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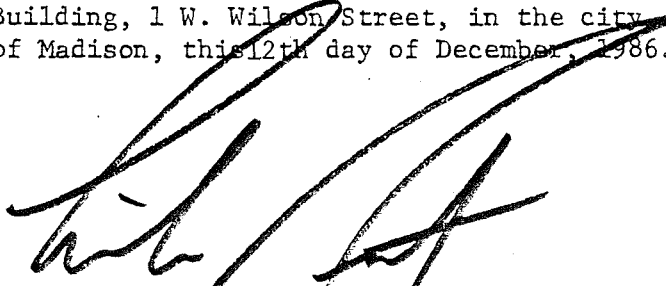
CERTIFICATE

STATE OF WISCONSIN)
) SS
DEPARTMENT OF HEALTH AND SOCIAL SERVICES)

I, Linda Reivitz, Secretary of the Department of Health and Social Services and custodian of the official records of the Department, do hereby certify that the annexed rules relating to criteria for the review of applications regarding air ambulance services and criteria for the review of applications regarding burn centers were duly approved and adopted by this Department on December 12, 1986.

I further certify that this copy has been compared by me with the original on file in the Department and that this copy is a true copy of the original, and of the whole of the original.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department at the State Office Building, 1 W. Wilson Street, in the city of Madison, this 12th day of December, 1986.



Linda Reivitz, Secretary
Department of Health and Social Services

SEAL:

3-1-87

ORDER OF THE
DEPARTMENT OF HEALTH AND SOCIAL SERVICES
REPEALING AND CREATING RULES

To repeal and recreate HSS 123.20 and to create HSS 123.31, relating to criteria for the review of applications regarding air ambulance services and criteria for the review of applications regarding burn centers.

Analysis Prepared by the Department of Health and Social Services

This rulemaking order makes two changes in ch. HSS 123, the Department's rules for implementing the Capital Expenditure Review Program under subch. III of ch. 150, Stats. The first change is the repeal and recreation of the section on special criteria for the review of applications for air ambulance services to take away the Department's authority to require a 1 to 2 year demonstration period as a condition of approval; to permit the Department to revoke an approval for specified reasons; to delete cost-effective criteria and add financial feasibility criteria; to make the concurrent review procedures similar to those found in other special review criteria sections of ch. HSS 123; and to insert data reporting requirements that are the same as those found in the other special review sections of the chapter.

The second change being made in ch. HSS 123 is to add special review criteria for applications for burn centers in hospitals. Section 150.61(2), Stats., as repealed and recreated by 1985 Wisconsin Act 29, identifies a burn center as one of six health care programs that may not be established without the prior approval of the Department. The special review criteria for burn center applications are concerned with need for services and the availability of required resources.

Pursuant to the authority vested in the Department of Health and Social Services by s. 150.03, Stats., the Department of Health and Social Services hereby repeals and recreates and creates rules interpreting ss. 150.61(2) and 150.69, Stats., as amended by 1985 Wisconsin Act 29, and s. 150.67(2), Stats., as follows:

SECTION 1. HSS 123.20 is repealed and recreated to read:

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

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

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

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

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

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

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

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

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

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

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

1. Trained personnel eligible to serve as ambulance attendants under ch. H 20 [HSS 110] will be available at all times for the treatment and transport of critically ill patients; and

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

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

1. Accept patients transported by the applicant; and
2. Provide the personnel required under par. (a)2.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Pay its full direct and indirect costs entirely from charges for the service; and

(c) Establish the separate cost center required under sub. (6)(b).

(10) REVOCATION OF APPROVAL. (a) Pursuant to ss. 150.11(4) and 150.75, Stats., the department may revoke any approval issued under this section for either of the following reasons:

1. The approval holder has not obtained a license under s. 146.50, Stats., and ch. H 20 [HSS 110] within the period specified in the approval or does not maintain this licensure; or

2. The approval holder misses any deadline specified in the timetable for implementing the project and fails to make a good faith effort to meet the deadline.

(b) The approval holder has a right under s. 227.42, Stats., to a contested case hearing to review a revocation under this subsection.

