statistically valid methodology acceptable to the department.

a. Utilization projections shall be based solely upon the projected market share population in the project's service area, as identified in ss. HSS 123.14 to 123.22, or in the state medical facilities plan. These forecasts shall take into consideration statistics on admissions or discharges, average length of stay, patient days, number of beds, and average occupancy, all by service, emergency room visits and outpatient visits.

b. Appropriate annual volume and capacity measures shall be included in the application. The department shall not approve expansion of facilities and services if occupancy or utilization projections show a decline from existing rates or if utilization rates have declined more than 2% a year on the average for the 3 years prior to application.

c. When utilization criteria specific to a service do not exist in ss. HSS 123.14 to 123.22 or in the SMFP, the department may only approve the expansion of facilities and services that have been operating at capacity based on standard industry measures for at least 3 years prior to application.

3. This paragraph does not apply to applications for the construction or operation of an ambulatory surgery center or home health agency.

(d) *Replacement rationale.* 1. The age of equipment or of a facility to be replaced shall be at least equal to its estimated useful life unless the applicant demonstrates that:

a. Failure to replace is not cost-effective;

b. The facility or equipment is not operational;

c. The equipment or facility is technologically obsolete; or

d. The equipment or facility is part of a larger project.

2. To determine estimated useful life of equipment and facilities, the department shall use the most recent edition of "Estimated Useful Lives of Depreciable Hospital Assets," a publication of the American hospital association.

(e) *Psychiatric and chemical dependency services.* 1. The department shall not approve construction of additional psychiatric and chemical dependency facilities or units if there are excess hospital beds in the service area.

2. The department shall not approve conversion to or expansion of psychiatric or chemical dependency beds in an existing service or unit unless there is a need for additional psychiatric or chemical dependency beds as stated in the SMFP.

3. No additional long-term psychiatric beds may be established until all long-term psychiatric facilities and units in the state are operating at 90% occupancy. Priority for expansion shall be given to existing facilities. In this subdivision, "long-term" means programs with average lengths of stay of more than 30 days.

(f) *ICU/CCU beds.* 1. The department shall not approve expansion of intensive care or coronary care unit (ICU/CCU) beds or establishment of a new ICU/CCU unless there is a need for additional ICU/CCU beds in the service area, as documented in the state medical facilities plan, and the existing unit to be expanded has been operating at least at 110% of the occupancy standard in s. HSS 123.27 (3) (c) and in the SMFP for the hospital's most recent fiscal year.

2. The department shall not approve renovation or replacement of ICU/CCU beds unless:

a. The existing unit has been operating at least at the occupancy standard in s. HSS 123.27 (3) (c) and in the SMFP for the hospital's most recent fiscal year; or

b. The renovation or replacement project will result in a reduction of ICU/CCU beds consistent with the occupancy standard in s. HSS 123.27 (3) (c) and in the SMFP.

3. Any new ICU/CCU shall be at least 4 beds in size.

4. The maximum number of ICU/CCU beds shall not exceed 9% of nonobstetrical bed capacity, except for hospitals of less than 50 beds.

5. Notwithstanding the provisions of subds. 2 to 4, a hospital may establish a close observation area in a single or semiprivate room with appropriate equipment and monitoring devices on a medical/surgical floor within direct proximity to the nurses station.

6. Any project relating to ICU/CCU expansion, renovation or establishment shall document that the requirements of the joint commission on accreditation of hospitals have been or will be met.

(g) *Rehabilitation facility.* 1. For purposes of this paragraph, "rehabilitation facility" means a facility or a distinct part of a facility which is operated for the primary purpose of restoring disabled persons to physical, psychological, social and vocational competency through an integrated program of medical evaluation of the patient's condition and

prognosis and treatment or training, and psychological, social or vocational evaluation and treatment or training.

2. The department shall not approve a project for the establishment of a new rehabilitiation facility unless all existing facilities in the health planning area or adjacent health planning area are operating at least at 90% occupancy. An exception to the 90% occupancy rate may be made if patients are required to travel more than 60 minutes by automobile to the nearest rehabilitation facility.

3. The department shall not approve expansion of an existing rehabilitation facility unless the existing facility is operating at least at 90% occupancy. If the proposed project is to be located in a hospital with excess bed capacity as determined under s. HSS 123.27 (10), the excess beds shall be converted to rehabilitation beds consistent with the requirements of sub. (13) (e).

4. Additional rehabilitation beds in the health planning area shall be determined on the basis of need projected under par. (c) utilizing an occupancy rate of 85%.

(h) *Diagnostic radiology services.* 1. The following factors shall be considered when evaluating the radiology service needs of a hospital:

a. Volume of patient load;

b. Market share population;

c. Availability of similar equipment in the area; and

d. Availability of qualified medical and professional staff and the degree of staff specialization.

2. Radiology equipment shall be sufficiently utilized in order to maintain the skills and efficiency of staff.

Note: The volume for certain more complex procedures should be or be projected to be as follows in order to maintain proficiency:

Procedure	*Minimum Volume*
Angiography (other than neuro)	125 examinations/year
Neuroangiography	125 examinations/year
Arthrography	125 examinations/year
Tomography, multidimensional	500 examinations/year

3. The department shall not approve a project relating to replacement of radiologic equipment or renovation or remodeling of space in the radiology service which involves 2 or more general diagnostic x-ray and fluoroscopic rooms excluding rooms for computed tomography, ultrasound and thermography, unless:

a. For a project involving a service consisting of 4 or more rooms, a minimum of 5,600 radiologic procedures will be provided per room per year;

b. For a project involving a service consisting of 3 rooms, a minimum of 11,200 procedures will be provided per year; or

c. For a project involving a service consisting of 2 rooms, a minimum of 5,600 radiologic procedures will be provided per year. This 5,600 procedures minimum does not apply if the equipment and its associated space are used only as emergency back-up and the back-up equipment is at the

end of its useful life, as determined in the most recent edition of "Estimated Useful Lives of Depreciable Hospital Assets," a publication of the American hospital association.

4. The department shall not approve the addition of general diagnostic x-ray and fluoroscopic rooms unless the existing units in a facility are providing at least 6,500 radiologic procedures per room per year.

(i) *Angiography and digital subtraction angiography.* 1. The department shall not approve an application for a new angiography service unless in the first full year of operation of the service or equipment the applicant will provide angiography procedures to a minimum of 300 patients. The opening of the proposed new angiography service or equipment shall not cause an existing angiography service in the same or a contiguous service area to fall below the standard of providing angiography procedures to at least 300 patients per year.

2. The applicant shall maintain at the same site as the proposed service or equipment:

a. An active surgical service, including neurosurgery, vascular surgery and trauma surgery;

b. Computerized tomography; and

c. Nuclear medicine.

3. An applicant with an existing angiography service who proposes to acquire a second angiography unit shall comply with subds. 1 and 2. The applicant shall have provided angiography procedures to a minimum of 800 patients during the fiscal year prior to the date the application is submitted. Applicants for a third angiography unit shall have provided angiography procedures to a minimum of 1,600 patients during the fiscal year prior to the date the application is submitted, in addition to complying with subds. 1 and 2. If the existing angiography room is also used for cardiac catheterization or interventional procedures, each cardiac catheterization patient served in the angiography room shall be counted toward the minimum established by this subdivision and the number of patients upon whom interventional procedures were performed in the angiography room shall be doubled and counted toward the minimums established by this subdivision.

(3) EFFICIENT AND ECONOMICAL USE OF RESOURCES. The department shall not approve a project unless the project will efficiently and economically use resources. To demonstrate economical resource use, the applicant shall establish that:

(a) The project's approach to providing services is more cost-effective than any alternative approach to providing like services;

(b) Other health care providers and agencies in the same service area have been informed of the applicant's project activities;

(c) The applicant has attempted to promote agreements for shared services; and

(d) No building space will be created as part of the project unless it will be used within one year of completion of the project or it is part of a bigger phased-in project under review.

(4) SUFFICIENT CASH FLOW AND RESERVES. (a) *Definitions.* In this subsection:

1. "Cash flow coverage" means positive cash flows from depreciation and amortization, plus fund earnings over the life of the indebtedness, divided by negative cash flows from payments of principal over the life of the indebtedness.

2. "Current ratio" means current assets divided by current liabilities.

3. "Debt burden" means principal plus interest, divided by net operating revenue.

4. "Debt ratio" means net long-term liabilities divided by the sum of net fixed assets and net working capital.

5. "Debt service coverage ratio" means the excess of revenue over expenses, plus depreciation and interest expenses, including amortization, divided by principal payment plus interest expenses, including amortization.

a. "Annual debt service coverage ratio" means a ratio with the data for both numerator and denominator from the same fiscal year.

b. "Maximum future debt service coverage ratio" means a ratio with numerator data from the first full year of debt service after project completion, and with denominator data based on maximum debt service in the future.

(b) *Sufficiency of cash reserves and cash flow.* The department shall not approve a project unless the applicant has sufficient cash reserves and cash flow to pay total project operating and capital costs.

(c) *Total project capital costs.* Total project capital costs shall include:

1. Physical asset costs, including but not limited to site acquisition and preparation, soil tests, construction, building or structure or office space acquisition, renovation, fixed equipment and major moveable equipment;

2. Total costs of professional services, including but not limited to planning consultant, architectural, cost estimation, legal, managerial and feasibility study fees;

3. Financing costs, including but not limited to financial advisory fees, fund raising expenses, and lendor or investment banker fees and interest;

4. Start-up costs, including but not limited to staff recruitment and deficit operation until expected revenue is realized; and

5. Contingencies, including but not limited to costs for unforeseen expenses and inflation.

(d) *Cost statement.* The application shall contain a complete statement of all capital and operating costs for the 3-year period beginning with the completion of the project. The statement shall distinguish increases in costs as a result of the project from increases attributable to other causes and explain all increases. The assumptions behind future cost and revenue projections shall be reasonable. Utilization projections contained in the need section of the application shall be comparable to those used in financial projections. The applicant shall include an estimate of how

much of the project's cost will be billed to all patients and how much of the project's cost will be billed only to patients who directly benefit from the project.

(e) *Revenue sources.* The applicant shall specify the revenue sources to be used to finance capital costs. These projected revenues shall be sufficient to cover debt service requirements.

(f) *Adequacy of resources.* The application shall demonstrate that adequate financial resources are available to the applicant to cover the proposed capital expenditure, start-up costs and any initial operating deficits.

(g) *Nondebt funding.* To minimize borrowing costs, the applicant shall use nondebt sources of funds to the extent practicable. On major construction, renovation or modernization projects in excess of $3,000,000 or 20% of a hospital's gross revenues, whichever is less, a goal of at least 10% nondebt funding shall be set. The hospital shall submit a plan indicating the means by which this goal will be reached or shall document that such a goal is not feasible. The department may accept a plan establishing a goal below 10% based on documentation submitted by the hospital. Nondebt sources include but are not limited to community support fund raising, tax subsidies, endowments, prospective accumulation of funds and any other accumulated reserves.

(h) *Understating cost prohibited.* The applicant may not understate the cost of a project to make the project appear more financially desirable.

(i) *Ability to pay capital costs.* 1. Information. An applicant proposing to borrow funds for a period of at least one year for the project exceeding the amount established in s. HSS 123.04 (1) (a) or (c) shall provide the department with the following information:

a. For the 3 fiscal years preceding application and the years during the construction period, an unrestricted fund revenue and expense statement, a statement of changes in financial position or cash flow and the unrestricted balance sheet and statement of changes in the fund balance. All financial statements shall be completed in accord with generally accepted accounting principles;

b. A complete set of financial forecasts for the 3 years following completion of the project, including an unrestricted fund revenue and expense statement, a statement of changes in financial position or cash flow and the unrestricted balance sheet and statement of changes in the fund balance. The financial forecasting shall be prepared in accord with generally accepted accounting principles; and

c. The probable future depreciation and debt principal payment schedules for the project.

2. Data sources. a. All financial statement values used to calculate the ratios referred to in subds. 3 and 4 shall be taken from the unrestricted balance sheet and the statement of revenues and expenses for the unrestricted fund, as defined by the American institute of certified public accountants. The only exception shall be funds restricted for financing the project. These funds may be used to calculate projected ratios.

b. Forecasts of financial performance shall be consistent with historical performance. Projected revenues and expenses shall be reviewed,

through a trend analysis, to determine their consistency with historical data and other projections provided in the application.

3. Historical financial performance. The department shall not approve a project unless the applicant has demonstrated, based on past performance, an ability to adequately manage the debt. Demonstration of the applicant's ability to adequately manage the debt shall be based on:

a. Whether for the 3 fiscal years preceding application the applicant has maintained an overall average current ratio of at least 1.2, unless a current ratio less than 1.2 is due to the last-in-and-first-out (LIFO) inventory methodology or other accounting changes;

b. Whether the increase in the debt ratio over the past 3 years exceeds 50%, unless a 50% increase is the result of the applicant's projected repayment plan and depreciation schedule; and

c. Whether the applicant's annual debt service coverage ratio has averaged at least 1.2 for the 3 fiscal years preceding application. Evaluation of the debt service coverage ratio shall consider capital expansion, modernization and renovation programs the applicant has undertaken within the 3 fiscal years preceding application.

4. Debt capacity. The department shall not approve a project unless it is reasonable for the applicant to incur the debt associated with the project. Demonstration of reasonableness shall be based on:

a. The applicant's demonstrated ability to pay long-term debt through present and future cash flow and profitability positions;

b. Whether the project will result in a debt ratio in excess of .8 for the 3 years following project completion;

c. Whether the maximum future debt service coverage ratio is at least 1.2;

d. Whether the debt burden exceeds 10%;

e. Whether the applicant's projected cash flow coverage ratio indicates that adequate funds are available to service the proposed debt; and

f. Whether the applicant will establish a depreciation reserve fund to be used to make required principal payments during the period that principal payments exceed depreciation.

5. Overall assessment. In order for a project to be approved, an overall assessment of the facility's debt capacity, based on subds. 3 and 4, shall establish that the facility has adequate capacity to incur the debt associated with the project. This assessment shall take into consideration the hospital's financial requirements as determined by the rate-setting authority and shall be completed by the department on all projects for which debt financing is proposed and for which the costs exceed 20% of the hospital's gross revenues or $3,000,000, whichever is less.

6. Credit enhancement. The applicant is not precluded from engaging in credit enhancement activities that would permit compliance with subds. 3 and 4. If a project would not otherwise be approved due to incapacity to incur the project debt, the department may with consent of the applicant, place conditions upon the project approval to improve to a

reasonable level the overall assessment of the applicant's capacity to incur the project debt.

7. Analysis sources. Sources which the department may use in analyzing an application pursuant to subds. 3 and 4 include, but are not limited to, nationally recognized hospital financial averages and standards which shall be evaluated on an annual basis.

Note: Examples of nationally recognized financial averages and standards for hospitals include those used by the U.S. department of housing and urban development, the health care financial management association, bonding agencies such as Standard and Poor's or Moody's, and the Wisconsin health facilities authority.

8. Outside consultant. a. If the department finds that the hospital does not have adequate capacity to incur the debt under subds. 2 to 7, the applicant shall be given an opportunity prior to the issuance of an initial finding by the department to submit an independent financial analysis performed by one consulting firm selected from a list approved by the department. The analysis performed by the consulting firm shall be based upon the information submitted by the hospital in its application or new information made available to the department at the same time as it is made available to the consulting firm and shall be consistent with the criteria set forth in this chapter. Any conclusion based upon information not submitted to the department shall be disregarded. The applicant shall request an extension of the review process sufficient in length for the consultant's analysis and subsequent departmental review to be completed.

b. The consultant's analysis shall include a consideration of the financial criteria set forth in this paragraph in establishing the future security of the proposed debt. This analysis may also include consideration of the market position, medical staff characteristics, other financial factors and management factors in considering the hospital's capacity to pay debt service.

c. The department shall not approve a project unless, in concluding its report, the consulting firm certifies that the financial analysis is being presented in conformity with the applicable guidelines established by the American institute of certified public accountants, the underlying financial assumptions provide a reasonable basis for forecasting and sufficient funds can be generated to meet the hospital's operating expenses, working capital needs and other financial requirements including the debt service requirements associated with the proposed debt.

Note: Proposed guidelines for prospective financial statements are being prepared by the Financial Forecasts and Projections Task Force of the American Institute of Certified Public Accountants, 1211 Avenue of the Americas, New York, N.Y. 10036.

(5) REASONABLE COST AND RATE INCREASES. (a) *Cost comparisons.* The department shall not approve a project unless the applicant's cost increases and projected rate increase requests are reasonable. To demonstrate that increases in rates, charges, and operating and capital costs are reasonable, the applicant shall establish:

1. That projected capital and operating costs are reasonable when compared to costs for projects of a similar kind and scope. The department shall consider factors such as the relative age of services the project is to be compared with, differences in wage rates and the utilization that similar services are generating; and

2. That the increased level of proposed charges or rates brought about by the project is reasonable when compared to those in other institutions offering services of a similar kind or scope. The department shall consider factors such as the relative age of services the project is to be compared with, differences in wage rate and the utilization that similar services are generating.

(b) *Incremental operating costs.* For proposed capital projects which exceed the lower of $3,000,000 or 20% of a hospital's gross revenues, incremental operating costs exceeding 30% of the proposed capital expenditure in any one year for the first 5 years following completion of the project shall be presumed unreasonable. Incremental operating costs shall be adjusted for inflation pursuant to s. HSS 123.10 (7) (a) 3. In this paragraph, "incremental operating costs" means operating costs over and above those which would have been incurred by the applicant had the project not been implemented.

(c) *Rate-setting analysis.* Pursuant to s. 150.69 (5), Stats., the rate-setting authority shall determine the effect on hospital rates of the project and provide an analysis to the department within 45 days after the department and the HSA receive a completed application. The department shall also ask the authority to advise the department and the HSA as to the reasonableness of the rate increase caused by the project.

(6) AVAILABILITY OF FINANCING AT MARKET RATES. The department may only approve a project for which financing is available at market rates. The department shall make this determination on the basis of information supplied by the applicant, as follows:

(a) The applicant shall state the most likely source of funds, the interest rate and cost of borrowing including interest, pay periods, restrictions on additional debt, prepayment, annual debt service requirements and the total number of years of the loan.

