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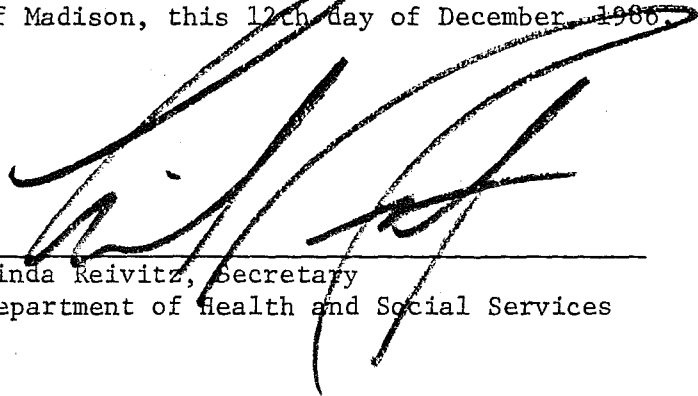
CERTIFICATE

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 applications to acquire innovative medical technology and criteria for the review of applications for organ transplant programs 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.



SEAL:

Linda Reivitz, Secretary
Department of Health and Social Services

2-1-87

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

To repeal and recreate HSS 123.05 and to create HSS 123.26, relating to applications to acquire innovative medical technology and criteria for the review of applications for organ-transplant programs.

Analysis Prepared by the Department of Health and Social Services

This rulemaking order makes two changes in ch. HSS 123, Wis. Adm. Code, the Department's rules for implementing the Capital Expenditure Review Program, subch. III of ch. 150, Stats. The first change is repeal and recreation of the section on innovative medical technology to replace present criteria for exempting applications for innovative technology from review under ch. HSS 123 with a list of innovative technologies and with criteria for determining whether other equipment and procedures are innovative medical technologies. Section 150.63(3), Stats., does not permit the Department to grant exemptions for innovative medical technology after December 31, 1985.

The second change being made in ch. HSS 123 is the addition of special criteria for reviewing applications from hospitals to set up human or artificial organ transplant programs. Chapter HSS 123 already includes special review criteria for renal (kidney) transplantation. The new review criteria apply to programs for heart, lung, liver, pancreas or bone marrow transplants. The rules cover need for these programs and required resources, including staff, medical support services and laboratory services; special criteria for the concurrent review of two or more applications; the requirement for separate approvals; and data reporting requirements for approved organ transplant programs.

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 creates rules interpreting ss. 150.61(2) and 150.63, Stats., as follows:

SECTION 1. HSS 123.05 is repealed and recreated to read:

HSS 123.05 INNOVATIVE MEDICAL TECHNOLOGY. (1) ACQUISITION.

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

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

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

1. Transplantation of artificial organs other than those approved by the U.S. food and drug administration for safety and efficacy;
2. Transplantation of animal organs; and
3. Transplantation of human organs other than skin, cornea and kidney, and the organs specified in s. HSS 123.26.

(b) For consideration of an addition to or deletion from the list of innovative medical technologies in par. (a), interested persons may petition the department under s. 227.015, Stats., to make the change through rulemaking.

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

1. Has not been proven safe;
2. Has not been proven clinically efficacious;
3. Has not been proven cost-effective;
4. Has not been proven appropriate for a clinical setting;
5. Is being assessed by the federal office of technology assessment; or
6. Is the first generation of a technology that is likely to undergo rapid change and improvement.

SECTION 2. HSS 123.26 is created to read:

HSS 123.26 ORGAN TRANSPLANT PROGRAM CRITERIA. (1) USE. The criteria set out in this section shall be used by the department to review applications for the establishment of a human or artificial heart, liver, lung, pancreas or bone marrow transplant program. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "Organ" means a human or artificial heart, liver, lung or pancreas or bone marrow.

(b) "Organ procurement" means, in reference to human organs, the process of coordinating the removal, preservation and transportation of donor organs, and maintaining a system to locate recipients for donated organs.

(c) "Program" means the offering of any one type of organ transplant to one or more patients, either on an ongoing or a one-time basis.

(d) "Transplant" means a process by which an organ is surgically implanted into a human patient.

(3) NEED FOR THE ORGAN TRANSPLANT PROGRAM. The department may approve an application under this section only if the applicant demonstrates on the basis of valid assumptions, data and methodology that all of the following conditions are met:

(a) There is a need for the proposed organ transplant program.

Determination of need for an organ transplant program shall be based on the following considerations:

1. The capacity of existing transplant programs in the state for the same organ; and

2. The annual volume of transplants of that type of organ provided to Wisconsin patients and patients from adjoining states;

(b) For each organ transplant program for which application is made, at least 10 transplants will be performed annually under the applicant's proposed program. In projecting the annual number of transplants, the applicant shall provide data on the incidence of conditions for which organ transplant has been recognized to be an effective and appropriate mode of treatment, the actual and projected number of transplant evaluations, and the number of patients referred to other organ transplant programs for transplant in the 5 years preceding the date of application along with data relating to patient origin, age and presenting condition; and

(c) The approval of an application would result in no more than 3 heart transplant programs in the state and no more than 2 programs in the state for the transplant of each of the other organs, and not more than one organ transplant program in any health planning area for each organ other than a heart. This paragraph does not apply to an application to establish an organ transplant program for the transplantation of bone marrow.