SECTION 2. HSS 123.31 is created to read:

HSS 123.31 BURN CENTER CRITERIA. (1) USE. The criteria set out in this section shall be used by the department in its review of applications relating to burn centers. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Burn center" means a discrete unit within a hospital that is equipped and staffed to provide care solely for persons who have been burned.

(b) "Dedicated burn bed" means a bed within a burn center which is used solely for the care of the severely burned patient.

(c) "Existing burn center" means the burn center located at the university of Wisconsin hospital and clinics in Madison or St. Mary's hospital in Milwaukee or another burn center subsequently approved under this section.

(d) "Planning area" means the entire state.

(e) "Severe burn" means any life-threatening burn; any burn of more than 25% body surface area; any burn of more than 20% body surface area to a person under 10 years of age or over 40 years of age; any burn

which destroys the skin and extends into underlying tissues covering 10% or more of the body surface area; any burn involving the face, eye, ear, hand, foot or perineum that is likely to result in functional or cosmetic impairment; any high voltage electrical burn; and any burn complicated by inhalation injury or major trauma.

(3) NEED FOR BURN CENTERS. (a) Except as provided in par. (c), the department shall not approve an application to either establish a burn center or to add dedicated burn beds to an existing burn center unless:

1. Each existing burn center in the state has operated at an annual average occupancy rate of at least 75% for each of the 2 12-month periods preceding the date of application; and

2. The applicant demonstrates on the basis of valid assumptions and relevant historical data that there is a need for the proposed burn center or additional dedicated burn beds. Determination of need shall be based upon:

- a. The capacity of existing burn centers in the state;

- b. The annual volume of patients who have been or who can appropriately be served in intensive care beds or other dedicated burn beds in the existing burn centers; and

- c. The anticipated relationships of the proposed burn center with other burn centers.

(b) Except as provided in par. (c), the department shall not approve an application to establish a burn center unless the applicant establishes the following:

1. There will be a sufficient number of severe burn patients in the planning area who need a burn center and cannot be served at an existing burn center to ensure a utilization level of at least 50 severe burn admissions the first year of operation and to sustain a level of at least 75 severe burn admissions each year after the first year; and

2. There will be a minimum of 6 dedicated burn beds in the proposed burn center, of which 2 will be intensive care beds.

(c) For a pediatric specialty hospital wanting to establish a burn center, the determination of need shall be based upon the following:

1. There is a sufficient number of pediatric severe burn patients in the planning area to ensure a utilization level of at least 25 severe burn admissions per year; and

2. There will be a minimum of 4 dedicated burn beds in the burn center and a minimum of an additional 2 intensive care beds capable of meeting intensive care needs of pediatric burn patients available within the facility.

(4) REQUIRED RESOURCES. The department shall not approve an application to establish a burn center unless the applicant:

(a) Has transfer agreements with hospitals not having a burn center to assure the transfer of the projected number of severe burn patients;

(b) Has transfer agreements with other acute care facilities having a burn center to assure quality patient care and optimal use of existing burn centers;

(c) Has a burn center which is distinct from other units in the hospital, with its own nursing station, intensive care beds, rooms and equipment;

(d) Has the capacity to provide emergency care and stabilization of severe burn patients; evaluation of burn severity; acute, convalescent and rehabilitative burn care, including skin banking; and basic and clinical research.

(e) Demonstrates that the existing emergency medical system is capable of adequately providing transportation for the severe burn patient from those areas of the state to be served by the proposed burn center;

(f) Has available, 24 hours a day, the services rated essential for hospital burn centers by the American burn association as listed in appendix G; and

(g) Has available the resources necessary for the projected number of severe burn patients, including the resources rated essential for burn centers by the American burn association as listed in appendix H.

(5) DATA REPORTING REQUIREMENT. All burn centers in the state shall provide the department and the appropriate HSA with data relating to the number of patients served, patient utilization, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the department. The department shall not request the information more than twice in a 12-month period.