(b) The applicant shall demonstrate that it has considered alternative sources of funding before obtaining financing and that the total cost of financing does not exceed market rates. The least costly debt funding for the project is presumed to be at market rates; and

(c) The applicant shall establish that the debt, which includes depreciation, interest, capitalized interest and debt principal repayment, will only be incurred consistent with prudent fiscal management.

(7) AVAILABILITY AND EFFECTIVE USE OF PERSONNEL. The department may not approve a project if health care personnel are not available or effectively used. The department shall make this determination on the basis of information supplied by the applicant, as follows:

(a) The application shall indicate the number of full-time-equivalent health care personnel necessary to provide the service and their job classifications. The application shall also contain information about the overall facility staffing and the medical staff including the number of active and associate staff members, their specialties and number of admissions for 5 years preceding application, and additions and deletions to the active staff in the past 3 years; and

(b) To demonstrate that personnel are available and would be effectively used, the applicant shall establish:

1. That health care personnel proposed to provide the service or staff the facility are not excessive in number or have higher job classifications when compared to numbers and classifications of staff of similar existing services or facilities;

2. That personnel proposed to provide a service will be shared by other health care providers in the area where similar services are being offered if sharing is appropriate and cost-effective; and

3. That personnel proposed to provide the service or staff the facility are sufficient in numbers to meet applicable state code and accreditation standards.

(8) CONSISTENCY WITH RATE-SETTING STANDARDS. The department shall not approve a project unless the project is consistent with legally valid standards for decision-making and legally valid methodology for setting rates established by the rate-setting authority. Legally valid standards and methodologies employed by the rate-setting authority may be used by the department in conducting reviews.

(9) PARITICIPATION IN UTILIZATION REVIEW. The department shall not approve a project unless the applicant participates in a utilization review program. The applicant shall demonstrate that:

(a) The utilization review will evaluate procedures, services, and treatments for all patients, regardless of payment source, on a sample basis;

(b) The utilization review process will include tissue or operative review, infection review, medical records review, and mortality and morbidity review;

(c) The project will be included, where relevant, in future medical audits by the applying facility; and

(d) All review data will be available for public disclosure to the extent consistent with s. 146.82, Stats. The review data shall keep confidential the identity of the patient and all health care personnel. Data shall be compared to outcome standards for mortality and morbidity.

Note: For more information on how utilization review is conducted, see the most recent *Accreditation Manual for Hospitals*, joint commission on the accreditation of hospitals.

(10) CONSISTENCY OF PROPOSED CONSTRUCTION COSTS WITH INDUSTRY AVERAGES. The department shall not approve a project if proposed construction costs are not within industry averages for similar types of construction, as evidenced by a comparison with costs of recent projects and an analysis of the cost estimate for the project under construction.

(11) APPROPRIATENESS OF ADDITIONS TO EXISTING SPACE. (a) The department shall not approve a project if it determines that proposed allocations of space for a service are inappropriate given need projections for the institution or service area as estimated under sub. (2), not supported by the projected patient utilization, not justified by the department's analysis of the applicant's functional space program or are based upon a functional space program or architectural design which does not promote efficient use of resources including but not limited to energy, personnel and capital.

(b) The proposed allocation of space shall be supported by projected patient utilization, as verified by the department. Verification shall in-

clude an assessment by the department of the soundness and reasonableness of the proposed allocation of space in light of the bed need determination in the SMFP.

(c) The applicant shall submit a complete functional space program and proposed schematic design. The allocation of space for each service and function affected by the project shall be justified based on the department's analysis of the applicant's functional space program. The department's analysis shall include the identification and use of nationally recognized programming methodologies and techniques.

Note: Examples of methodologies are those used by the Canadian department of national health and welfare, and by the U.S. department of defense, veteran's administration. These may be examined at the Bureau of Planning and Development, Room 280, One West Wilson Street, Madison, Wisconsin.

(12) COST-EFFECTIVENESS OF CONSTRUCTION OR RENOVATION ALTERNATIVES. The department shall not approve a project unless the applicant demonstrates that the project is more cost-effective than any other construction or renovation alternative. Demonstration of cost-effectiveness shall be as follows:

(a) *Alternatives analysis.* The application shall contain an analysis which compares the cost-effectiveness of the project and alternatives.

1. The applicant shall submit a comprehensive analysis of alternative methods for the provision of the project services or functions. The applicant's analysis shall include consideration of the following alternatives:

a. Continuation of the status quo;

b. Variation to the functional program;

c. Renovation of the existing facility;

d. Change in the use of an existing facility;

e. New construction; and

f. Available equipment alternatives.

2. The applicant shall provide a life cycle cost analysis, on forms provided by the department, for the alternatives being considered.

(b) *Outside evaluation of existing plant.* The applicant shall have an outside party evaluate the existing physical plant from the standpoint of code compliance, structural integrity, conditions of mechanical, electrical and energy utilization systems, and functional deficiencies, and prepare a report, a copy of which shall be submitted to the department. This evaluation may be verified by the department.

(13) CONSISTENCY WITH COST CONTAINMENT STRATEGIES. The department shall not approve a project unless the project is in keeping with strategies to contain rising health care costs.

(a) *Preadmission testing.* For any project related to inpatient care, the hospital shall maintain a program that provides for laboratory tests, x-rays and physical examinations on a less costly ambulatory basis prior to hospital admission.

(b) *Hospital long-range planning.* The applicant shall demonstrate that the project has been considered in the hospital's long range strategic planning and has the approval of the hospital's governing board.

(c) *Closed hospitals.* The department shall not approve reopening of a hospital if there are excess beds in the service area, as stated in the SMFP, or if other existing hospitals have been able to accommodate patients in the area during the period in which the hospital was closed. A hospital is considered closed if:

1. The approval has been surrendered or revoked under ss. 50.32 to 50.39, Stats.; or

2. The provider agreement has been voluntarily or involuntarily terminated.

(d) *Least costly setting.* The applicant shall establish that the project will facilitate the care of patients in the least costly setting, including on an outpatient basis unless the service is not adapted to a lesser-cost setting.

(e) *Reduction of beds.* 1. In this paragraph "nonhealth-related expenditures" means expenditures for parking facilities, alteration or addition of plumbing, heating, cooling or electrical systems, and projects limited to nonpatient areas, such as waiting areas, cafeterias, dietary departments, central supply, maintenance storage areas, medical libraries, chapels, laundries, housekeeping departments, medical records, classrooms, meeting rooms and administrative offices.

2. If a service area is identified in the SMFP pursuant to s. HSS 123.27 as having excess beds when beds are summed across all servicees, the department shall not approve a project proposing renovation, construction or modernization of a hospital in that service area unless the project:

a. Would result in a bed decrease for the service area based upon the applicant's proportion of the excess beds in the service area as identified in the SMFP pursuant to s. HSS 123.27 (10). The department may adjust upward or downward the magnitude of decrease to reflect the size of the patient unit. Bed deactivation completed under s. HSS 123.30 shall constitute a bed decrease for purposes of this paragraph;

b. Is in a service area served by one hospital and would result in a net bed decrease for the service area based on the number of excess beds in the service area;

c. Is from a hospital operating at the SMFP occupancy standard, where the actual length of stay for a hospital does not exceed its expected length of stay by greater than 10%;

d. Involves only clinical equipment replacement or nonhealth-related expenditures;

e. Is by or on behalf of a hospital for which the total number of patient days of care increased by at least 5% over the past 3 years as the result of a contract with a health maintenance organization whose physicians were previously not on the medical staff of the hospital, but only if for the year prior to application the hospital was operating at greater than 80% of the occupancy standard in the SMFP; or

f. Involves reduction of excess beds and conversion of the space associated with those beds to outpatient services or projects limited to nonpatient areas. This does not apply to projects which result in conversion of inpatient beds to other inpatient beds. Projects under this subparagraph shall meet the criteria set forth in par. (g).

(g) *Excess capacity conversion.* 1. For projects involving reduction of excess beds and conversion of the space associated with those beds to outpatient services at a cost below $3,000,000 or 20% of the hospital's gross revenues, whichever is less, or totalling less than 15% of the hospital's gross square footage, the department shall not approve the project unless:

a. The project will result in a net reduction of beds;

b. The project will reduce the hospital's inpatient financial requirements the third year after project completion; and

c. The project will produce sufficient revenues to pay a portion of the costs related to the excess beds being reduced;

2. That portion of any project involving reduction of excess beds and conversion of the space associated with those beds to outpatient services shall be exempt from the review criteria set forth in subs. (1) and (13) (e) and the standards set forth in ss. HSS 123.27 and 123.30.

3. For any project that only involves reduction of excess beds and conversion of space associated with those beds to outpatient or nonpatient areas, the department shall issue its initial finding under s. 150.71 (2), Stats., within 5 working days after the department receives the recommendation of the HSA under s. 150.71 (1), Stats., or, if there is no HSA, within 60 days after the department publishes its notice under s. 150.67 (1), Stats.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.14 Ambulatory surgery center criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications for the construction or operation of new ambulatory surgery centers. The applicable criteria of s. HSS 123.13 shall also be used in the review of projects subject to this section.

(2) DEFINITIONS. In this section:

(a) "Ambulatory surgery center" means a facility, not part of a hospital, in which ambulatory surgical procedures are performed.

(b) "Ambulatory surgical procedure" means a surgical procedure which:

1. Is commonly performed on an inpatient basis;

2. May safely be performed on an outpatient basis;

3. Is not commonly performed and may not safely be performed in physician offices;

4. Requires a dedicated operating suite and a postoperative recovery room or short-term convalescent room;

5. If performed under general anesthesia, is usually limited to 90 minutes duration; and

6. Is performed in a facility that holds itself out as performing ambulatory surgical procedures on a routine, organized basis with scheduled hours of operation and dedicated staff.

(c) "Total surgical procedures" means all surgeries performed in dedicated operating room suites.

(3) NEED. (a) The department shall not approve an application if there is not a need for an ambulatory surgery center.

(b) The need for an ambulatory surgery center in an acute care service area shall be based on the percentage of ambulatory surgical procedures to total surgical procedures being performed either in an ambulatory surgical center or in a hospital in that service area. Unless the number of ambulatory surgical procedures performed in the service area is less than 40% of total surgical procedures according to the most recent department survey, an application for an additional ambulatory surgery center shall be disapproved.

(c) The project's location shall promote an equitable geographic distribution of ambulatory surgery centers in the service area.

(d) An application shall include:

1. A projection of the number of surgical procedures to be performed at the center within 3 years following project initiation; and

2. A utilization plan for the center. The plan shall contain utilization estimates for at least the first 5 years of operation, projected on a monthly basis for the first year and on a quarterly basis for subsequent years. Assumptions and methods used in the utilization projections shall be reasonable and clearly documented.

(e) The department shall not approve additional ambulatory surgery centers unless each approved or existing ambulatory surgery center in the service area is performing at least 500 surgical procedures per operating room annually.

(f) The development of ambulatory surgery centers which will provide a variety of surgical services shall receive priority over those which will provide surgical services in limited specialty areas, unless a specific need has been demonstrated for a special service facility.

(4) REQUIRED RESOURCES. The department shall not approve an application unless the applicant demonstrates that:

(a) The center is in compliance with requirements established under applicable state and federal programs;

(b) The center will be staffed to operate at least 5 days a week;

(c) The center will have arrangements to provide for emergency transport of patients when necessary;

(d) The center will be no more than 15 minutes travel time from a hospital, unless the applicant demonstrates that longer travel time does not endanger patients; and

(e) The center will have policies which facilitate hospitalization of patients when necessary. All surgeons who perform surgery within the center shall have surgical privileges at a local hospital.

(5) COST CONTAINMENT. The department shall not approve an application unless:

(a) The project's per procedure charge is lower than the historical hospital charge per procedure in the acute care service area; and

(b) The applicant demonstrates that the project's services will be coordinated with other community health resources such as hospitals and clinics. The demonstration shall include furnishing copies of memoranda of agreement, correspondence or contracts.

(6) FINANCIAL FEASIBILITY. The department shall not approve an ambulatory surgery center unless the applicant demonstrates that the facility is financially feasible. The applicant shall document:

(a) The method and source of financing, including interest and other costs related to the establishment of the center;

(b) Direct costs, including construction, equipment, depreciation, interest, advertising or promotion, paraprofessional, clerical and professional staff, supplies, maintenance and leasing;

(c) Indirect costs, including space, management support and other relevant overhead costs;

(d) Proof of sufficient finances to operate the center; and

(e) Written policies on provision of services without charge to low-income persons.

(7) UTILIZATION REVIEW. The center shall have:

(a) A written plan for reviewing patient care, including criteria for identifying those patients requiring review and a mechanism for periodically evaluating the patient review process; and

(b) Written policies and procedures for utilization review consistent with state and federal standards. The review shall consider medical necessity of the service, quality of patient care and rates of utilization.

(8) PHYSICIAN SUPPORT. The department shall not approve a project if physician support is not demonstrated by the applicant. The applicant shall document that at least 10 physicians have provided written commitments to use the center and shall state location, hospital affiliation and number of surgeries to be performed annually by each physician. The projected annual surgeries to be performed by physicians who have provided written commitments shall comprise at least 50% of the surgeries projected by the ambulatory surgery center during the first full year of operation.

(9) DATA REPORTING REQUIREMENTS. Ambulatory surgery centers shall provide the department and the HSA, on request, with data relating to operating costs and to numbers, types, and origin of patients and other demographic information. The information shall be provided not more often than twice a year unless current data are required for the review of a proposal for the addition of a new ambulatory surgery center in the service area.

(10) EXCEPTION FROM OTHER CRITERIA. An applicant for approval to construct or operate a new ambulatory surgery center is exempt from the requirements of ss. HSS 123.13 (1), (2), (4) (g) and (i), (5) (c), (8), and (13), and 123.27 to 123.30.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.15 Cardiac program criteria. (1) USE. The criteria set out in this section shall be used by the department in its review of projects relating to cardiac surgery or cardiac catheterization services. The applicable criteria of s. HSS 123.13 shall also be used in the review of projects subject to this section.

(2) DEFINITIONS. In this section:

(a) "Adult cardiac catheterization service" means the offering and provision of cardiac catheterization to persons age 13 and above.

(b) "Adult cardiac surgery service" means the offering and provision of cardiac surgery to persons age 13 and above.

(c) "Cardiac catheterization laboratory" means one or more cardiac catheterization rooms.

(d) "Cardiac catheterization procedure" means the performance of one or more of the following procedures, either singly or in conjunction with other procedures, during a single visit to a cardiac catheterization laboratory: left or right heart catheterization with hemodynamic studies; combined left and right heart catheterization and coronary angiography; left heart catheterization and coronary angiography with or without left ventriculography; coronary arteriography with ventriculography; percutaneous transluminal angioplasty performed in an institution with a cardiac surgery program; or a diagnostic or therapeutic electrophysiological intracardiac study. "Cardiac catheterization procedure" does not include the insertion of pulmonary artery catheters or transvenous pacemakers.

(e) "Cardiac catheterization room" means a room used for the performance of cardiac catheterization procedures.

(f) "Cardiac catheterization service" means the specialized facilities, equipment, personnel and other institutional resources to perform cardiac catheterization procedures and to provide directly related inpatient services before and after the procedures.

(g) "Cardiac surgery" means an operation performed on the heart and intrathoracic great vessels which requires the temporary use of cardiopulmonary bypass equipment during surgery.

(h) "Cardiac surgery procedure" means the performance on a patient of one or more of the following procedures during a single visit of the patient to an operating room: coronary artery bypass; valve repair or replacement; congenital heart disease repair or palliative procedure other than a valve procedure; and the performance of miscellaneous cardiac surgery procedures for tumor of the heart, trauma of the heart, or aneurysm of the thoracic aorta, pericardiectomy, pulmonary artery embolectomy, or postmyocardial infarction including procedures for left ventricular aneurysm.

(i) "Cardiac surgery service" means cardiac surgery procedures and all of the specialized rooms, equipment, personnel and other resources to perform cardiac surgery, including all directly related inpatient services provided to cardiac surgery patients before and after cardiac surgery.

(j) "Coronary artery bypass graft procedure" means a procedure by which blocked coronary arteries or vessels are bypassed by grafting another vein to circumvent the blocked area.

(k) "Dedicated" means offering only adult cardiac services or only pediatric cardiac services.

(l) "Pediatric cardiac catheterization capacity" means the sum of the pediatric cardiac catheterization capacity of each facility in the state which has provided cardiac catheterization services to at least 10 pediatric patients in each of the 3 most recent calendar years prior to project review.

(m) "Pediatric cardiac catheterization service" means the offering and provision of cardiac catheterization to infants and children ages 12 and below.

(n) "Pediatric cardiac surgery service" means the offering and provision of cardiac surgery to infants and children ages 12 and below.

(o) "Planning area" has the meaning prescribed in s. HSS 123.03 (22) for health planning area, except that for dedicated pediatric services "planning area" means the entire state.

(3) NEED FOR CARDIAC SURGERY SERVICES. (a) *Evaluation.* The department shall not approve an application relating to cardiac surgery services unless additional cardiac surgery services are needed. The department shall determine need for additional services based on its evaluation of documentation supplied by the applicant and the criteria in this subsection. The validity of all assumptions upon which projections made by an applicant are based as well as the validity of the data and methodology used in making these projections shall be documented in the application.

(b) *Expected number of surgery candidates and applicants.* Applicants shall supply the department with projections of:

1. The annual number of cardiac surgery candidates in the planning area, taking into consideration the number of candidates identified by referring physicians, facilities and other sources in the area, calculated separately for adult and pediatric candidates. Projections shall be based on relevant historical data and shall include the geographical origins of the candidates by zip code and county;

2. The annual number of adult and pediatric cardiac surgery patients to be served by the applicant, based on:

a. The incidence of heart conditions for which cardiac surgery has been recognized to be an effective and appropriate mode of treatment;

b. The probable impact of anticipated technological advances and the introduction of new cardiac surgical and nonsurgical techniques to treat cardiovascular disease; and

c. The number of candidates identified in subd. 1. who have received cardiac surgery in the past 5 years or who can reasonably be expected to be served in the next 5 years.