(4) REQUIRED RESOURCES. The department may approve an application under this section only if the applicant demonstrates that all of the following conditions are met:

(a) The applicant has an arrangement with a medical school to support graduate medical education and organ transplant research programs;

(b) The organ transplant program will be able to meet the following minimum staffing requirements:

1. The program has a director who is a physician licensed in Wisconsin with at least 12 months experience in an organ transplant program; and

2. For each type of organ transplant to be performed, the program has a physician on staff who is licensed as a physician in Wisconsin and is experienced in the performance of the transplant of that organ;

(c) The organ transplant program will be able to provide the following services 24 hours a day through staff experienced and trained in the performance of the transplant of that type of organ or those types of organs and the age group being served:

1. Medical support services, including:

a. Anesthesiology;

- b. Cardiology, including special diagnostic services, electrocardiogram (EKG), nuclear cardiology, cardiac ultrasound and a cardiac rehabilitation program;
- c. Endocrinology;
- d. Gastroenterology, including endoscopy;
- e. Hematology and oncology;
- f. Immunology services, both specialist and laboratory;
- g. Infectious disease services, both specialist and laboratory;
- h. Intensive care;
- i. Nephrology, including a renal dialysis capability;
- j. Neurology, including diagnostic services, electroencephalogram (EEG) and evoked potentials;
- k. Nursing;
- l. Organ procurement, including transplant coordinator services;
- m. Pathology, with experience in diagnosing rejection;

- n. Pediatrics;
- o. Psychiatry and psychology;
- p. Pulmonary disease; and
- q. Diagnostic and therapeutic radiology, including angiography, ultrasound, computed tomography, nuclear medicine imaging and cardiac catheterization;

2. Laboratory services, including:

- a. Special chemistry;
- b. Histocompatibility; and
- c. Blood banking; and

3. Ancillary services, as follows:

- a. Dietetics;
- b. Occupational therapy;
- c. Pharmacy;
- d. Physical therapy;

e. Rehabilitation and recreation therapy; and

f. Social services;

(d) In the case of an application to establish a heart or a heart and lung transplant program, the site at which the transplant will be performed has provided cardiac catheterization and cardiac surgery services for at least 3 years preceding the date of application; and

(e) In the case of an application submitted by or on behalf of more than one hospital:

1. The requirements of pars. (b) and (c) will be met at each hospital where organ transplants are performed, or at a physically contiguous hospital;

2. Each type of organ transplant will be performed by one distinct team with another team available to back up the first team until 20 transplants per year have been performed, but separate teams may be used for adult and pediatric procedures;

3. The hospitals are contractually bound to provide all services required under this subsection for an organ transplant program;

4. All hospitals are located in one county or in counties contiguous to that county; and

5. The hospitals agree to share data and participate in joint organ transplant research programs.

(5) FINANCIAL FEASIBILITY. The department shall not approve an application unless the applicant demonstrates that the project is financially feasible by:

(a) Documenting that the projected average costs of organ transplants are similar to costs for similar services provided in similar settings; and

(b) Documenting the net financial impact on its hospital rates.

(6) CONCURRENT REVIEW. The provisions in s. HSS 123.08(10) shall be used for concurrent review when there are 2 or more applications for programs to transplant the same type of organ. The department shall approve the application or applications receiving the highest score based on a comparative analysis of the applications using all applicable review criteria in s. HSS 123.13, the review criteria in subs. (3) to (5) and in addition giving preference to the application which provides:

(a) The most comprehensive array of organ transplant services;

(b) The most comprehensive array of services relating to the organ being transplanted;

(c) The best geographical accessibility for persons requiring organ transplants; and

(d) The greatest opportunities for training physicians and nurses involved in services related to organ transplants, without unnecessarily duplicating similar training programs in the state.

(7) SEPARATE APPROVALS REQUIRED. A separate approval is required to establish a program for the transplant of each type of organ.

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

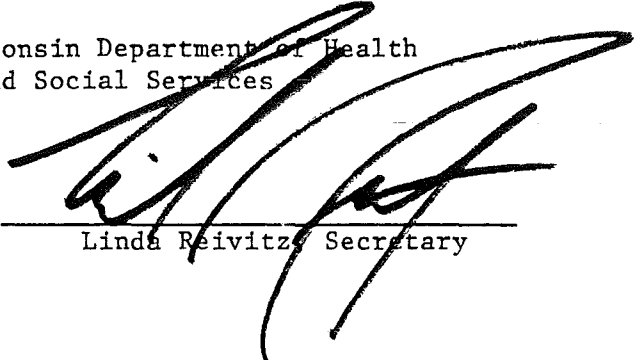
(9) REVISION OF THE RULE. The department shall review this section within 2 years after its effective date.

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

Linda Reivitz
Secretary

December 12, 1986

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Madison, WI 53707

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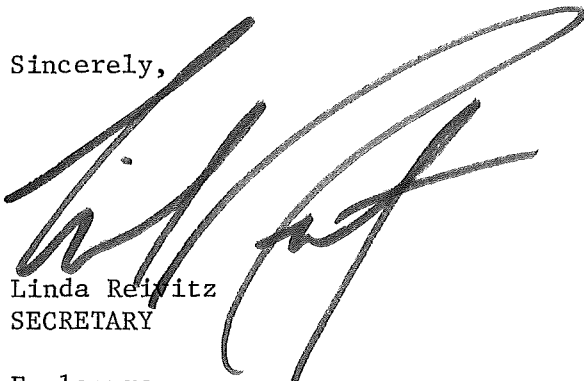
Mr. Orlan Prestegard
Revisor of Statutes
9th Floor - 30 on the Square
Madison, Wisconsin 53702

Dear Mr. Prestegard:

As provided in s. 227.20, Stats., there is hereby submitted a certified copy of HSS 123.05 and 123.26, administrative rules relating to applications to acquire innovative medical technology and criteria for the review of applications for organ transplant programs.

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

Sincerely,



Linda Reivitz
SECRETARY

Enclosure