Appendix G

ESSENTIAL BURN SERVICES FOR A HOSPITAL WITH A BURN CENTER

[s. HSS 123.31(4)(f)]

A hospital with a burn center shall have the following services staffed by qualified specialists available 24 hours per day:

1. Surgical:

- a. Cardio-Thoracic Surgery;
- b. General Surgery;
- c. Neurological Surgery;
- d. Obstetrics-Gynecological Surgery;
- e. Ophthalmic Surgery;
- f. Oral Surgery -- Dental;
- g. Orthopaedic Surgery;
- h. Otorhinolaryngological Surgery;
- i. Plastic Surgery; and
- j. Urological Surgery.

2. Non-Surgical:

- a. Anesthesia;
- b. Medicine:
 - 1. Cardiology;
 - 2. Endocrinology;
 - 3. Gastroenterology;

4. Hematology;
 5. Infectious Diseases;
 6. Internal Medicine;
 7. Nephrology; and
 8. Pulmonary Diseases;
- c. Pathology:
 1. Clinical;
 2. Anatomic; and
 3. Blood Bank;
 - d. Neurology;
 - e. Pediatric;
 - f. Physical Medicine/Rehabilitation;
 - g. Psychiatry; and
 - h. Radiology:
 1. Diagnostic; and
 2. Angiography.

Appendix H

ESSENTIAL BURN RESOURCES FOR A HOSPITAL WITH A BURN CENTER

[s. HSS 123.31(4)(g)]

A hospital with a burn center shall have the following resources:

1. An emergency department, with:
 - a. One or more physicians in at least their 3rd post-doctoral year who have special competence in care of the critically injured and are on duty 24 hours a day in the emergency room;
 - b. RNs, LPNs and nurses' aides in adequate numbers, with at least one RN on each shift;
 - c. Airway control and ventilation equipment, including laryngoscopes and endotracheal tubes of all sizes, a bag mask resuscitator and a source of oxygen;
 - d. Bronchoscopes of all sizes;
 - e. Suction devices;
 - f. An electrocardiograph, an oscilloscope and a defibrillator;
 - g. An apparatus to establish central venous pressure monitoring;
 - h. All standard intravenous fluids and administration devices, including intravenous catheters;
 - i. Sterile surgical kits for procedures that are standard for the emergency room;
 - j. Gastric lavage equipment;
 - k. Appropriate drugs and supplies;
 - l. Roentgenographic diagnostic equipment;

- m. A two-way radio linkage with emergency medical transport vehicles to permit communication with essential on-call physicians; and
 - n. A section on burn care in the emergency room procedures manual.
2. A post-anesthetic recovery room, with:
- a. RNs and other essential personnel available 24 hours a day;
 - b. Physician (usually anesthesiologist) supervision available from within the hospital 24 hours a day; and
 - c. Appropriate monitoring equipment, including an electrocardiograph, an oscilloscope and a defibrillator.
3. For the burn center:
- a. A designated director;
 - b. An electrocardiograph, an oscilloscope and a defibrillator;
 - c. Cardiac output monitoring equipment;
 - d. A mechanical ventilator and a respirator;
 - e. A bed scale;
 - f. Pulmonary function measuring devices;
 - g. Temperature control devices;
 - h. Pressure distribution beds;
 - i. Appropriate drugs, intravenous fluids and supplies;
 - j. Physical therapy services and hydrotherapy services;
 - k. Occupational therapy services;
 - l. Immediate access to clinical laboratory services;
 - m. A nurse-to-patient ratio of at least 1:2 on each shift (includes all nursing personnel);

- n. A physician in at least his or her second post-doctoral year, on duty in the unit 24 hours a day or immediately available to the unit from within the hospital;
 - o. One physical therapist for every 7 patients, based on 2 treatments required each day;
 - p. One occupational therapist for every 10 patients;
 - q. Social workers in numbers appropriate to the need;
 - r. The daily services of a dietitian;
 - s. A respiratory therapist available 24 hours a day;
 - t. Airway control and ventilation devices;
 - u. Oxygen sources with concentration controls; and
 - v. A cardiac emergency cart.
4. A renal dialysis center equipped and staffed for 24-hour service each day.
5. Special capabilities in radiology: angiography of all types.
6. Clinical laboratory services available 24 hours a day, including:
- a. Routine blood and urine studies;
 - b. Blood gases and pH determinations;
 - c. Standard chemistries for blood, urine and other body fluids;
 - d. Coagulation studies;
 - e. Serum and urine osmolality;
 - f. Microbiology;
 - g. A comprehensive blood bank with adequate storage facilities in the hospital or access to a community central blood bank; and
 - h. Blood-typing and cross-matching.