(c) *Anticipated volume of procedures.* 1. An application relating to adult cardiac surgery service shall demonstrate that the project will have a sufficient number of open heart surgery candidates and sufficient resources to perform a minimum of 200 adult cardiac surgery procedures a year by the third year of operation.

2. An application relating to dedicated pediatric cardiac surgery services shall demonstrate that the service will have a sufficient volume of pediatric cardiac surgery candidates and sufficient resources to perform a minimum of 130 pediatric cardiac surgery procedures a year by the third year of operation, including at least 75 coronary artery bypass procedures.

(d) *Capacity of existing facilities.* 1. The department shall not approve an application unless the number of cardiac surgery procedures performed in the health planning area in the preceding 12 months exceeds 80% of the total capacity of all hospitals in the area that provide cardiac surgery services.

2. The cardiac surgery capacity of a hospital is the smallest estimate of capacity calculated for that hospital when capacity is calculated by each of the subparagraphs, as follows:

a. Calculate operating room capacity by multiplying the number of priority operating rooms by 1.35 which is the average number of cardiac surgery procedures performed per operating room per work day statewide calculated by dividing the standard length of a workday or 8 hours by the statewide average duration of a cardiac surgery procedure including setup and cleanup which is 5.94 hours and the product by 260 which is the standard number of work days in a year an operating room is nominally available for performing cardiac surgery given current operating patterns. In this subparagraph, "priority operating rooms" means operating rooms dedicated to cardiac surgery plus operating rooms in which cardiac surgery is given priority in scheduling.

b. Calculate intensive care unit (ICU) capacity by multiplying the number of priority ICU beds by 365 days and the product by the occupancy rate at reasonable operating capacity, and divide that product by the average length of stay in the ICU according to the most recent department cardiac surgery survey. In this subparagraph, "priority ICU beds" means the number of ICU beds dedicated primarily to postoperative care of cardiac surgery patients plus the number of beds for which cardiac surgery patients have scheduling priority or, in facilities not having dedicated or priority beds for these patients, the greater of either 30% of the number of ICU beds available for postoperative cardiac surgery patients or, if consistent over time and well-documented, the facility's actual ratio of ICU patient days for these patients to ICU patient days for all surgical patients multiplied by the number of ICU beds available for cardiac surgery patients. In this subparagraph, "occupancy rate at reasonable operating capacity" means 80% for facilities with more than 6 ICU beds available for the postoperative care of cardiac surgery patients and 70% for facilities with 6 or fewer ICU beds available for these patients.

c. Calculate surgeon capacity by multiplying 240 which is the number of cardiac surgery procedures per year that a full-time cardiac surgeon is nominally deemed to be capable of performing without excessive strain, given adequate demand and sufficient backup resources by, the number of full-time equivalent (FTE) surgeons who are currently performing these procedures at the hospital. The number of full-time equivalent cardiac surgeons shall be proportionately adjusted for the portion of a surgeon's cardiac surgery practice performed at other hospitals and for ongoing commitments such as teaching and research which significantly reduce the amount of time available for cardiac surgery.

3. The department shall review periodically the specified number values included under subd. 2.a. to c. based on the most recent year for which statewide data is available and shall adjust them through rule-making procedures in s. 227, Stats., to reflect actual experience and practice.

(e) *Utilization of existing facilities.* 1. The department shall not approve an application to establish a new adult cardiac surgery service unless each existing adult cardiac surgery service in the same planning area has performed the lesser of 350 open heart surgery procedures or 100% of its capacity as determined in par. (d) for those procedures in each of the 3 years preceding the year in which the department receives the application.

2. The department shall not approve an application for a new dedicated pediatric surgery service unless each dedicated cardiac pediatric surgery service in the state has performed a minimum of 250 pediatric cardiac surgery procedures in each of the 3 years preceding the year in which the department receives the application.

(4) NEED FOR CARDIAC CATHETERIZATION SERVICES. (a) *Capacity.* 1. The department shall not approve an application for a new or expanded cardiac catheterization service unless the number of cardiac catheterization procedures performed in the preceding 12 months in the planning area is greater than 80% of the planning area's capacity as determined by the department.

2. The department shall analyze each facility's capacity using comparative analysis techniques to ascertain how the resources of the facility are used.

3. In analyzing capacity pursuant to subds. 1. and 2., the department shall consider the number of cardiologists, cardiovascular technicians, cardiac catheterization nurses and technicians, medical intensive care beds available and utilized for cardiac catheterization patients, electrophysical set-ups, and special procedures rooms used for cardiac catheterization procedures.

(b) *Number of cardiac catheterization candidates.* The department shall not approve an application relating to cardiac catheterization services, equipment or facilities unless there is a need for the services, equipment or facilities. The determination of need shall be based upon an evaluation of the following factors which the applicant shall document in the application:

1. The projection of the annual number of adult and pediatric cardiac catheterization candidates, calculated separately, based in part on the number identified by referring physicians, facilities, and other sources.

Projections shall be based upon relevant historical data including the current number of identified candidates and shall include geographical origins of the candidates by zip code and county;

2. The projection of the number of adult and pediatric cardiac catheterization patients to be served by the applicant, based upon the following factors:

a. The incidence of conditions for which cardiac catheterization has been recognized to be an effective and appropriate mode of diagnostic evaluation and treatment; and

b. The number of potential candidates identified in subd. 1., where the population to be served has received cardiac catheterization services in the past 5 years or can reasonably be expected to be served in the next 5 years. In making these projections, the applicant shall consider the probable impact of anticipated technological advances and the introduction of new techniques to diagnose and treat cardiovascular disease. The insertion of pulmonary artery catheters or transvenous pacemakers shall not be counted in determining the number of cardiac catheterization procedures performed, and an application for the purchase of fluoroscopic equipment to perform these procedures shall not be considered by the department as an application for a cardiac catheterization laboratory; and

3. The validity of the underlying assumptions upon which the projections are based, and the validity of the data and the methodology used to calculate the projected number of adult and pediatric cardiac catheterization candidates and patients.

(c) *Establishment of a new cardiac catheterization service.* 1. The department shall not approve an application to establish a new cardiac catheterization service unless each of the following conditions, where applicable, is satisfied:

a. An application to establish an adult service or a combined adult and pediatric service clearly demonstrates that the project will have a sufficient volume of candidates and sufficient resources to perform a minimum of 300 adult cardiac catheterization procedures a year by the third year of operation;

b. An application to establish a dedicated pediatric cardiac catheterization service clearly demonstrates that the proposed service will have a sufficient volume of candidates and sufficient resources to perform a minimum of 150 pediatric cardiac catheterization procedures a year by the third year of operation;

c. A minimum of 500 cardiac catheterization procedures and other angiographic procedures has been performed each year for 3 consecutive years in each existing cardiac catheterization room in the planning area in which the program would be located.

d. The application is accompanied by an application from the same applicant to establish a cardiac surgery service and both applications are approved by the department.

2. The specific assumptions, data, methodology, and calculations used with respect to this paragraph shall be documented in the application.

(d) *Additional cardiac catheterization rooms.* 1. The department shall not approve an application to add an additional cardiac catheterization room in a facility already offering cardiac catheterization services unless a mininmum of 500 cardiac catheterization procedures has been performed each year for 3 consecutive years in each cardiac catheterization room located in facilities in the planning area that have an existing cardiac surgery service, and utilization is not expected to drop below this level in the 3 years following approval. The minimum number of cardiac catheterization procedures may be adjusted downward to reflect other recognized uses for angiographic facilities.

2. The department shall not approve an application to add an additional cardiac catheterization room in a facility that does not have an existing cardiac surgery service.

(4) DATA REPORTING REQUIREMENT. Cardiac surgery and cardiac catheterization services shall provide the department and the appropriate HSA with data relating to the number of patients served, patient utilization, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the department. The department shall not request the information more often than twice a year.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.16 Perinatal service criteria. (1) USE. The criteria in this section shall be used by the department to review applications relating to perinatal care centers, high-risk obstetric services or neonatal intensive care units. The applicable criteria of s. HSS 123.13 shall also be used in the review of projects subject to this section.

(2) DEFINITIONS: In this section:

(a) "Genetic associate" means a health care professional who is trained and has experience in obtaining family genetic history, providing genetic counseling in uncomplicated cases and referring complicated cases to clinical genetic services.

(b) "High-risk obstetric service" means a service held out as combining specialized facilities and staff for the intensive care and management of high-risk maternal and fetal patients before and during birth, and to high-risk maternal patients following birth.

(c) "Low birth-weight" means under 5 pounds, 8 ounces, or under 2,500 grams.

(d) "Neonatal" means pertaining to the first 28 days following birth.

(e) "Neonatal intensive care bed" means a bed in a neonatal intensive care unit that is equipped with temperature support, oxygenation, a prolonged ventilation device, infusion pumps and continuous cardiopulmonary monitoring.

(f) "Neonatal intensive care unit" means a collection of neonatal intensive and intermediate care beds in a service combining specialized facilities, staff, and support services necessary for the intensive care and management of high-risk neonatal patients.

(g) "Neonatal intermediate care bed" means a bed in a neonatal intensive care unit that is equipped with temperature support, oxygenation, ventilating assistance, infusion pumps and continuous cardiopulmonary monitoring, for the care of a patient who requires a less intensive care and a lower ratio of nursing personnel to patient than a patient in an intensive care bed.

(h) "Perinatal" means pertaining to the mother, fetus or infant, in anticipation of and during pregnancy, and in the first year following birth.

(i) "Perinatal care center" or "center" means an organized, hospital-based health care service which includes a high-risk obstetrics service and a neonatal intensive care unit capable of providing case management for the most serious types of maternal, fetal and neonatal illness and abnormalities.

(3) NEED FOR PERINATAL SERVICES. (a) *Need for services in the planning area.* The department shall not approve an application subject to review under this section unless there is a need for the proposed project in the health planning area to be served by the applicant.

(b) *Calculation of projected bed need.* Except as provided in par. (cm), determination of need for the total of neonatal intensive and intermediate care beds in a health planning area shall be calculated in the following manner:

1. Divide the annual number of low birth-weight live births in the health planning area for the most recent year by the number of live births in the health planning area in that year;

2. Divide the result by 80; and

3. Multiply the result times 4, and the product times the projected annual number of live births in the health planning area in the year which is 5 years after the year in which the application is dated.

(c) *Adjustment of projected bed need.* The projected neonatal intermediate and intensive care bed need figure computed under par. (b) may be adjusted by the department to reflect the number of patients who use facilities located out of state or in adjacent health planning areas, and the number of patients from adjacent areas who use facilities within the health planning area.

(cm) *Bed need calculations in high occupancy planning areas.* 1. In any health planning area in which the average neonatal occupancy rate is in excess of 95%, the department may approve additional beds in a number sufficient to reduce the average neonatal occupancy rate to 75% in the health planning area if both of the following conditions are met:

a. The neonatal unit at the facility proposing the increase is operating at an occupancy rate of at least 90% for the 12 months preceding the receipt of an application; and

b. The project would result in either a conversion of hospital beds to neonatal intensive care unit beds at the facility proposing the project, or a reduction in hospital approved bed capacity which is equivalent to the increase in neonatal intensive care unit bed capacity at the facility proposing the project.

2. a. The allowable neonatal bed capacity in a health planning area which is operating at over 95% occupancy is calculated by dividing the most recently available annual neonatal patient days in perinatal care centers in the health planning area by the number of days in the year and then dividing that result by 0.75. The allowable neonatal bed capacity is then subtracted from the approved neonatal bed capacity in neonatal centers in the planning area to obtain the number of additional beds that may be approved by the department.

b. The data source for the most recently available total annual neonatal patient days shall be from the annual survey of hospitals or the HSA, whichever has the most current data.

(d) *Additional beds needed in the planning area.* The number of additional neonatal intermediate and intensive care beds needed in a health planning area shall be determined by subtracting existing and approved beds from the projected bed need.

(e) *Minimim delivery base for a new center.* The department shall not approve an application to establish a new perinatal care center unless the minimum projected annual number of deliveries within the health planning area from which the center expects to draw its high risk patients is 15,000 deliveries a year within 5 years from the date of application.

(f) *Minimum number of deliveries.* The department shall not approve an application subject to review under this section unless the applicant demonstrates that the center currently performs, or documents that upon initiation of service it will perform or currently performs the highest number of deliveries in the health planning area but not less than 1,400 deliveries per year, at least 1,500 deliveries annually, except that an application for renovation may be approved for a facility having fewer than 1,500 births if it is the only perinatal care center in the health planning area and it meets all other criteria in this section; and

(g) *Minimum number of beds.* The department shall not approve an application under this subsection unless the applicant demonstrates that the center has or will have in the case of a new service a minimum of 15 neonatal intermediate and intensive care beds and an occupancy rate of at least 75%. For renovation of an existing perinatal care center, an exception to the 15-bed minimum may be made where an annual average occupancy rate of 90% has been met by the center during the 2 years preceding the application or the hospital is part of a neonatal consortium identified in the state medical facilities plan and the applicant hospital demonstrates the highest occupancy rate in the consortium.

(h) *Existing center in the planning area.* The department shall not approve an application to establish a new perinatal care center in a health planning area where a perinatal care center already exists unless the existing centers in the health planning area meet all standards under this subsection and have operated at an annual average occupancy rate of 75% or more for the 2 years preceding the date of application.

(i) *Priority given to expand or renovate an existing center.* For a health planning area where a need is indicated for additional high-risk perinatal services or for the neonatal intensive care or high-risk obstetrics components of these services, an application to expand or renovate these services at an existing perinatal care center shall be given priority over pro-

posals to establish new high-risk perinatal services at other institutions in the health planning area.

(4) REQUIRED RESOURCES. The department shall not approve an application under this section unless:

(a) Both the neonatal intensive care and high-risk obstetrics components are located in the same facility;

(b) The applicant documents that the center has formal relationships with all hospitals that the center serves in the same or any other health planning area. Formal relationships shall include patient and service consultation and outreach education for staff;

(c) The applicant documents that the center has established, or will establish, a 24-hour telephone consultation service to physicians, other professionals and hospitals in the service area of the center;

(d) The applicant documents that the perinatal care center has or will have, at minimum, the following staff:

1. A director or co-director who shall be either a board-certified obstetrician with extensive training and expertise in maternal-fetal medicine or a board-certified pediatrician with extensive training and experience in neonatology;

2. Registered nutritionists with special knowledge of perinatal dietary management. In addition to meeting the normal and special needs of high-risk mothers and neonatal patients, the nutritionists shall have the ability to identify nutritional problems and plan for their treatment;

3. A genetic associate;

4. One or more medical social workers who have experience in the socioeconomic and psychological problems of high-risk mothers, infants and families;

5. For the high-risk obstetrics component of a maternal-fetal service, an obstetrician with a diploma of special competence in maternal-fetal medicine to be director, and a registered professional nurse with advanced training and experience in normal and high-risk obstetric care to direct the antepartum, intrapartum and postpartum nursing care of maternal patients; and

6. For the neonatal intensive care component of a neonatal service, a board-certified neonatologist to be director, and a registered professional nurse preferably with an advance degree in maternal-child or pediatric nursing and with experience and training in neonatal nursing to direct the nursing care given to high-risk neonates. The neonatal intensive care unit shall maintain minimum ratios of one registered nurse for every 2 intensive care patients and one registered nurse for every 4 intermediate care patients;

(e) The applicant documents that the center shall provide at minimum:

1. In-house 24-hour clinical laboratory services with capability to perform microstudies;

2. Anesthesia services available in-house 24 hours a day, and provided by a person with experience in the administration of obstetrical anesthesia;

3. In-house 24-hour x-ray and ultrasound services;

4. A developmental follow-up service for the continued evaluation of the neonatal patient following discharge and for the provision of postpartum maternal services including extended care of the mother, returning the mother to the referring physician or returning the mother to the referring facility; and

5. a. A 24-hour emergency transport service for high-risk mothers, high-risk neonatal patients, and mothers accompanying high-risk neonatal patients. The emergency transport service may be provided either through agreements with ambulance services outside of the perinatal care center or through a transport system operated by the perinatal care center.

b. The necessary equipment for high-risk neonatal transport shall include an infant transport incubator with a self-contained power source, an infant respirator, humidified air/oxygen supply, pump-controlled intravenous fluid therapy, emergency medications, monitoring equipment for an infant's temperature, heart rate and environmental oxygen concentrations, and transcutaneous PO_2 partial pressure of oxygen monitoring capabilities.

c. Transport personnel for high-risk maternal patients shall include a physician or nurse or other health care professional such as a paramedic or respiratory therapist who has undergone a program of in-service training in the preparation and transport of high-risk maternal patients. That individual's only responsibility is the care of the mother.

d. Transport personnel for high-risk neonatal patients shall include a physician or nurse or other health care professional such as a paramedic or respiratory therapist who has undergone a program of in-service training in the preparation and transport of high-risk neonatal patients. That individual's only responsibility is the care of the neonatal patient.

6. Family planning services as part of the perinatal services and abortion services, or information as to where such services may be obtained. Nothing in this subdivision may be construed:

a. To require any individual to perform or assist in the performance of any procedure or to provide any information if contrary to his or her religious beliefs; or

b. To require any hospital to make its facilities available for the performance of any procedure or provision of any information if prohibited by the hospital on the basis of religious beliefs.

(5) DATA REPORTING REQUIREMENT. All perinatal services in the state shall provide the department and the appropriate HSA with data relating to the number of patients served, patient utilization, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the depart-

ment. The department shall not request the information more often than twice a year.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; am. (3) (b) (intro.), cr. (3) (cm), Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.17 End-stage renal disease service criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications relating to end-stage renal disease services. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Acute dialysis" means dialysis which, because of emergency medical necessity, is furnished to a patient on a temporary inpatient basis in a hospital. "Acute dialysis" may be dialysis for acute renal failure or acute dialysis for chronic renal failure.

(b) "Agreement" means a written document executed between an ESRD unit and another unit in which the other unit agrees to furnish specified services to patients and to assume responsibility for obtaining reimbursement for those services.

