# Chapter HSS 123

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

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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 Register, January, 1987, No. 373

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. 361, 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 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;
- Holding oneself out through acknowledgement, advertising or promotion as providing a service or having a unit;
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- 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.

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 tech-

nology 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 rule-making.
- (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. Register, January, 1987, No. 378

- (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 determination 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

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- (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 construction 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 construction, 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
- 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 overrun, 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 WITH-OUT 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 Register, January, 1987, No. 373

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.

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 minimum 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, hospitalbased 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 Register, January, 1987, No. 373

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 proposals 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:
- 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 in-

travenous fluid therapy, emergency medications, monitoring equipment for an infant's temperature, heart rate and environmental oxygen concentrations, and transcutaneous PO<sub>2</sub> 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 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; 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. H 52 [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.

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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 establihised 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-ofstate 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 Register, January, 1987, No. 373

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:
- 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;
- 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 feed-back 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

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- (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.
- (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 EXTRACORPORDAL SHOCK WAVE LITHOTRIPSY 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

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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
- 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: Register, January, 1987, No. 373

- 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;

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- (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 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 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 Register, January, 1987, No. 378

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;

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- (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;
  - 1. 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;

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- (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 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, Register, January, 1987, No. 373

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 ser-

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- 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.
- 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 Register, January, 1987, No. 373

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 hospital'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
- 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 depart-

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ment 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.

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- (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:

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- 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 alterna-Register, January, 1987, No. 378

tive 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,

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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.

## APPENDIX A

Designated Health Planning Areas in Wisconsin Under 42 USC 300L [HSS 123.03 (19)]

Health Service Area #1

Columbia, Dane, Dodge, Grant, Green, Iowa, Jefferson, Lafayette, Richland, Rock, Sauk counties

Health Service Area #2

Kenosha, Milwaukee, Ozaukee, Racine, Walworth, Washington, Waukesha counties

Health Service Area #3

Calumet, Fond du Lac, Green Lake, Marquette, Outagamie, Waupaca, Waushara, Winnebago counties

Health Service Area #4

Brown, Door, Kewaunee, Manitowoc, Marinette, Menominee, Oconto, Shawano, Sheboygan counties

Health Service Area #5

Barron, Buffalo, Chippewa, Clark, Crawford, Dunn, Eau Claire, Jackson, La Crosse, Monroe, Pepin, Pierce, Polk, Rusk, St. Croix, Trempealeau, Vernon counties

Health Service Area #6

Adams, Florence, Forest, Juneau, Langlade, Lincoln, Marathon, Oneida, Portage, Taylor, Vilas, Wood counties

Health Service Area #7

Ashland, Bayfield, Burnett, Douglas, Iron, Price, Sawyer, Washburn counties

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