7. Special requirements for the operating suite:
 - a. A surgical RN team leader for burn care;
 - b. A section on intra-operative burn care in the operating suite procedural manual;
 - c. A cardiopulmonary bypass pump and oxygenator;
 - d. An operating microscope;
 - e. Thermal control equipment for the patient;
 - f. Thermal control equipment for blood;
 - g. A fracture table;
 - h. Roentgenographic equipment;
 - i. Endoscopes, all varieties;
 - j. An electrocardiograph, an oscilloscope and a defibrillator;
 - k. Direct blood pressure monitoring equipment;
 - l. Temperature monitoring equipment;
 - m. Blood flow rate monitoring equipment;
 - n. A dermatome; and
 - o. A mechanical ventilator and a respirator.

8. A sufficient number of RNs, LPNs and nurses' aides trained in:
 - a. Burn care;
 - b. General trauma;
 - c. Advanced cardiopulmonary resuscitation;
 - d. Respiratory care;
 - e. General catheter care;
 - f. Monitoring and record-keeping; and

g. Areas such as trauma, surgery, neurological surgery and pediatrics for those nursing personnel assigned to special care areas such as intensive care units.

9. Quality assurance programs, as follows:

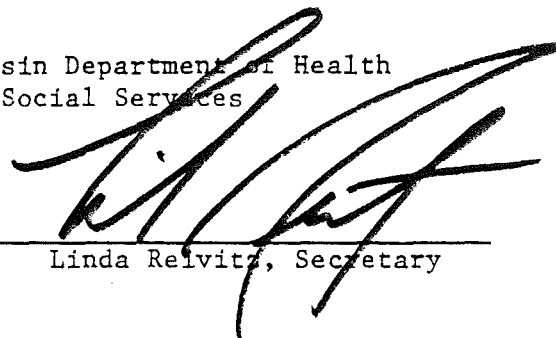
- a. Medical care evaluations - morbidity and mortality review, including review of emergency room deaths, multidisciplinary burn conferences, medical audits, medical nursing audits, utilization review and medical records review;
- b. Disaster planning and rehearsal; and
- c. A planned system for patient transfers after consultation and with prior agreement.

10. Education provided or arranged by the hospital, as follows:

- a. Formal programs in continuing education for staff physicians, nurses, allied health personnel and community physicians;
- b. An outreach program consisting of telephone and on-site consultations with physicians in the community and outlying areas; and
- c. Public education on burn prevention in the home, in industry, on the highways, and on athletic fields; on standard first aid; and on problems confronting the medical profession, hospitals, and the public in regard to optimal care for burn victims.

The repeal and rules contained in this order shall take effect on the first day of the month following their publication in the Wisconsin Administrative Register as provided in s. 227.22(2), Stats.

Wisconsin Department of Health
and Social Services



Date: December 12, 1986

By: _____
Linda Reivitz, Secretary

SEAL:



State of Wisconsin

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

1 West Wilson Street, Madison, Wisconsin 53702

Anthony S. Earl
Governor

RECEIVED

Linda Reivitz
Secretary

December 12, 1986

DEC 12 1986

Mailing Address:
Post Office Box 7850
Madison, WI 53707

Revisor of Statutes
Bureau

Mr. Orlan Prestegard
Revisor of Statutes
9th Floor - 30 on the Square
Madison, Wisconsin 53702

Dear Mr. Prestegard:

As provided in s. 227.20, Stats., there is hereby submitted a certified copy of HSS 123.20 and 123.31, administrative rules relating to criteria for the review of applications regarding air ambulance services and criteria for the review of applications regarding burn centers.

These rules are also being submitted to the Secretary of State as required by s. 227.20, Stats.

Sincerely

Linda Reivitz
SECRETARY

Enclosure