(c) "Approved" means authorized to operate under ch. 150, Stats., ch. HSS 152 and 42 CFR 405.

(d) "Arrangement" means a written document executed between an ESRD unit and another unit in which the other unit agrees to furnish specified services to patients with the ERSD unit retaining responsibility for the services and for obtaining reimbursement for them.

(e) "Chronic maintenance dialysis" means dialysis regularly furnished on an outpatient basis to an ESRD patient at a renal dialysis facility or center, at any level of patient involvement.

(f) "Chronic maintenance dialysis station" or "station" means a designated space with the plumbing, electrical system, dialysis machine, bed or lounge chair and other equipment needed to perform dialysis on an ESRD patient.

(g) "Dialysis" means a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane.

(h) "Dialysis machine" means the device used to perform dialysis which does not require approval of the department and may be used as back-up support for a station, for care of acute patients or for patients who require isolation.

(i) "End-stage renal disease" or "ESRD" means the stage of kidney impairment that is irreversible and requires a regular course of dialysis or renal transplantation to maintain life.

(j) "Furnishes directly" means the the ESRD unit provides the service through the unit's own staff and employes or through persons under direct contract to furnish services for the facility.

(k) "Hemodialysis" means a procedure whereby blood is passed through an artificial kidney and the waste projects diffuse across a man-

made membrane into a bath solution, known as dialysate, after which the cleansed blood is returned to the patient's body.

(l) "Hospital-based renal dialysis facility" or "facility" means a hospital unit approved by the department under ch. HSS 152 and 42 CFR 405 to furnish chronic maintenance dialysis, with or without self-care dialysis training, or inpatient dialysis.

(m) "Inpatient dialysis" means dialysis which, due to medical necessity, is furnished to an ESRD patient on a temporary hospital inpatient basis.

(n) "Outpatient dialysis" has the meaning prescribed for "chronic maintenance dialysis" in par. (e).

(o) "Pediatric" means the offering and provision of services to children age 16 and below.

(p) "Peritoneal dialysis" means a procedure whereby dialysate is introduced into and removed periodically from the patient's abdominal cavity and the waste products pass through the peritoneal membrane into the abdominal cavity and are removed with the dialysate.

(q) "Renal dialysis center" or "center" means a hospital-based unit approved by the department under ch. HSS 152 and 42 CFR 405 to furnish a variety of diagnostic, rehabilitative and therapeutic dialysis services required for the care of ESRD patients, including inpatient dialysis furnished directly or by arrangement.

(r) "Renal transplantation" means a process by which a kidney is excised from a live or cadaveric donor and then implanted in an ESRD patient. Renal transplantation includes supportive care furnished to the donor and recipient prior to and following implantation.

(s) "Renal transplantation center" means a hospital unit approved by the department under ch. HSS 152 and 42 CFR 405 to furnish renal transplantation and other medical and surgical specialty services required for the care of the donor and renal transplant patient, including inpatient dialysis furnished directly, by arrangement or by agreement.

(t) "Renal transplant surgeon" means a physician licensed in Wisconsin who is board-eligible or board-certified by the American board of surgery, or by an equivalent certifying body as determined by the department on recommendation of the Wisconsin chronic renal disease advisory review committee established under ch. HSS 152, and who is experienced in the performance of renal transplants and the care of renal transplant patients in an accredited institution.

(u) "Self-care dialysis" means chronic maintenance dialysis performed by a trained ESRD patient or patient helper, or both, at home or in a facility or center approved under ch. HSS 152 and 42 CFR 405.

(v) "Self-care training program" means a program which formally trains ESRD patients, patient helpers, or both, to perform dialysis.

(w) "Self-care training station" means a station used to train self-care patients, patient helpers or both to perform dialysis.

(3) NEED FOR CHRONIC MAINTENANCE DIALYSIS SERVICES. (a) *New facilities and centers.* The department shall not approve an application to establish a new facility or center unless:

1. Other approved facilities or centers in the health planning area or adjacent health planning areas are unable to provide the service, or patients are required to travel more than 90 minutes by automobile to an approved facility or center;

2. The applicant demonstrates that the facility or center will have at least 6 stations and an average of 4.5 or more dialyses per station per week in a metropolitan statistical area of 500,000 population or greater, or will have at least 3 stations and an average of 4.0 or more dialyses per station per week in a metropolitan statistical area with a population under 500,000 or an area not included in a metropolitan statistical area;

3. Each existing approved facility and center in the same or adjacent health planning areas has a utilization rate of at least 80% as calculated in par. (c) 1 or 2. An exception to the 80% utilization rate standard may be made by the department if the patients are required to travel more than 90 minutes by automobile to an existing approved facility or center; and

4. There is no pending application to expand an existing facility or center in the same or adjacent health planning areas.

(b) *New pediatric facilities or centers.* 1. The department shall not approve an application to establish a new pediatric facility or center unless the applicant demonstrates that the facility or center will have at least 3 pediatric stations, will have an average of 4.0 or more dialyses per station per week and will be located in a metropolitan statistical area of 500,000 population or greater.

2. Pediatric centers or facilities are not subject to par. (a) 2. to 4.

(c) *Applications from existing facilities and centers.* The department shall not approve an application of an existing facility or center unless there is a need for the project. In determining whether a need for the project exists, the department shall consider:

1. The utilization of chronic maintenance hemodialysis stations. a. A center or facility having 5 or fewer stations and proposing to add stations up to a total not exceeding 6 shall be approved only after the facility or center meets or exceeds a utilization rate of 80% over the previous three months. The utilization rate is determined by dividing the total number of chronic maintenance hemodialysis treatments per week in the facility or center by the maximum number of chronic maintenance hemodialysis treatments required per week in the facility or center. The maximum number of chronic maintenance hemodialysis treatments required of a facility or center having 5 or fewer stations shall be one treatment per chronic maintenance hemodialysis station per day times 6 days of operation per week times the number of chronic maintenance hemodialysis stations in the facility or center.

b. Expansion beyond 6 hemodialysis stations in a facility or center shall be approved only after the facility or center meets or exceeds a utilization rate of 80%. The utilization rate is determined by dividing the total number of chronic maintenance hemodialysis treatments per week in the facility or center by the maximum number of chronic maintenance

hemodialysis treatments required per week in the facility or center. The maximum number of chronic maintenance hemodialysis treatments required of a facility or center having 6 or more hemodialysis stations shall be 2 treatments per chronic maintenance hemodialysis station per day times 6 days of operation per week times the number of chronic maintenance hemodialysis stations.

c. Self-care hemodialysis training stations shall be excluded from calculations under subpars. a. and b. at the rate of one exclusion for each 6 successfully trained home patients per station within the year preceding the application date;

2. The utilization of chronic maintenance peritoneal dialysis stations.

a. The department shall not approve an application for a chronic maintenance peritoneal dialysis station unless the applicant is already approved for chronic maintenance hemodialysis services.

b. A facility or center proposing to establish peritoneal dialysis stations shall demonstrate that at least one of the facility's patients is in need of this type of treatment per proposed station.

c. A center or facility proposing to expand peritoneal dialysis services shall be approved only after the facility or center meets or exceeds a utilization rate of 80%. The utilization rate is determined by dividing the total number of chronic maintenance peritoneal dialysis treatments per week in the facility or center by the maximum number of chronic maintenance peritoneal dialysis treatments possible per week in the facility or center. The maximum number of chronic maintenance peritoneal dialysis treatments possible per week is one treatment per station per day times 6 days of operation per week times the number of chronic maintenance peritoneal dialysis stations.

d. Self-care peritoneal dialysis training stations used for the purpose of self-care training shall be excluded from consideration under subpars. a. to c. as active treatment stations at the rate of one exclusion for each 6 successfully trained home patients per station within the year preceding the application date;

3. The utilization of self-care training stations. A facility or center proposing to establish or expand a self-care training program shall have trained at least 6 patients for home dialysis per existing station within the year preceding the date of application;

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

5. Alternative methods of providing care and treatment for ESRD patients; and

6. The existence of a documented medical emergency situation or seasonal influx of patients.

(4) REQUIRED RESOURCES. The department shall not approve an application for a chronic maintenance dialysis service unless the service complies with ch. HSS 152 and 42 CFR 405.

(5) NEED FOR RENAL TRANSPLANTATION SERVICES. (a) For the purpose of review of applications for the establishment of renal transplantation services, the state shall constitute a single planning area. The population

base required to support a single renal transplantation center shall be at least 2 million persons.

(b) The department may not approve an application to establish a renal transplantation center unless there is a need for the center. Determination of need for a renal transplantation center shall be based upon the following considerations:

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

2. The inability of existing renal transplantation centers in Wisconsin and adjoining states to provide services to patients from Wisconsin.

(c) Applicants proposing to establish renal transplantation centers shall demonstrate that:

1. They will perform at least 25 transplants the first year of operation and at least 50 transplants the second year of operation; and

2. It is not possible for existing renal transplantation centers to provide the service.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.18 Radiation therapy service criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications relating to radiation therapy services and to review applications relating to megavoltage radiation therapy machines. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Dosimetrist" means an individual who assists in the development of treatment plans for patient receiving radiation therapy. The dosimetrist's background may be in physics, radiation therapy or dosimetry.

(b) "Level I facility" means a facility providing radiation therapy services that is capable of treating all forms of cancer, treats more than 300 patients annually, has postgraduate training programs in radiation oncology, conducts cancer treatment research and disseminates research findings.

(c) "Level II facility" means a facility providing radiation therapy services that is capable of treating most forms of cancer, that treats more than 300 patients annually.

(d) "Level III facility" means a facility providing radiation therapy services that is capable of treating some forms of cancer.

(e) "Megavoltage radiation therapy machine" or "machine" means a radiation therapy machine with energy capability in excess of one million volts, of which there are 4 types:

1. "Cobalt radiation therapy machine" means a machine having both rotational and fixed gantry capabilities, a minimum source-axis distance (SAD) of 80 centimeters, and the necessary attachments for blocking trays and wedge filters and an assortment of filters;

2. "Low energy linear accelerator" means a machine having a stationary or rotational gantry-mounted photon beam equal to or less than 7 MeV without electron capability;

3. "Medium energy linear accelerator" means a machine which can provide an x-ray beam at 8 to 15 MeV and has an electron therapy capability at a series of energies up to 15 MeV; and

4. "High energy linear accelerator" means a machine which can provide x-ray and electron therapy energy capability of 16 to 25 MeV or more.

(f) "Medical physicist" means an individual with an advanced degree in physics who has 2 to 3 years of full-time radiation therapy experience working under the direction of a certified clinical radiation physicist in the clinical setting or an individual certified or eligible for certification by the American board of radiology.

(g) "MeV" or "megavoltage" means energy capability in excess of one million volts.

(h) "Radiation oncologist" means a physician who is certified by the American board of radiology in therapeutic radiology, or its equivalent or a physician certified by the American board of radiology in general radiology, who has spent a minimum of one and preferably 3 to 4 years in training under the supervision of a qualified radiation oncologist and who is in the full-time practice of radiation oncology.

(i) "Radiation oncology" means a clinical and scientific specialty devoted to the management of patients with cancer and other neoplasms by ionizing radiation alone or combined with other cancer treatment modalities.

(j) "Radiation therapy service" or "service" means a clinical medical service in which patients with cancer, other tumors, or neoplasms are treated with ionizing radiation.

(k) "Radiation therapy technologist" means an individual who has completed an approved training program and is registered as a radiation therapy technologist by the American registry of radiologic technologists.

(l) "Treatment visit" means one patient visit where radiation is specifically applied to at least one cancer or other tumor or neoplasm site.

(3) NEED FOR RADIATION THERAPY SERVICES. The department shall not approve an application relating to a radiation therapy service or megavoltage radiation therapy machine unless the applicant demonstrates that the project will be adequately utilized and is needed.

(a) *Utilization.* 1. The department shall not approve an application under this subsection unless the applicant demonstrates that each machine will have sufficient resources and patient volume to treat, with each piece of equipment, an average of 300 patients annually within 3 years following initiation of the service. However, for level III facilities located more than one hour's normal driving time from a level I or II facility, the department may adjust this requirement downward to a number no lower than 200 patients annually.

2. The department shall not approve an additional machine unless every other machine in the health planning area in the same level of facility is performing at least 6,000 treatment visits a year. However, for level III facilities located more than one hour's normal driving time from a level I or II facility, the department may adjust the existing unit utilization requirement downward to a number no lower than 4,000 treatment visits annually.

(b) *Need determination methodology.* 1. Need shall be determined based on the number of patients currently being treated or to be treated, the cancers to be treated and the location of other services and machines accessible to the patients served.

2. The methodology used to determine expected utilization of the project shall include the following components:

a. The incidence of cancer in the health planning area;

b. The origin by zip code of cancer patients to be served by the service, machine or facility;

c. The severity of illness of the population to be served, as shown by medical records;

d. The number of cancer patients treated annually or referred for treatment to other radiation therapy facilities or services, as shown by patient medical records;

e. The number of treatment visits annually; and

f. Any unusual needs of the population to be served which would influence patient utilization of the proposed service or machine.

(4) FACILITY LEVEL. For the purpose of reviewing applications under this section, the department shall classify all facilities providing radiation therapy services by facility level.

(a) *Level III facilities.* Level III facilities shall meet the requirements of this paragraph.

1. Personnel requirements are:

a. A radiation oncologist on the hospital's active or associate medical staff or on a consultant basis;

b. A medical physicist employed by the hospital or on a consultant basis; and

c. A minimum of 2 radiation therapy technologists for each megavoltage radiation therapy machine. The technologists may be shared with other hospital services or with other hospitals or may be obtained through contracted services.

2. Equipment and facility requirements are:

a. Megavoltage radiation therapy equipment;

b. A colbalt radiation therapy unit or a low energy linear accelerator;

c. Treatment planning computational capability on a consulting basis;

d. Follow-up facilities;

e. Data storage and retrieval, either in-house or shared;

f. Radiation physics facilities and part-time office space;

g. An electronics shop on a shared basis; and

h. A machine shop on a shared basis.

(b) *Level II facilities.* Level II facilities shall meet the requirements of this paragraph.

1. Personnel requirements are:

a. Two radiation therapy technologists for each megavoltage radiation therapy machine;

b. Two full-time radiation oncologists;

c. One full-time medical physicist for every 400 patients;

d. A full-time registered or licensed practical nurse;

e. A dosimetrist; and

f. A full-time machinist or mold technician.

2. Personnel listed under subd. 1 b. to f. may be shared with other hospital services or with other hospitals or may be obtained through contracted services.

3. Equipment and facility requirements are:

a. A cobalt radiation therapy machine or a low energy linear accelerator. The facility may also have a medium energy linear accelerator;

b. Kilovoltage radiation therapy equipment or a linear accelerator with electron capability or both;

c. Discrete radioactive sources;

d. A treatment planning simulator;

f. Access to a minor surgical suite;

g. Follow-up facilities;

h. A mold room;

i. Data storage and retrieval, either in-house or shared;

j. A radiological physics facility;

k. An electronics shop, either in-house or shared; and

l. Access to computerized tomography services.

(c) *Level I facilities.* Level I facilities shall meet the requirements of this paragraph.

1. A level I facility shall meet the personnel requirements of par. (b) and in addition have:

a. One medical physicist for every 300 patients. If there is only one, that one shall be board-certified. If there is more than one, one shall be board-certified;

b. One full-time radiation biologist; and

c. A residency training program for radiation therapy, approved by the American medical association and the American board of radiology.

2. The facility shall meet the equipment and facility requirements of par. (b).

(5) PROGRAM REQUIREMENTS FOR RADIATION THERAPY SERVICES. (a) Level I and II facilities shall have:

1. A multi-disciplinary tumor board consisting, at minimum, of the following professionals: a radiation oncologist, a medical oncologist, a surgeon trained in cancer surgery, a diagnostic radiologist, a pathologist and, to the extent possible, the referring and attending physician; and

2. A tumor registry approved by the American college of surgeons.

(b) Level III facilities shall have a formal agreement with a tumor board of a level I or level II facility, and shall participate in an approved tumor registry.

(c) Each facility providing radiation therapy services or proposing to initiate radiation therapy services shall meet the requirements of ss. HSS 157.09, 157.10, 157.12 and 157.14 and 10 CFR 20, 30 and 35.

(6) DATA REPORTING REQUIREMENT. Radiation therapy services shall provide the department and the appropriate HSA with data relating to the number of patients served, patient utilization, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the department. The department shall not request the information more often than twice a year.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.19 Computed tomography criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications relating to computed tomography equipment. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head and body.

(b) "Head equivalent computed tomography" or "HECT" means a weighted approach to assess CT utilization, taking into account the relative time necessary to perform different studies, as expressed in head equivalent units, with the HECT count derived by multiplying the actual or projected utilization figure for each type of procedure by the following factors and totalling the weighted utilization figures:

1. Head scan without contrast, 1.00;

2. Head scan with contrast, 1.25;

3. Head scan combined, 1.75;

4. Body scan without contrast, 1.50;

5. Body scan with contrast, 1.75;

6. Body scan combined, 2.75; and

7. Any spine scan, 3.00.

(c) "Residual salvage value" means the estimated amount for which the CT equipment can be sold, less any dismantling, removal or other costs, when retired from operation.

(d) "Scan" means the series of images or slices necessary for CT diagnosis of one anatomical area.

(3) NEED FOR COMPUTED TOMOGRAPHY SERVICES. The department shall not approve an application for fixed-base CT equipment unless the applicant demonstrates that:

(a) It has an approved bed capacity of at least 100 beds, or demonstrates to the department's satisfaction that there are clinical and financial justifications for waiving this requirement;

(b) Its 3-year projected utilization uses the methodology found in appendix B or another nationally recognized projection methodology. The applicant shall provide a rationale for all assumptions used in the utilization calculations. Justifiable modifications for changes in the inpatient to outpatient ratio may be used;

(c) The proposed equipment will perform 1,500 HECTs the first year of operation, 1,750 HECTs the second year of operation and 2,000 HECTs every year thereafter; and

(d) The projected changes for the proposed service and, where applicable, any physician charges are comparable to charges for similar services provided in similar settings.

(4) MOBILE CT SERVICES. (a) For an application relating to a mobile CT service, the applicant shall be the person acquiring the CT equipment.

(b) The applicant shall meet the standards under sub. (3) (b) to (d).

(5) MULTIPLE SCANNER INSTALLATIONS. The department shall not approve an application for additional CT equipment unless:

(a) The existing CT scanner performed 4,000 or more HECTs during the 12-month period preceding the date of application;

(b) The applicant provides the department with a 3-year utilization history of the existing scanner; and

(c) The applicant meets the standards under sub. (3) for the additional scanner.

(6) EQUIPMENT REPLACEMENT. (a) The department shall not approve an application for a replacement scanner unless the applicant demonstrates that:

1. The highest residual salvage value from among three bids for the replaced equipment has been obtained, and this value has been applied toward the purchase of new equipment; and

2. The original scanner will not be used by the applicant after the expiration of the 6-month transition period. The 6-month transition period shall begin on the operational date of the replacement scanner.

(b) The replaced original scanner shall be considered additional CT equipment for purposes of this review. An applicant using the original scanner after the replacement scanner's 6-month transition period has expired shall submit an application for its approval under this chapter.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.20 Air ambulance service criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications to implement air transport services under s. 150.61 (2), Stats., and other applications relating to air ambulance services. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Air ambulance" means any aircraft operated under authority of 14 CFR 135, Subch. A, which is specifically designed, constructed, modified or equipped and staffed to be used primarily for the transportation of ill or injured persons.

(b) "Air ambulance services" means "air transport services" as used in s. 150.61 (2), Stats., which is the regular offering of transportation to ill or injured persons in an air ambulance.

(3) PLANNING AREAS. For purposes of this section, there shall be 2 planning areas in the state. Area I shall consist of health planning areas 2, 3 and 4. Area II shall consist of health planning areas 1, 5, 6 and 7.

(4) NEED FOR AIR AMBULANCE SERVICES. The department shall not approve an application relating to air ambulance services unless there is need for the services. To establish need, the applicant shall:

(a) Demonstrate that the services will make life-saving differences for patients with acute conditions;

(b) Project the annual number of patients in the planning area with an illness or injury requiring intervention and transport and for whom transport time is crucial. In making that projection, the applicant shall take into account:

1. The origin, by hospital or sending site, and diagnoses of the patients to be transported; and

2. The availability and adequacy of existing land and air transportation; and

(c) Demonstrate that approval of the air ambulance would not result in there being more than one airplane-type air ambulance and one helicopter-type air ambulance in that planning area.

(5) REQUIRED RESOURCES. (a) The department shall not approve an application relating to air ambulance services unless the applicant demonstrates that:

1. Trained personnel eligible to serve as ambulance attendants under ch. HSS 110 will be available at all times for the treatment and transport of critically ill patients; and

2. Appropriate personnel trained in the diagnosis and treatment of critically ill patients are available at all times in the hospital to which patients are transported.

(b) The applicant shall provide the names of hospitals to which patients are going to be transported and have a written agreement with each hospital. The agreement shall state that the hospital will:

1. Accept patients transported by the applicant; and

2. Provide the personnel required under par. (a) 2.

(6) FINANCIAL FEASIBILITY. The department shall not approve an application relating to air ambulance services unless the applicant demonstrates that the services are financially feasible by:

(a) Documenting the projected direct and indirect costs of providing the services, including costs of personnel, equipment, facilities and supportive services;

(b) Establishing a separate cost center for all direct costs and procedures which incorporates full cost accounting methods for allocating any indirect costs;

(c) Documenting that the projected charges for providing the services, including personnel, equipment, facility and supportive service charges, are reasonable; and

(d) Documenting the net financial impact on hospital rates.

(7) CONCURRENT REVIEW. (a) The provisions in s. HSS 123.08 (10) shall be used for concurrent review when there are 2 or more applications for the same planning area. The department shall approve the application receiving the highest score based on a comparative analysis of the applications using all applicable review criteria in s. HSS 123.13 and the review criteria in subs. (4) to (6). In addition, preference shall be given to the application which:

1. Proposes a multifacility or shared service arrangement and, if more than one application proposes a multifacility or shared service arrangement, the one that provides written documentation which demonstrates the greatest number and diversity of referring specialists; and

2. Provides the best geographical accessibility for the population being served in the planning area as determined by an analysis by the department of areas where the applicant intends to focus its resources and marketing strategies for the proposed service. Each applicant shall provide the department with the number of anticipated patient referrals from each identified market area and the patient origin by hospital or sending site for all referrals.

(b) The department shall approve the application that is determined to be the most feasible after a review of the following considerations:

1. The number of specialized services in the project's receiving hospital or hospitals, such as burn, pediatric intensive care, dialysis, perinatal and organ transplantation services;

2. The intensive care capability of the project's receiving hospital or hospitals in terms of specialized units, number of beds and staffing; and

3. The specialized operating room capability of the receiving hospital or hospitals.

(8) DATA REPORTING REQUIREMENTS. All air ambulance approval holders shall provide the department and the appropriate HSA with data relating to the number of patients served, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the department for purposes of evaluation and project review. The department may not request the information from each service more than twice in a 12-month period.

(9) PROJECT IMPLEMENTATION TIMETABLE. A timetable for implementing the project shall be included in the approval. The timetable shall specify deadlines by which the approval holder must do each of the following:

(a) Meet its projected utilization under sub. (4) (b);

(b) Pay its full direct and indirect costs entirely from charges for the service; and

(c) Establish the separate cost center required under sub. (6) (b).

(10) REVOCATION OF APPROVAL. (a) Pursuant to ss. 150.11 (4) and 150.75, Stats., the department may revoke any approval issued under this section for either of the following reasons:

1. The approval holder has not obtained a license under s. 146.50, Stats., and ch. HSS 110 within the period specified in the approval or does not maintain this licensure; or

2. The approval holder misses any deadline specified in the timetable for implementing the project and fails to make a good faith effort to meet the deadline.

(b) The approval holder has a right under s. 227.42, Stats., to a contested case hearing to review a revocation under this subsection.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; r. and recr. Register, February, 1987, No. 374, eff. 3-1-87.

HSS 123.21 Home health agency criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications for the operation of home health agencies. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Acute care hospital discharges under age 65" means the number of discharges of patients under age 65 from hospitals to home or self-care or to home care provided by a home health agency as reported on the most recent hospital discharge survey conducted by the department.

(b) "Home health agency" has the meaning specified in s. HSS 133.02 (3).

(c) "Population age 65 and over" means the estimated population of persons age 65 and over not residing in institutions, as reported by the state department of administration.

(d) "Service area" means the counties designated by the applicant within which the proposed services are to be delivered.

(e) "Therapy service" means physical, occupational, speech or other therapy, medical social service, home health aide service, or any other medically oriented service except skilled nursing care.

(f) "Unduplicated admissions" means the number of patients served by a home health agency during a calendar year regardless of the number of times an individual was admitted to the agency during the year, as reported to the department.

(3) NEED FOR SERVICES. (a) *Unserved population in need of service.* The department shall not approve an application for the operation of a home health agency unless the unserved population in need of service in the county as calculated under this paragraph exceeds 100 people. The department shall calculate the unserved population in need of service in a county by subtracting the population currently being served in the county from the population base in need of service in the county.

1. The population base in need of service in a county is the sum of 6% of the acute care hospital discharges under age 65 plus 6% of the population age 65 and over.

2. The population currently being served in a county is the sum of the following:

a. The total number of unduplicated admissions of all home health agencies approved to provide services in the county as reported to the department for the most recently completed calendar year;

b. The increase, if any, in the unduplicated admissions of each agency reporting in subpar. a. over their unduplicated admissions reported for the year previous to the most recently completed calendar year;

c. The total number of projected third year unduplicated admissions, as stated in the approval, for each agency approved within the past 3 years if greater than the actual number of unduplicated admissions experienced by the agency during the calendar year reported in subpar. a. If an agency's third year projections are counted under this subparagraph, the total number under subpar. a. shall be reduced by the number of unduplicated admissions the agency reported, if any, to the department under subpar. a; and,

d. The total number of projected third year unduplicated admissions reported in all applications for which an initial finding has been issued but for which a final decision has not been issued.

(b) *Projected utilization.* The applicant shall provide the department with the projected utilization of its service. These projections shall include:

1. A description of the assumptions and methodology used to project utilization;

2. The applicant's proposed service area; and,

3. Annual unduplicated admission projections for the agency's first 3 years of operation based upon relevant historical data, sources of potential referrals, the estimated number of unduplicated admissions from each referral source as identified in sub. (6) (a) through (d), and any other sources of clients outside the normal referral sources.

(4) LIMITATIONS. The applicant may only provide home health services to patients residing in the counties stated in the approval or license.

(5) CAPABILITY OF PROVIDING RESOURCES. The department shall not approve a new home health agency unless the agency employs or demonstrates it has, or can establish, formal contracts for the necessary multidisciplinary professional staff capable of meeting service needs of home care patients. The applicant shall provide copies of written contractual agreements with a provider of each therapy service to be offered, letters of intent to enter into contractual agreements or employment relationships once a certificate of approval and license have been obtained, or documentation that the therapy service will be provided by a person now employed by the applicant.

(6) RELATIONSHIP TO EXISTING HEALTH CARE SYSTEM. The department may disapprove a new home health agency if the applicant fails to provide the department with the following:

(a) Letters of support, which shall include estimates of future referrals from physicians, clinics, social service agencies, county departments of social services and any other health or social service referral source;

(b) A copy of a written referral agreement or letter of support from each hospital in the agency's service area from which the proposed agency anticipates referrals including an estimate of the number of projected annual referrals;

(c) A copy of a written referral agreement or letter of support from each long-term care facility in the agency's service area from which the proposed agency anticipates referrals, including an estimate of the number of projected annual referrals;

(d) Copies of written referral agreements or letters of support which include estimates of future referrals from county or state programs providing alternatives to institutionalization, such as the department's community options program; and

(e) A copy of a formal plan of the home health agency for promoting community awareness of the service within the service area.

(7) FINANCIAL FEASIBILITY. The department shall not approve a new home health agency unless the applicant demonstrates that the agency is financially feasible by:

(a) Documenting the method and source of financing, including interest and other costs related to the establishment of the agency;

(b) Documenting direct costs, including depreciation, interest, advertising or pomotion, paraprofessional, clerical, and professional staff, supplies, maintenance and leasing;

(c) Documenting indirect costs, including space, management support and other relevant overhead costs;

(d) Demonstrating that it has sufficient finances to operate the agency for at least 90 days without reimbursement by producing either a letter of credit from a lending institution or an audited financial statement showing adequate cash reserves; and

(e) Demonstrating that its projected nonprofessional and professional charges for nursing services and therapy services, on a per visit basis, are comparable to rates charged by other home health agencies located in the service area the applicant will serve and are sufficient to cover the operating costs documented in par. (b) and (c) given the number of projected admissions documented in sub. (3) (b).

(8) CONCURRENT REVIEWS. If 2 or more concurrently reviewed applications meeting the requirements of subs. (3), (5), (6) and (7) and the criteria in s. HSS 123.13 propose to establish a home health agency in the same county and there is not sufficient unserved population in need of service in the county to approve all of the applicants, the department shall approve the application or applications which score the highest based on a comparative analysis and a rank ordering according to:

(a) Whether the applicant is an existing licensed agency currently providing home health care services;

(b) Whether the applicant has demonstrated it will more effectively use personnel as documented in s. HSS 123.13 (7);

(c) Whether the applicant will charge lower nonprofessional and professional fees for nursing and therapy services as documented in sub. (7) (e);

(d) Whether the applicant has a more extensive service area as documented in sub. (3) (b) and supported by written referral agreements in sub. (6) (a) through (d);

(e) Whether the applicant offers a broader range of services based in part on the documentation provided in sub. (5); and,

(f) Whether the applicant presents the stronger documentation of potential sources and number of referrals as documented in sub. (6) (a) through (d).

(9) INVALIDATION OF AN APPROVAL. (a) The department may declare an approval for a new home health agency invalid if the approval holder has not obtained a license under s. 141.15, Stats., and ch. HSS 133 within one year from the date of the approval, pursuant to s. 150.75, Stats. The approval holder has a right to a hearing under s. 227.42, Stats., to review an invalidation under this paragraph.

(b) Since the department is relying on the representations in the application to be accurate and truthful when granting an approval, the continuing validity of an approval depends on substantial compliance by the applicant with the rates it has represented it will charge. Therefore the approval of any home health agency is invalid under s. 150.75, Stats., if the agency charges rates substantially in excess of those authorized in the approval during the first 2 years of operation. As used in this paragraph, "substantial compliance" means the rates charged in the first 2 years of operation will not exceed the rates established in the approval by more than 5%.

(10) DATA REPORTING REQUIREMENTS. Home health agencies shall provide the department and the HSA with data relating to operating costs and to numbers, types, and origin of patients and other demographic information. The information shall be provided on request of the department, but not more often than twice a year unless current data are required for the review of a proposal for the addition of a new home health agency in the county.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.22 New medical technology criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications for approval to acquire technology determined under s. HSS 123.05 (6) no longer to constitute innovative medical technology, unless technology-specific criteria have been adopted under sub. (4). The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITION. In this section, "acquire technology" means to obtain technology by purchase, donation, on-site development, lease or comparable arrangement.

(3) REVIEW CRITERIA. The department shall not approve an application to acquire for general medical use any technology previously exempted from review under s. 150.63 (2), Stats., and subsequently determined under s. HSS 123.05 (6) no longer to constitute innovative medical technology unless:

(a) The technology has been classified by the U.S. food and drug administration as a class I, class II, or class III device under 21 USC 360c to k;

(b) The applicant demonstrates that the technology has documented clinical applications;

(c) The applicant identifies the specific discharge diagnoses for which the technology's clinical application is efficacious;

(d) The applicant demonstrates that the expected patient utilization for each efficacious clinical application of the technology will be sufficient to justify its costs. The number of expected patients shall consist of the total of inpatients discharges, outpatients and referral patients, by diagnosis type, in the year preceding application;

(e) The applicant demonstrates that the capital costs, operating expenses and charges are reasonable and cost beneficial. Capital costs of the technology include any facilities necessary to house the technology, and the direct and indirect resource expense associated with the provision of the service rendered by the technology. In evaluating reasonableness, the department may consider:

1. The unit cost of the services provided; and

2. Savings realized by reduction in health care costs due to the technology's effectiveness in advancing diagnosis or therapy.

(f) The application meets the technology-specific criteria adopted pursuant to sub. (4).

(4) TECHNOLOGY-SPECIFIC CRITERIA. The department finds that the public health and welfare necessitates adopting rules governing acquisition of technology under this section pursuant to the emergency rule-making procedures set forth in s. 227.24, Stats. The department may publish emergency rules pursuant to this subsection on or after the effective date of the rule adopted under s. HSS 123.05 (6) (b) determining the technology no longer to be innovative medical technology. Rules adopted under this subsection shall set forth technology-specific criteria to be used in the review of applications subject to this section and shall consider cost containment as the first priority.

(5) PARTICIPATION IN DATA BASE DEVELOPMENT. Notwithstanding s. HSS 123.08 (9), as a condition of approval, the applicant shall participate with the department in developing and maintaining a data base for departmental use in future reviews of other applications under this section.

(6) DEVELOPMENTAL PHASES. The applicant may include in a single application developmental phases of the technology which may require future capital expenditures.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; am. (1) and (4), Register, March, 1986, No. 363, eff. 4-1-86.

HSS 123.23 Hospital merger projects criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications under s. HSS 123.08 (12). If the criteria set out in this section are met, the criteria of ss. HSS 123.13 to 123.19 shall not be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Conditions beyond the control of the hospital" means a natural disaster or actual inflation rates which exceed those established using the hospital market projections of data resources, inc.

(b) "Weighted average" means each hospital's average rate prior to merger multiplied by the number of cases each rate is based on divided by the total number of cases for both hospitals.

(3) REVIEW CRITERIA. The department shall not approve an application under this section unless the applicant demonstrates that:

(a) The project will result in a net bed decrease for the proposed merged or consolidated hospital which meets the requirements of ss. HSS 123.13 (13) (e) and 123.27 (10) for the merging or consolidating hospital which has the greatest number of excess beds, as measured under those provisions;

(b) For service consolidation projects there will be an actual reduction in financial requirements in the third and subsequent years following completion of the project when compared to total financial requirements of the hospitals prior to merger or consolidation;

(c) The proposed rates exclusive of increases associated with conditions beyond the control of the merged or consolidated hospital to be establihsed in the approval under s. 150.75 (3), Stats., will be less than the weighted average of the rates of the hospitals prior to merger or consolidation;

(d) Resources will be more efficiently and economically used, when compared to the hospitals prior to merger or consolidation; and

(e) There will be a net reduction in the full-time equivalent employes by the third year after merger or consolidation.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; reprinted to correct error in (3) (a), Register, May, 1985, No. 353.

HSS 123.24 Magnetic resonance imaging criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications relating to magnetic resonance imaging. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Health service area" means a health planning area identified in appendix A, except that health planning areas 3 and 4 constitute one health service area and health planning areas 6 and 7 constitute one health service area for purposes of this section.

(b) "Magnetic resonance imaging" or "MRI" means a diagnostic technique that employs magnetic and radio frequency fields to produce images of body structures and organs.

(c) "Scan" means a series of images done at one patient visit.

(3) NEED FOR MAGNETIC RESONANCE IMAGING SERVICES. (a) The department shall not approve an application under this section if the approval of an additional MRI device would mean that the maximum number of MRI devices permitted in the health service area would be exceeded. The department shall establish this number for each service area by:

1. Ascertaining for each area the annual total number of inpatient clinically-applicable MRI discharges. This shall be accomplished by employing the methodology in appendix F and using the latest available statewide hospital discharge survey data adjusted by the overall percentage difference between the discharge survey data and admissions data from the most recent annual hospital survey;

2. Determining the estimated annual total number of MRI procedures for each area. This shall be accomplished by multiplying the number obtained under subd. 1. by 1.6666, to arrive at estimated total procedures, including outpatient procedures; and

3. Arriving at the maximum number of MRI devices in each area. This shall be accomplished by dividing the number obtained under subd. 2. by 3,400, and rounding each result to the nearest whole number.

(b) The department shall not approve an application under this section unless the applicant projects a minimum of 2,000 annual MRI procedures by:

1. Ascertaining its annual total number of hospital inpatient clinically-applicable MRI discharges by employing the methodology in appendix F and using the actual hospital inpatient discharge data for the 12-month period preceding the date of application. Any percentage of hospital inpatient discharges in designated major ICD-9-CM groupings shall be documented by the applicant. The combined documented percentage for

all applicants shall not exceed 100% of these discharges for any hospital; and

2. Determining the estimated annual total number of MRI procedures by muliplying the number obtained under subd. 1. by 1.6666, to arrive at estimated total procedures, including outpatient procedures.

(c) The department shall not approve an application under this section unless the applicant provides referral agreements with appropriate physicians and clinics indicating a commitment to use the MRI service or refer patients to the MRI service. These agreements shall include estimates of the number of MRI scans for patients of each member of the applicant's medical staff and for patients referred by in-state and out-of-state physicians.

(4) REQUIRED RESOURCES. The department shall not approve an application under this section unless:

(a) The applicant proves that the proposed MRI device has been classified by the U.S. food and drug administration as a class I, class II or class III device under 21 USC 360c to k;

(b) The applicant provides written documentation that the area housing the MRI device, including necessary arrangements for mobile MRI equipment, will be constructed in accordance with standards established by the U.S. food and drug administration, the manufacturer and the national electrical manufacturers association and in accordance with applicable federal and state standards;

(c) The applicant includes with the application a written plan for an ongoing quality assurance program for MRI which includes at least the following:

1. A safety manual governing the equipment and its location, providing coverage of security measures and hazards;

2. Procedures for managing emergencies within the MRI facility or with mobile equipment, in conformity with accepted medical practices; and

3. Protocols that ensure that all MRI scans performed are medically necessary and will not unnecessarily duplicate other services;

(d) The applicant documents that adequate numbers of at least the following personnel will be available, either through direct employment or through an agreement with the manufacturer or a service contract, consistent with the applicant's projected utilization determined under sub. (3) (b), patient needs and the facility's operational needs:

1. A director of the MRI service who is a board-certified or board-eligible radiologist, whose primary responsibility over the last 3 years has been in the interpretation of cross-sectional imaging for all body areas and who has had at least 60 hours of instruction in the methods and principles of MRI at a facility with an operational MRI device;

2. One or more licensed physicians who have attained a thorough knowledge of the methods and principles of MRI through continuing medical education (CME) credits, experience or post-graduate education which qualifies them to interpret MRI scans in the specialty field appropriate to each physician;

3. A medical physicist who is certified by the American board of radiology and has a thorough knowledge of MRI techniques; and

4. Technologists who have been specially trained in MRI methods;

(e) The applicant demonstrates that MRI will function as an integrated component of a comprehensive diagnostic imaging inpatient or outpatient service, by documenting in writing that it has access, either on-site or through formal referral arrangements, to equipment and personnel for conventional radiology, computed tomography, ultrasound, angiography and nuclear medicine;

(f) The applicant demonstrates that the proposed MRI service will serve as a regional resource for physicians by providing the department with the following:

1. A written plan for a system of referrals, which shall include a feedback mechanism for providing patient information to the referring physician and facility;

2. A written plan for maintaining current listings of appropriate clinical applications of MRI for the guidance of on-site and referring physicians and facilities; and

3. A written plan for a continuing education and training program, which shall include education of all interested physicians in the specific indications and contraindications of MRI use; and

(g) The applicant provides a written plan for scheduling patients that ranks patients in order of priority according to standards of need and appropriateness rather than source of referral.

(5) FINANCIAL FEASIBILITY. The department shall not approve an application unless the applicant demonstrates that the project is financially feasible by:

(a) Documenting that the projected average total cost per MRI procedure, including but not limited to fixed and variable operating costs, is similar to costs for similar MRI services provided in similar settings. In projecting the average total cost per MRI procedure, the applicant shall base this calculation on the projected utilization determined under sub. (3) (b);

(b) Documenting that the projected average charge per MRI procedure, excluding the charges for professional fees, ancillary services and hospitalization, is similar to charges for similar MRI services provided in similar settings;

(c) Documenting the projected overall charge per MRI procedure, which includes at least the average charge per MRI procedure under par. (b) plus charges for professional fees; and

(d) Documenting the net financial impact on its hospital rates, if the applicant is hospital-based.

(6) MOBILE MRI EQUIPMENT. For an application relating to mobile MRI equipment, the applicant shall be the person acquiring the MRI equipment.

(7) CONCURRENT REVIEW. The provisions in s. HSS 123.08 (10) shall be used for concurrent review when there are 2 or more applications. The

department shall approve the application or applications receiving the highest score based on a comparative analysis of the applications using all applicable review criteria in s. HSS 123.13, the review criteria in subs. (3) to (6) and the following special review criteria:

(a) Preference shall be given to the application proposing a multifacility or shared service arrangement and, if more than one application proposes a multifacility or shared service arrangement, the one that provides written documentation demonstrating the greatest number and diversity of patient referrals from referring specialists;

(b) Preference shall be given to the application providing the best geographical accessibility for the population being served in the health service area as determined by an analysis by the department of the geographical market areas that have been identified by each applicant as areas where the applicant intends to focus its resources and marketing strategies for the proposed MRI device. Each applicant shall provide the department with the number of anticipated patient referrals from each identified market area and the patient origin by county for all referrals; and

(c) Preference shall be given to the application providing the greatest number of MRI scan hours per week in relation to the number of qualified staff set forth in sub. (4) (d).

(8) DATA REPORTING REQUIREMENTS. All entities in the state having MRI shall provide the department and the appropriate HSA with data relating to the number of patients served, patient utilization, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the department for purposes of evaluation and project review. The department may not request the information more often than twice a year.

(9) REVISION OF THE RULE. The department shall review this section within 2 years of its effective date.

History: Cr. Register, March, 1986, No. 363, eff. 4-1-86; am. (2) (a), Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.25 Extracorporeal shock wave lithotripsy criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications relating to extracorporeal shock wave lithotripsy. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "ESWL procedure" means one patient treatment which includes setup time, using a computerized fluoroscopic x-ray system to position the stone in the passage of the shock waves and to monitor stone destruction, coordinating the shock waves with the electrocardiogram, delivering the shock waves and cleanup time.

(b) "Extracorporeal shock wave lithotripsy" or "ESWL" means a noninvasive technique for disintegrating urinary stones by focusing shock waves on a urinary stone from outside the body.

(c) "Lithotriptor" means the device used to generate the shock waves which disintegrate the urinary stones.

(d) "Percutaneous stone surgery" means removal of urinary stones by means of an incision through the skin rather than by ESWL.

(e) "Urinary stones" mean renal or kidney and ureteral calculi.

(3) NEED FOR ESWL SERVICES. The department shall not approve an application under this section unless:

(a) Approval would result in no more than one lithotriptor in the health planning area and no more than 2 lithotriptors statewide, not including any lithotriptor under an exemption granted pursuant to s. 150.63, Stats.; and

(b) The applicant demonstrates that the proposed lithotriptor will have sufficient resources, referrals and patient volume to support 800 procedures annually within 3 years following initiation of the service. Multifacility, free-standing, shared service and mobile ESWL applicants shall include patient volume from all participating hospitals, clinics and physician groups. A bilateral treatment of kidney stones shall count as 2 ESWL procedures. The department shall analyze the 3-year utilization projection based on written documentation provided by the applicant which includes:

1. The proposed area from which the applicant will draw its patients, including other states;

2. A description of the assumptions and methodology used to project utilization; and

3. The projected utilization from the proposed area under subd. 1. substantiated by referral agreements with appropriate physicians indicating their intent to use the lithotriptor or refer their patients to the lithotriptor. These agreements shall include estimates of the number of ESWL procedures for patients of each member of the applicant's medical staff and for patients referred by in-state and out-of-state physicians.

(4) REQUIRED RESOURCES. The department shall not approve an application under this section unless:

(a) The applicant proves that the proposed lithotriptor has been classified by the U.S. food and drug administration as a class I, class II or class III device under 21 USC 360c to k;

(b) The applicant provides written documentation that the area housing the lithotriptor, including necessary arrangements for mobile ESWL equipment, will be constructed in accordance with standards established by the U.S. food and drug administration and the manufacturer and in accordance with applicable federal and state standards;

(c) The applicant includes with the application a written plan for an ongoing quality assurance program for ESWL which includes at least the following:

1. A safety manual governing the equipment and its location, providing coverage of security measures and hazards;

2. Procedures for managing emergencies within the ESWL facility or with mobile equipment, in conformity with accepted medical practices; and

3. Protocols that ensure that all ESWL procedures performed are medically necessary and will not unnecessarily duplicate other services;

(d) The applicant documents that at least the following personnel will be available when patients are undergoing treatment:

1. A urologist who has attained a thorough knowledge of extracorporeal shock wave lithotripsy either by documented specific training or postgraduate education and experience;

2. An anesthesiologist; and

3. A technician with documented education and experience in radiology and lithotriptor technology;

(e) The applicant demonstrates in writing that it is able to provide the following care as needed for the patient to sustain operation of the ESWL service:

1. Medical services, which include at least:

a. Anesthesiology;

b. Cardiology;

c. Radiology, including diagnostic x-ray, fluoroscopy, intravenous pyelogram tomography, ultrasound, and placement of percutaneous nephrostomy for percutaneous stone surgery; and

d. Urology, capable of performing percutaneous nephrostomy, ureteroscopy, medical management of calculi, transurethral ureteral manipulation of the calculi, and surgery to remove calculi from the urinary tract;

2. Nursing services;

3. Laboratory services, as follows:

a. Chemistry;

b. Hemotology;

c. Microbiology; and

d. Urinalysis; and

4. Ancillary services, which include at least:

a. Pharmacy; and

b. Recovery room;

(f) The applicant demonstrates that many physicians will have access to and use the lithotriptor by providing the department with the following:

1. A written plan for a system of referrals, which shall include a feedback mechanism for providing patient information to the referring physician and facility; and

2. A written plan for a continuing education and training program, which shall include education of all interested physicians in the specific indications and contraindications of ESWL use; and

(g) The applicant provides a written plan for scheduling patients that ranks patients in order of priority according to standards of need and appropriateness rather than source of referral.

(5) FINANCIAL FEASIBILITY. The department shall not approve an application unless the applicant demonstrates that the project is financially feasible by:

(a) Documenting that the projected average total cost per ESWL procedure, including but not limited to fixed and variable operating costs, is similar to costs for similar ESWL services provided in similar settings. In projecting the average total cost per ESWL procedure, the applicant shall base this calculation on the projected utilization determined under sub. (3) (b);

(b) Documenting that the projected average charge per ESWL procedure, excluding the charges for professional fees, ancillary services and hospitalization, is similar to charges for similar ESWL services provided in similar settings;

(c) Documenting the projected overall charge per ESWL procedure, which includes at least the average charge per ESWL procedure under par. (b) plus charges for professional fees, ancillary services and hospitalization; and

(d) Documenting the net financial impact on its hospital rates, if the applicant is hospital-based, including the net change in surgical revenues which results from substitution of the new technology.

(6) MOBILE ESWL EQUIPMENT. For an application relating to mobile ESWL equipment, the applicant shall be the person acquiring the ESWL equipment.

(7) CONCURRENT REVIEW. The provisions in s. HSS 123.08 (10) shall be used for concurrent review when there are 2 or more applications. The department shall approve the application or applications receiving the highest score based on a comparative analysis of the applications using all applicable review criteria in s. HSS 123.13, the review criteria in subs. (3) to (6) and the following special review criteria:

(a) Preference shall be given to the application proposing a multifacility or shared service arrangement and, if more than one application proposes a multifacility or shared service arrangement, the one that provides written documentation demonstrating the greatest number and diversity of patient referrals from referring specialists;

(b) Preferences shall be given to the applicant providing the best geographical accessiblity for the population being served in the health service area as determined by an analysis by the department of the geographical market areas that have been identified by each applicant as areas where the applicant intends to focus its resources and marketing strategies for the proposed lithotriptor. Each applicant shall provide the department with the number of anticipated patient referrals from each identified market area and the patient origin by county for all referrals; and

(c) Preferences shall be given to the application providing the greatest number of ESWL procedure hours per week in relation to the number of qualified staff set forth in sub. (4) (d).

(8) DATA REPORTING REQUIREMENTS. All entities in the state having lithotriptors shall provide the department and the appropriate HSA with data relating to the number of patients served, patient utilization, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the department for purposes of evaluation and project review. The department may not request the information more often than twice a year.

(9) REVISION OF THE RULE. The department shall review this section within 2 years of its effective date.

History: Cr. Register, March, 1986, No. 363, eff. 4-1-86.

HSS 123.26 Organ transplant program criteria. (1) USE. The criteria set out in this section shall be used by the department to review applications for the establishment of a human or artificial heart, liver, lung, pancreas or bone marrow transplant program. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Organ" means a human or artificial heart, liver, lung or pancreas or bone marrow.

(b) "Organ procurement" means, in reference to human organs, the process of coodinating the removal, preservation and transportation of donor organs, and maintaining a system to locate recipients for donated organs.

(c) "Program" means the offering of any one type of organ transplant to one or more patients, either on an ongoing or a one-time basis.

(d) "Transplant" means a process by which an organ is surgically implanted into a human patient.

(3) NEED FOR THE ORGAN TRANSPLANT PROGRAM. The department may approve an application under this section only if the applicant demonstrates on the basis of valid assumptions, data and methodology that all of the following conditions are met:

(a) There is a need for the proposed organ transplant program. Determination of need for an organ transplant program shall be based on the following considerations:

1. The capacity of existing transplant programs in the state for the same organ; and

2. The annual volume of transplants of that type of organ provided to Wisconsin patients and patients from adjoining states;

(b) For each organ transplant program for which application is made, at least 10 transplants will be performed annually under the applicant's proposed program. In projecting the annual number of transplants, the applicant shall provide data on the incidence of conditions for which organ transplant has been recognized to be an effective and appropriate mode of treatment, the actual and projected number of transplant evaluations, and the number of patients referred to other organ transplant programs for transplant in the 5 years preceding the date of application

along with data relating to patient origin, age and presenting condition; and

(c) The approval of an application would result in no more than 3 heart transplant programs in the state and no more than 2 programs in the state for the transplant of each of the other organs, and not more than one organ transplant program in any health planning area for each organ other than a heart. This paragraph does not apply to an application to establish an organ transplant program for the transplantation of bone marrow.

(4) REQUIRED RESOURCES. The department may approve an application under this section only if the applicant demonstrates that all of the following conditions are met:

(a) The applicant has an arrangement with a medical school to support graduate medical education and organ transplant research programs;

(b) The organ transplant program will be able to meet the following minimum staffing requirements:

1. The program has a director who is a physician licensed in Wisconsin with at least 12 months experience in an organ transplant program; and

2. For each type of organ transplant to be performed, the program has a physician on staff who is licensed as a physician in Wisconsin and is experienced in the performance of the transplant of that organ.

(c) The organ transplant program will be able to provide the following services 24 hours a day through staff experienced and trained in the performance of the transplant of that type of organ or those types of organs and the age group being served:

1. Medical support services, including:

a. Anesthesiology;

b. Cardiology, including special diagnostic services, electrocardiogram (EKG), nuclear cardiology, cardiac ultrasound and a cardiac rehabilitation program;

c. Endocrinology;

d. Gastroenterology, including endoscopy;

e. Hematology and oncology;

f. Immunology services, both specialist and laboratory;

g. Infectious disease services, both specialist and laboratory;

h. Intensive care;

i. Nephrology, including a renal dialysis capability;

j. Neurology, including diagnostic services, electroencephalogram (EEG) and evoked potentials;

k. Nursing;

l. Organ procurement, including transplant coordinator services;

m. Pathology, with experience in diagnosing rejection;

n. Pediatrics;

o. Psychiatry and psychology;

p. Pulmonary disease; and

q. Diagnostic and therapeutic radiology, including angiography, ultrasound, computed tomography, nuclear medicine imaging and cardiac catheterization.

2. Laboratory services, including:

a. Special chemistry;

b. Histocompatibility; and

c. Blood banking; and

3. Ancillary services, as follows:

a. Diatetics;

b. Occupational therapy;

c. Pharmacy;

d. Physical therapy;

e. Rehabilitation and recreation therapy; and

f. Social services.

(d) In the case of an application to establish a heart or a heart and lung transplant program, the site at which the transplant will be performed has provided cardiac catheterization and cardiac surgery services for at least 3 years preceding the date of application; and

(e) In the case of an application submitted by or on behalf of more than one hospital:

1. The requirements of pars. (b) and (c) will be met at each hospital where organ transplants are performed, or at a physically contiguous hospital;

2. Each type of organ transplant will be performed by one distinct team with another team available to back up the first team until 20 transplants per year have been performed, but separate teams may be used for adult and pediatric procedures;

3. The hospitals are contractually bound to provide all services required under this subsection for an organ transplant program;

4. All hospitals are located in one county or in counties contiguous to that county; and

5. The hospitals agree to share data and participate in joint organ transplant research programs.

(5) FINANCIAL FEASIBILITY. The department shall not approve an application unless the applicant demonstrates that the project is financially feasible by:

(a) Documenting that the projected average costs of organ transplants are similar to costs for similar services provided in similar settings; and

(b) Documenting the net financial impact on its hospital rates.

(6) CONCURRENT REVIEW. The provisions in s. HSS 123.08 (10) shall be used for concurrent review when there are 2 or more applications for programs to transplant the same type of organ. The department shall approve the application or applications receiving the highest score based on a comparative analysis of the applications using all applicable review criteria in s. HSS 123.13, the review criteria in subs. (3) to (5) and in addition giving preference to the application which provides:

(a) The most comprehensive array of organ transplant services;

(b) The most comprehensive array of services relating to the organ being transplanted;

(c) The best geographical accessibility for persons requiring organ transplants; and

(d) The greatest opportunities for training physicians and nurses involved in services related to organ transplants, without unnecessarily duplicating similar training programs in the state.

(7) SEPARATE APPROVALS REQUIRED. A separate approval is required to establish a program for the transplant of each type of organ.

(8) DATA REPORTING REQUIREMENTS. Organ transplant programs shall provide the department and the appropriate HSA with data relating to the number of patients served, patient utilization, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the department. The department may not request the information more than twice in a 12-month period.

(9) REVISION OF THE RULE. The department shall review this section within 2 years after its effective date.

History: Cr. Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.27 State medical facilities plan. (1) PLAN REQUIREMENT. The department shall prepare and adopt a state medical facilities plan (SMFP) at least once every 3 years, pursuant to s. 150.83, Stats., in order to determine the number and type of hospital beds needed in each acute care service area of the state. The plan shall designate acute care service areas, describe the hospital system in the state, identify needed and surplus hospital beds, describe needed and surplus health services and include other components useful to the department in reviewing project applications. Applications submitted for review under s. HSS 123.08 (4) shall be consistent with the standards and findings set forth in the SMFP.

(2) ACUTE CARE SERVICE AREAS. The department shall designate acute care service areas in the SMFP. The department shall define those areas using the methodology provided in this subsection and the SMFP, and shall update the areas at least every 3 years. Acute care service areas shall not be construed to limit or inhibit the development of multihospital systems, hospital consolidations or mergers between hospitals in different service areas. Calculations used in determining acute care service areas shall be based on information contained in the hospital discharge survey conducted by the department. Hospitals seeking approval

under this chapter shall participate in the discharge survey and the department's annual survey of hospitals.

(a) *Methodology.* 1. Definitions. In this paragraph:

a. "Market strength" means the number of patients from a zip code area that go to a hospital divided by the total number of patients from the zip code area that are hospitalized.

b. "Milwaukee area hospitals" means those hospitals located in the cities of Brookfield, Cudahy, Menomonee Falls, Milwaukee, New Berlin, Oconomowoc, Waukesha, Wauwatosa and West Allis.

c. "Zip code area" means the delivery boundaries used by the U.S. postal service and mapped by the department in a publication entitled, *Population Estimates and Maps for Five-Digit Zip Code Areas in Wisconsin.*

2. Criteria for defining areas. Acute care service areas shall be defined by means of a methodology which:

a. Identifies where persons from a given geographic area go for hospital care; and

b. Groups hospitals which, based on recorded use, draw patients from the same service population base. Groupings of hospitals sharing d service populations shall be generated by a computer analysis, using the methodology set forth in this paragraph and the SMFP.

3. Areas defined by population served. Acute care service areas shall be defined by the population served by the hospitals rather than by governmental or other common geographical boundaries. A specific geographic area may be included in more than one service area, depending upon the relevant portion of the population seeking care in 2 or more service areas.

4. Market strength. An acute care hospital's market strength in a zip code area shall be calculated for all zip codes from which the hospital draws patients. The hospital's market strength in a zip code area shall be equal to the number of patients from the zip code area that go to the hospital divided by the total number of patients from that zip code area that are hospitalized.

a. The hospital's overall average market strength shall be the weighted average of all of its individual market strength ratios. The overall market strength shall be computed for every hospital. Hospitals shall be rank-ordered by their average market strength from lowest to highest.

b. The hospital with the lowest overall market strength shall be selected and the average market strength for all other hospitals in the state shall be calculated for those zip code areas served by the hospital with the lowest overall market strength.

c. The combined market strength of the hospital with the lowest market strength and the hospital with the highest market strength shall be compared to the average market strength of the hospital with the lowest market strength. If there is a significant improvement of at least 10% in the overall market strength, the hospitals shall be combined into one service area. If there is not a significant improvement of at least 10%, the hospitals shall remain separate.

d. The hospital with the second to the lowest overall average market strength shall be selected next, and compared to the average market strength for other hospitals or groups of hospitals that may have already been clustered. The combined market strength of the lowest and highest market strength hospital or cluster of hospitals shall be compared in a manner described in this subdivision. The clustering procedure shall continue until all hospitals have been tested.

5. Adjustments in sample size before calculating market strength. The following adjustments in the sample size shall be made prior to the calculations in subd. 4:

a. In order to eliminate sampling errors due to low sample sizes, all zip codes with less than 20 discharges shall be dropped from the data used to cluster hospital service areas;

b. In order to eliminate errors due to random patient usage, all zip codes in which a hospital's market strength is less than .01 shall be dropped from the data used to cluster hospital service areas; and

c. In order to minimize the effect that low market strengths due to referrals for specialized services has on expanding the size of hospital service areas, overall market strength shall be calculated by using 100% of all remaining data for hospitals serving less than 30 zip codes in Wisconsin, 95% of all remaining data for hospitals serving between 30 and 69 zip codes in Wisconsin, 90% of all remaining data for hospitals serving between 70 and 119 zip codes in Wisconsin, 85% of all remaining data for hospitals serving between 120 and 149 zip codes in Wisconsin, and 80% of all remaining data for hospitals serving 150 or more zip codes in Wisconsin.

6. Grouping of Milwaukee area hospitals.@@ Milwaukee area hospitals shall be grouped based on the following analysis:

a. The overlap of zip code areas in which a hospital maintains a market strength of greater than 10%;

b. The location of the zip code area with the greatest market strength concentration if the market strength of greater than 10% is split between several hospitals;

c. The concentration of the market strength between 5 and 10% if there is no zip code area in which a hospital has a market strength greater than 10%; and

d. In the case of a pediatric hospital, the market strength for pediatric patients.

(b) *Revision of the methodology.* The department shall review the methodology for defining acute service areas at least every 3 years and shall revise the methodology, if warranted.

(c) *Redefinition of acute care service areas.* 1. By January 1, 1987, and at least every 3 years after that date, the department shall update acute care service areas.

2. a. An existing acute care service area shall be modified between updates if there is a corporate merger or consolidation between facilities in adjacent service areas or if a hospital closes.

b. In the event of a merger or consolidation, the service areas of the affected facilities shall be combined when the merger or consolidation involves 2 single hospital service areas or a single hospital and multiple hospital service areas.

c. If the merger or consolidation involves 2 multiple hospital service areas, the methodology set out in this section and in the SMFP shall be used to redefine the service areas for the affected facilities.

d. In the event of the closing of a hospital, market shares and the service population shall be distributed among remaining hospitals based upon preexisting patient origin patterns.

3. a. A hospital or HSA may request a revision of an acute care service area if a significant change in patient origin patterns has occurred since the hospital discharge survey conducted by the department was completed. The request shall be accompanied by documentation which includes patient origin data for the hospital and all other facilities in its service area. The data shall be from at least a 2-month representative sample over a one-year period. The survey implementation, form design and methodology shall be acceptable to the department.

b. Hospitals in the service area shall participate in any special survey under subpar. a., with any cost of the survey borne by the hospital or HSA making the request.

c. The acute care service area methodology described in this subsection and in the SMFP shall be used to recompute the requesting facility's service area. The acute care service area shall be modified if warranted by the recomputation.

(3) ACUTE CARE BED NEED DETERMINATION. The department's methodology for determining need for acute care beds shall be identified in the SMFP and shall proceed as follows:

(a) *Calculation of market share population.* 1. Market share population figures shall be calculated based upon all discharges from the hospitals within a service area, adjusted for the number of residents from other states who are hospitalized in Wisconsin and the number of Wisconsin residents who are hospitalized in other states, and published in the SMFP. By using all discharges, the market share population shall reflect tertiary referrals.

2. The market share population shall be determined by utilizing the hospital discharge survey conducted by the department, supplemented by information on patient origin from adjoining states if available.

3. Population projection calculations shall be based on the latest estimates provided by the university of Wisconsin applied population laboratory and the state department of administration.

(b) *Updating of population estimates and bed need projections.* 1. The department shall update current population estimates for purposes of determining bed need and shall publish the estimates in the SMFP at least every 3 years.

2. The department shall update acute care bed need projections at least every 3 years to reflect 7-year population projections.

3. The department shall compare bed need projections in an acute care service area to the most recent approved bed capacity in the area when determining need or excess.

(c) *Future acute care bed need.* 1. Discharge rate and length of stay. For purposes of bed need determination, categories of patient services as defined in the SMFP are medical/surgical, pediatrics, obstetrics and ICU/CCU.

a. The discharge rate for medical and surgical patients shall be calculated by dividing the number of persons for the age categories 15 to 44 years of age, 45 to 64 years of age, 65 to 74 years of age and 75 years of age and older, who have not been excluded as obstetric patients, alcohol and drug abuse rehabilitation patients, or psychiatric patients, hospitalized in an acute care service area by the total number of persons for each age category in the acute care service area's market share population. The length of stay shall be calculated for medical and surgical patients by dividing the number of medical and surgical patients by the number of medical and surgical patient days.

b. The discharge rate for pediatric patients shall be calculated by dividing the number of persons under 15 years of age, excluding newborns, hospitalized in an acute care service area by the total number of persons under 15 years of age in the acute care service area's market share population. Length of stay shall be calculated for pediatric patients in an acute care service area by dividing the number of pediatric patients into the number of pediatric patient days.

c. The discharge rate for obstetrics patients shall be calculated by dividing the number of patients in an acute care service area who are admitted with ICD-9-CM diagnostic codes 630.0, 633.0 to 633.2, 633.8, 633.9, 640.0 to 646.9 and 648.0 to 676.0 by one-half the number of persons between 15 and 45 years of age in the acute care service area's market share population. Length of stay shall be calculated for obstetrics patients in an acute care service area by dividing the number of obstetrics patients into the number of obstetric patient days.

d. The discharge rate and length of stay calculations in subpars. a. to c. shall exclude patients in an acute care service area with ICD-9-CM diagnostic codes 290 to 316, except 303 to 305, admitted to an acute care hospital with an inpatient psychiatric service and patients with ICD-9-CM diagnostic codes 303 and 304 admitted to an acute care hospital with a chemical dependency service.

Note: The ICD-9-CM diagnostic codes can be found in the *International Classification of Diseases - 9th Revision - Clinical Modification* published in 1978 by the Commission on Professional and Hospital Activities, Ann Arbor, Michigan.

2. Pediatric hospitals. Bed need for a pediatric hospital including calculation of market share population, discharge rate and length of stay shall be based on age groupings under 5 years of age excluding newborns, 5 to 14 years of age, 15 to 19 years of age and 21 years of age and over. Market share population for zip codes which are served by the facility shall be calculated by multiplying the market share by the age group population in the zip code area served. Estimates of zip code population shall be based on information available through the state department of administration and estimates of age distribution shall be based on information available through the U.S. census bureau. Changes in age distribution between the last and next decennial census shall be based on esti-

mates of change in which the zip code is located or, if appropriate, for the state as a whole. The market share population shall be adjusted to account for in and out migration from and to adjoining states.

3. Future bed need. The department shall determine future acute care bed need by proceeding through the following methodology, which is described more fully in appendix C, table C1 and in the SMFP:

a. Multiply the discharge rate by the length of stay and the product by the projected service area population to get projected patients days;

b. Divide projected patient days by 365 days in a year to get the projected average daily census; and

c. Divide the projected average daily census by the occupancy standards under subd. 8. and appendix D to get the number of needed beds.

4. Comparison of current rates to statewide rates. To calculate bed need in a service area, the department shall compare the current actual discharge rate and the current actual average length of stay for the service area to the statewide projected average discharge rate and statewide projected average length of stay. The department shall adjust the statewide average discharge rate and length of stay to include values one standard deviation above the projected statewide discharge rate and length of stay. In each case, the lower figure shall be used to calculate projected patients days.

5. Adjustment in rates. The department shall determine the projected statewide discharge rate and length of stay by applying national trend data available from the national center for health statistics by adjusting the current statewide discharge rate and length of stay based upon national data from the national center for health statistics. This data shall be projected 5 years forward and assumed constant from that point onward for projection purposes. The department shall update national trends annually, subject to data availability, based on the 7 most recent years of experience. As new national information becomes available, the oldest year's data shall be excluded from trend calculations.

6. Intensive care days. Intensive care and coronary care patient days, excluding neonatal intensive care days, shall be calculated as a percentage of total nonobstetrical patient days for a service area as reported in the most recent annual survey of hospitals. This percentage, not to exceed 9%, shall be multiplied by the sum of projected pediatric patient days and medical and surgical patient days in subds. 1. or 2. The resulting number shall be the projected intensive care and coronary care unit patient days for the service area.

7. Total patient days. Total unadjusted medical/surgical patient days shall be determined by the total of patient days for the following age categories: 15-44 years, 45-64 years, 65-74 years and 75 years of age and over. This sum shall be used to calculate unadjusted medical/surgical bed need.

8. Occupancy standards. Occupancy standards shall be based upon the total number of beds by service category currently in an acute care service area as identified in the annual survey of hospitals not to exceed a hospital's approved bed capacity. The specific standards are listed in appendix D.

9. ICU/CCU bed adjustments. The total number of needed ICU/CCU beds based on calculations made in subd. 6. and the occupancy standard in appendix D shall be subtracted from the unadjusted medical/surgical bed need. This number shall be the total number of needed beds for medical/surgical services.

(d) *Modifications to acute care bed need projections.* 1. A hospital or HSA may request a change in the acute care bed need projections if any of the following has occurred:

a. A population shift in the service area has occurred which was not identified in the latest Wisconsin population projections used in the SMFP;

b. The market share in a service area has significantly changed since the most recent hospital discharge survey was conducted; or

c. Actual hospital utilization varies significantly from estimates in the SMFP.

2. Documentation of changes in population shall be based on a special study conducted by the hospital or HSA or by a special census conducted by a municipality. Documentation of changed market share shall be based on patient origin data for the hospital and all other facilities in its service area for at least a 2-month representative sample over a 1-year period. Documentation of changes in hospital utilization shall be based on patient utilization data for all hospitals in the acute care service area during a 12-month period. Survey implementation, forms design and methodology shall be acceptable to the department.

3. All hospitals in the service area shall participate in any special survey under subd. 2, with any cost of the survey borne by the hospital or HSA making the formal request.

4. The methodology described in this subsection, appendix C, table C1 and the SMFP shall be used to recompute bed need for the acute care service area based upon updating of population or market share information.

(4) PSYCHIATRIC AND CHEMICAL DEPENDENCY HOSPITAL BEDS. (a) *General considerations.* 1. Service areas for psychiatric and chemical dependency hospital beds shall be identified separately in the SMFP, along with a listing of the total approved bed capacity in each area.

2. The current and projected population shall be based upon the number of persons residing within the service area boundary, until the hospital discharge survey conducted by the department allows allocation by market share for special hospitals.

3. Estimates of surplus or needed beds shall be identified by service area in the SMFP and updated at least every 3 years.

(b) *Psychiatric service areas and bed need.* 1. Service areas for short-term inpatient psychiatric services shall be based on patient origin information from the latest hospital discharge survey and, if necessary, from the latest survey of activity of boards organized under s. 51.42., Stats. The department shall revise the service areas when patient origin data becomes available for special hospitals through the hospital discharge survey. The entire state shall be the service area for purposes of determining need for long-term psychiatric services.

2. To calculate bed need in a service area, the actual use rate and length of stay for all hospitals in the service area shall be compared to the statewide average use rate and length of stay as reported in the department's annual survey of hospitals. The actual use rate and length of stay for the service area or the statewide average use rate and length of stay, whichever is less, shall be used to calculate projected patient days. Inpatient short-term psychiatric bed need shall be determined by using the methodology in appendix C, table C-2 and in the SMFP which is summarized as follows:

a. Multiply the use rate by the length of stay and the product by the projected service area population to get projected patient days;

b. Divide the projected patient days by 365 days in a year to get projected average daily census; and

c. Divide the projected average daily census by the appropriate occupancy standard in appendix D to get the number of needed beds.

3. No provision may be created under this paragraph or under interim rules s. HSS 123.27 (3) (b) as created under s. 2020 (11) (b) of 1983 Wisconsin Act 27 which would result in disapproval of any project application:

a. Limited to geriatric psychiatry;

b. Declared complete by the department under rules in effect immediately prior to the effective date of this chapter; and

c. Upon which the department has not rendered a final decision as of the effective date of this chapter.

(c) *Chemical dependency service areas and bed need.* 1. For purposes of establishing need for chemical dependency inpatient services, service areas shall be the same as health planning areas. These service areas may be modified in the SMFP as more precise patients origin information for special hospitals becomes available.

2. To calculate bed need in a service area, the actual use rate for all hospitals in the service area as reported in the department's annual survey of hospitals shall be compared to the statewide average use rate adjusted to one standard deviation above the mean. The actual length of stay for all hospitals in the service area as reported in the department's annual survey of hospitals and the lower of the actual or adjusted statewide average use rate shall be used to calculate projected patient days. Chemical dependency bed need shall be determined by using the methodology in appendix C, table C-3 and in the SMFP which is summarized as follows:

a. Multiply the use rate by the length of stay and the product by the projected service area population to get projected patient days;

b. Divide projected patient days by 365 days in a year to get the projected average daily census; and

c. Divide the projected average daily census by the occupancy standard in appendix D to get the number of needed beds.

(5) CAPACITY REDUCTION. (a) *Reduction strategies.* The SMFP shall contain details and implementation strategies for a policy to facilitate

reduction of excess bed capacity, and shall give attention to phasing out or consolidating facilities and services.

(b) *Phase-out or consolidation.* A population may be more efficiently served by one large hospital or service, rather than 2 or more smaller hospitals or services. Reduction of excess capacity in existing facilities or services in the service area may best be achieved by closing entire units rather than several beds on each floor or unit. The department may determine that one larger facility prevents duplication of costly facilities and equipment, permits an adequate volume of patients to support it, and makes optimum use of the services of trained and specialized personnel. The department may also determine that specialized services requiring a large capital investment, high operational cost, and highly specialized personnel should be planned on a regional basis to reflect referral patterns and should ordinarily be provided by a regional center.

(c) *Overbedded areas.* Applicants shall implement approaches developed by the department and published in the SMFP to reduce excess beds in service areas. Bed reduction shall be consistent with improvement plans in s. HSS 123.13 (1) (b), reduction criteria in s. HSS 123.13 (13) (e), bed deactivation/reactivation in s. HSS 123.30 (4) and the calculation of a proportionate share of the excess in sub. (10).

(6) HOSPITAL OCCUPANCY. (a) *Medical/surgical beds.* The department shall identify in the SMFP hospitals with medical/surgical occupancy rates that rank in the bottom 25% of their overall bedsize group statewide for 2 consecutive years. In this paragraph "bedsize group" means all general hospitals in the state with an approved bed capacity of less than 50 beds, 50 to 99 beds, 100 to 249 beds, or 250 beds and over. Hospitals with medical/surgical occupancy rates in the bottom 25% of their bedsize group but which exceed 95% of the occupancy standard in appendix D shall be excluded from the requirement.

(b) *Pediatric beds.* 1. The department shall identify in the SMFP hospitals with pediatric occupancy rates that rank in the bottom 25% of their bedsize group statewide for 2 consecutive years. In this paragraph, "bedsize group" means all pediatric units of 10 to 19 beds or of 20 or more beds. All hospitals with pediatric occupancy rates in the bottom 25% of their bedsize group but which exceed 95% of the standard in appendix D shall be excluded from the requirement.

2. Pediatric units with fewer than 10 beds and without dedicated nursing staff shall be classified as medical/surgical beds for purposes of the SMFP.

(c) *Obstetrics programs in Green Bay, Madison and Milwaukee.* 1. For hospitals located in a central city with a population of at least 50,000 or in a city with a population of at least 50,000 contiguous to the central city, the department shall identify in the SMFP obstetrics units performing fewer than 730 deliveries a year except when the hospital is in a service area by itself or in a service area with only one other hospital, or when only one of the hospitals in the service area is located in the central city with a population of at least 50,000 or in a city contiguous to the central city with a population of at least 50,000. In this paragraph, "central city" means the population center of a MSA.

2. If there are 2 or more hospitals in an acute care service area and one or more hospitals have the obstetrics bed capacity to absorb another hos-

pital's deliveries, movement toward obstetrics unit consolidation shall be encouraged. The department shall identify in the SMFP hospitals which have the potential for consolidation and shall develop strategies for implementing consolidation of obstetrics units.

(7) HOSPITAL EFFICIENCY OF OPERATION. (a) The department shall request on a quarterly basis that the Wisconsin hospital rate-setting commission indicate which hospitals have excess staffing under s. 54.21 (2) (b) 3., Stats., and s. HRSC 3.025 (3), have an adjusted average charge per admission for all patients as calculated under s. HRSC 3.07 (2) (b) which is above the 75th percentile of charges for the hospital's peer group devised under s. 54.11 (2), Stats., and have unnecessary or inappropriate medical care utilization under s. 54.23 (3), Stats., based on data submitted by hospitals in their latest rate requests.

(b) The department may ascertain the following by analysis only if the Wisconsin hospital rate-setting commission does not provide the department with the information requested under par. (a).

1. Whether a hospital's full-time equivalent employe per patient day ratio, factored for outpatient and inpatient activity, is more than one standard deviation above the mean for hospitals in the same peer group established for purposes of hospital rate-setting;

2. Whether a hospital all-patient charge per admission adjusted for salary differentials between areas of the state is more than one standard deviation above the mean for hospitals in the same peer group established for purposes of hospital rate-setting; and

3. Whether the actual length of stay at a hospital exceeds the expected length of stay by greater than 10%.

(8) HOSPITAL CHARGES. (a) The department shall publish in the SMFP a summary of price information for the 25 most heavily used charge elements in hospitals, based on information that may be provided to the rate-setting authority or as collected by the department if unavailable from the rate-setting authority.

(b) The department shall publish in the SMFP information on hospitals that indicates the ratio of a hospital's average charge for a particular diagnosis-related group (DRG), as defined under 42 USC 1395ww, to its medicare reimbursement for that DRG. Ratios for an individual DRG at a hospital shall be published only when the facility has treated 4 or more cases in the diagnosis-related group during the preceding year.

(9) SUMMARY OF CAPITAL BUDGET REPORTS. The department shall publish in the SMFP a summary of the 5-year capital budget reports submitted by individual hospitals under s. HSS 123.29. The department shall use the 5-year capital budget reports and the summary in revising the state medical facilities plan and in predicting future hospital capital and financing demands.

(10) PROPORTIONATE SHARE OF EXCESS. For each acute care service area in which excess beds have been identified in the SMFP, the department shall indicate in the SMFP each hospital's proportionate share of the excess. This shall be based on the methodology in appendix E which is summarized as follows:

(a) An overall weighted occupancy rate for a hospital shall be calculated by applying the appropriate occupancy standard in appendix D to a facility's approved bed capacity by SMFP service category as reported in the SMFP, excluding inpatient psychiatric and chemical dependency beds. Hospitals which have deactivated beds under s. HSS 123.30 (4) shall have the weighted occupancy rate applied to the approved bed capacity minus the deactivated beds. Hospitals for which the actual occupancy rate in the most recent SMFP exceeds the overall weighted occupancy rate shall be excluded from the calculations in pars. (b) and (c).

(b) The current share of the service area excess for a hospital shall be based on a comparison of the hospital's actual occupancy rate published in the SMFP with the weighted occupancy rate calculated under par. (a). A determination shall be made of the number of beds which when subtracted from a hospital's approved bed capacity will enable the hospital to operate at the overall weighted SMFP occupancy standard established in par. (a).

(c) Each hospital's current share of the service area excess, as determined under par. (b), shall be increased or decreased on a proportional basis to the projected service area excess published in the SMFP. This shall be considered the hospital's proportionate share of the excess.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.28 Relation of capital expenditure review to rate-setting. (1) PREAPPROVAL RELATIONSHIP. (a) *Information requirements.* 1. Any hospital intending to submit an application for review of a project pursuant to this chapter shall provide a copy of the application to the rate-setting authority and shall furnish proof with its application that it has submitted a copy of the application to the rate-setting authority.

2. The application is not complete under s. HSS 123.08 (4) (c) until the application has been submitted to the rate-setting authority.

(b) *Analysis.* 1. Pursuant to s. 150.69, Stats., the rate-setting authority is required to submit its analysis of the financial information section to the department and HSA within 45 days after the application is determined complete.

2. The rate-setting authority's analysis is required to contain the effect of the proposed project cost on the hospital's rates as established under s. HRSC 3.02.

3. The rate-setting authority may provide information to the department and HSA on the financial feasibility, affordability and advisability of hospital-related projects. The department may, in cooperation with the rate-setting authority, further define and specify the analyses of the rate-setting authority.

(2) PROJECTS INITIATED WITHOUT DEPARTMENTAL APPROVAL. (a) Pursuant to s. 150.11 (2), Stats., no person may recover through charges or rates any depreciation, interest or principal repayments or any operating expense associated with a project subject to this chapter when the project has not been approved by the department.

(b) The department shall inform the rate-setting authority of the depreciation, interest or principal repayments or operating expenses associated with projects initiated without departmental approval. If specific

information on project cost is not available from the person who has initiated a project without approval, the department shall estimate the costs based on the experience of similar facilities and services.

(3) POSTAPPROVAL RELATIONSHIP. (a) *Limitation on rates.* Rates established for purposes of medical assistance reimbursement under 42 USC 1396 and ss. 49.43 to 49.49, Stats., or by the rate-setting authority under ch. 54, Stats., to cover the cost of an approved project shall not exceed the rates established in the approval by more than 5% during the 3-year period following the completion of the project, pursuant to s. 150.79, Stats., unless the hospital demonstrates to the satisfaction of the rate-setting authority that the excess was due to conditions beyond its control or due to failure to achieve the nondebt funding goal established under s. HSS 123.13 (4) (g) despite making a good faith effort to do so. In this paragraph, "conditions beyond the hospital's control" means a natural disaster or actual inflation rates which exceed those established using the hospital market basket projections of data resources, incorporated.

(b) *Monitoring.* The hospital shall maintain for 3 years following project completion a separate accounting cost center for the costs associated with the specific project approved under this chapter in order to allow comparison of actual per-unit operating costs and rates charged with those projected in the application.

(c) *Impact on medical assistance.* Pursuant to s. 150.79, Stats., reimbursement of costs in excess of those stated in the approval by more than 5% shall be disallowed for purposes of setting rates under medical assistance under 42 USC 1396 and ss. 49.43 to 49.49, Stats.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85.

HSS 123.29 Hospital capital budget report. (1) HOSPITAL REPORT. Each hospital shall submit an initial 5-year capital budget report to the department as required by s. 150.81, Stats., and shall send copies to the HSA for the area in which the hospital is located and to the rate-setting authority.

(2) SUBMISSION OF REPORT. Each hospital shall annually, after submitting its initial report under sub. (1), submit its proposed 5-year capital budget to the department, the HSA and the rate-setting authority. The report shall be submitted at the end of the hospital's fiscal year, the date of which shall be recorded with the department. The report may be updated at any time during the fiscal year.

(3) FORMAT. The report shall be on a form prescribed by the department and shall include:

(a) A summary of the hospital's present financial position and ability to undertake capital projects;

(b) A summary of major capital projects now in progress;

(c) An estimate of the total capital investment to be made by the hospital in each of the next 5 years; and

(d) For each project subject to review under this chapter:

1. A statement of the project objectives;

2. The cost and anticipated source of project financing; and

3. The anticipated application submission date.

Note: For a copy of the form to be used for the capital budget report, write to the Bureau of Planning and Development, P.O. Box 1808, Madison, Wisconsin 53701.

(4) SIGNATORIES. A hospital's capital budget report shall be signed by the person who supervised its preparation and by the chairperson or president of the hospital board of trustees.

(5) COMPLETION REQUIREMENTS. (a) No application for project approval from a hospital, except for an application for the purchase or other acquisition of another hospital, is complete under s. HSS 123.08 (4) (c) until the department receives the required 5-year capital budget report from the applicant.

(b) Beginning in calendar 1985 no application may be declared complete unless the project was listed in the hospital's annual capital budget report or an update was filed with the department at least one year preceding application. The department may waive this requirement for projects to remedy code deficiencies, damage due to natural disaster, an emergency situation that threatens patient safety or in order to facilitate batching of applications for concurrent review under s. HSS 123.08 (10). Projects that involve only the replacement of equipment or projects submitted by or on behalf of 2 or more hospitals participating in a joint venture shall be exempt from this requirement.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; am. (5), Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.30 Approved bed capacity. (1) GENERAL REQUIREMENTS. Every hospital shall have a bed capacity approved by the department under sub. (2). The department shall maintain and periodically update for each hospital a file of 4 categories of approved beds, namely, the number of psychiatric beds, the number of chemical dependency beds, the number of neonatal intensive and intermediate care beds and the number of all other hospital beds.

(2) APPROVAL OF BED CAPACITY. (a) Any mutually signed statement between the department and a hospital specifically agreeing to the number of approved beds in the hospital shall be recognized as the approved bed capacity of the hospital for each category.

(b) In the absence of an agreement, approved bed capacity shall be either of the following, at the discretion of the department:

1. The number of psychiatric beds, chemical dependency beds, neonatal intensive and intermediate care beds, and all other hospital beds stated in the most recent approval granted by the department under this chapter or its predecessor; or

2. A count by the department of psychiatric beds, chemical dependency beds, neonatal intensive and intermediate care beds, and all other hospital beds.

(c) Any patient rooms and their associated beds which, for any 2-year period commencing on or after the effective date of these rules, have not accommodated inpatients because of physical modification or alternative uses shall be deducted from the number agreed to in par. (a) or approved or counted by the department under par. (b).

(3) CHANGES IN APPROVED BED CAPACITY. (a) Any increase or decrease in a hospital's bed capacity for each category as a result of a project shall be stated in the project approval and shall take place on the date of project completion and result in a new approved bed capacity for the facility.

(b) A hospital shall submit a signed statement to the department reporting any decrease in its approved bed capacity which does not require approval under ch. 150, Stats. The statement shall be submitted prior to the reduction date and the previously approved bed capacity less those beds shall be considered the facility's new approved bed capacity.

(4) BED BANKING. (a) Hospital beds that have been deactivated under s. HSS 123.13 (1) (b) or (13) (e) for more than 5 years following project completion and have not been reactivated under sub. (5) shall be deducted from the facility's approved bed capacity.

(b) Hospitals may voluntarily deactivate beds by notifying the department in writing prior to its occurrence. Hospital beds that have been voluntarily deactivated and which have not been reactivated under sub. (5) (b) shall be deducted by the department from the hospital's approved bed capacity.

(5) REACTIVATION OF BEDS. (a) A hospital which has deactivated some of its beds in order to meet the provisions of s. HSS 123.13 (1) (b) or (13) (e) may reactivate the beds within 5 years of project completion if the hospital operates at 110% of the overall occupancy standard as stated in appendix D and in the SMFP for at least one year.

(b) A hospital which has activated beds under sub. (4) (b) may reactivate the beds within 5 years of deactivation if the hospital operates at 110% of the overall occupancy standard as stated in appendix D and in the SMFP for at least one year.

(c) The number of beds to be reactivated under pars. (a) and (b) shall be sufficient only to return the hospital's occupancy level to the overall occupancy standard as stated in the SMFP.

(d) The hospital shall notify the department of its intent to reactivate beds. The department shall acknowledge receipt of the notice and may require that the hospital provide additional information on which the department may base its determination whether beds may be reactivated, and, if so, how many.

(e) Review under this chapter to reactivate beds shall be required only if the reactivation otherwise requires approval of the Department under s. HSS 123.04 (1). Reactivation of beds up to a hospital's approved bed capacity is not considered an increase in approved bed capacity for purposes of s. HSS 123.04 (1) (e).

(6) CONSISTENCY WITH STATE MEDICAL FACILITIES PLAN. (a) The approved bed capacity, updated through approvals and notifications of bed decreases or bed banking, shall be used in developing the state medical facilities plan. A hospital shall, based on its approved bed capacity, report in the department's annual survey of hospitals the number of its beds in each service category identified in the SMFP. Where feasible, existing data collection mechanisms shall be used to obtain this information.

(b) Approved bed capacity shall be consistent with information on file with other bureaus in the department and survey results including the department's annual survey of hospitals.

History: Cr. Register, March, 1985, No. 351, eff. 4-1-85; am. (1) and (2) (b), Register, January, 1987, No. 373, eff. 2-1-87.

HSS 123.31 Burn center criteria. (1) USE. The criteria set out in this section shall be used by the department in its review of applications relating to burn centers. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Burn center" means a discrete unit within a hospital that is equipped and staffed to provide care solely for persons who have been burned.

(b) "Dedicated burn bed" means a bed within a burn center which is used solely for the care of the severely burned patient.

(c) "Existing burn center" means the burn center located at the university of Wisconsin hospital and clinics in Madison or St. Mary's hospital in Milwaukee or another burn center subsequently approved under this section.

(d) "Planning area" means the entire state.

(e) "Severe burn" means any life-threatening burn; any burn of more than 25% body surface area; any burn of more than 20% body surface area to a person under 10 years of age or over 40 years of age; any burn which destroys the skin and extends into underlying tissues covering 10% or more of the body surface area; any burn involving the face, eye, ear, hand, foot or perineum that is likely to result in functional or cosmetic impairment; any high voltage electrical burn; and any burn complicated by inhalation injury or major trauma.

(3) NEED FOR BURN CENTERS. (a) Except as provided in par. (c), the department shall not approve an application to either establish a burn center or to add dedicated burn beds to an existing burn center unless:

1. Each existing burn center in the state has operated at an annual average occupancy rate of at least 75% for each of the 2 12-month periods preceding the date of application; and

2. The applicant demonstrates on the basis of valid assumptions and relevant historical data that there is a need for the proposed burn center or additional dedicated burn beds. Determination of need shall be based upon:

a. The capacity of existing burn centers in the state;

b. The annual volume of patients who have been or who can appropriately be served in intensive care beds or other dedicated burn beds in the existing burn centers; and

c. The anticipated relationships of the proposed burn center with other burn centers.

(b) Except as provided in par. (c), the department shall not approve an application to establish a burn center unless the applicant establishes the following:

1. There will be a sufficient number of severe burn patients in the planning area who need a burn center and cannot be served at an existing burn center to ensure a utilization level of at least 50 severe burn admissions the first year of operation and to sustain a level of at least 75 severe burn admissions each year after the first year; and

2. There will be a minimum of 6 dedicated burn beds in the proposed burn center, of which 2 will be intensive care beds.

(c) For a pediatric specialty hospital wanting to establish a burn center, the determination of need shall be based upon the following:

1. There is a sufficient number of pediatric severe burn patients in the planning area to ensure a utilization level of at least 25 severe burn admissions per year; and

2. There will be a minimum of 4 dedicated burn beds in the burn center and a minimum of an additional 2 intensive care beds capable of meeting intensive care needs of pediatric burn patients available within the facility.

(4) REQUIRED RESOURCES. The department shall not approve an application to establish a burn center unless the applicant:

(a) Has transfer agreements with hospitals not having a burn center to assure the transfer of the projected number of severe burn patients;

(b) Has transfer agreements with other acute care facilities having a burn center to assure quality patient care and optimal use of existing burn centers;

(c) Has a burn center which is distinct from other units in the hospital, with its own nursing station, intensive care beds, rooms and equipment;

(d) Has the capacity to provide emergency care and stabilization of severe burn patients; evaluation of burn severity; acute, convalescent and rehabilitative burn care, including skin banking; and basic and clinical research;

(e) Demonstrates that the existing emergency medical system is capable of adequately providing transportation for the severe burn patient from those areas of the state to be served by the proposed burn center;

(f) Has available, 24 hours a day, the services rated essential for hospital burn centers by the American burn association as listed in appendix G; and

(g) Has available the resources necessary for the projected number of severe burn patients, including the resources rated essential for burn centers by the American burn association as listed in appendix H.

(5) DATA REPORTING REQUIREMENT. All burn centers in the state shall provide the department and the appropriate HSA with data relating to the number of patients served, patient utilization, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the department.

The department shall not request the information more than twice in a 12-month period.

History: Cr. Register, February, 1987, No. 374, eff. 3-1-87.